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**Towards the development of an acceptable and user-friendly self-sampling
intervention for diagnosing sexually transmitted infections among young
women in eThekweni District Municipality, South Africa**

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Dedication

This degree is dedicated to my parents, my late mother Mrs Sibusiso Annatoria Dwayisa, and my father Mr Canaan Sthembiso Dwayisa, who has seen every part of my journey. Words are not enough to express the appreciation that I feel for all your teachings, rebukes, support, encouragement, and prayers that have all contributed to my perseverance. Although you passed on right at the beginning of this PhD journey, Mom, I know you were proud to see me begin. Your warmth and unwavering support will forever remain etched in my heart. I am grateful for the sacrifices you both made to afford me every opportunity to succeed. And now, this is the culmination of your love, hard work, dedication, and all that you endured for me. I am immensely grateful to God for blessing me with such amazing parents.

True to this scripture: *For I know the plans I have for you,” declares the Lord, “plans to prosper you and not to harm you, plans to give you hope and a future. **Jeremiah 9:11***

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Declaration

I declare that the thesis, which I hereby submit for the degree Doctor of Philosophy in Public Health at the University of Pretoria, is my own work and has not previously been submitted by me for a degree at another university.

Signature: _____ Date:

Declaration of publications

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Executive summary

Background

Sexually transmitted infections (STIs) remain a major global health issue, disproportionately affecting young women, despite healthcare advancements. South Africa, particularly KwaZulu-Natal Province, has the highest STI prevalence in sub-Saharan Africa. The current syndromic management approach faces challenges that deter young women from seeking care. Self-sampling interventions are promising solutions, being user-friendly and effective for detecting both symptomatic and asymptomatic infections. This thesis aims to understand young women's preferences for self-sampling approaches towards the development of a user-friendly self-sampling intervention to diagnose STIs in young women, to promote uptake and improve health outcomes. The study focused on young women in the eThekweni Metropolitan Municipality, South Africa.

Methods

We employed a sequential exploratory design and a mixed-method approach across multiple phases. Initially, a scoping review mapped evidence on self-sampling interventions for STIs in women, informing the study's objectives. The second phase involved a systematic review and meta-analysis to compare the diagnostic accuracy of self-collected specimens with those collected by healthcare workers. In the third phase, the nominal group technique (NGT) identified barriers to clinic-based STI healthcare and key attributes for a self-sampling intervention. Finally, a discrete choice experiment (DCE) was conducted to understand young women's preferences based on the identified attributes. The findings were synthesised to develop an acceptable and user-friendly self-sampling intervention for young women in underserved communities.

Results

The scoping review highlighted disparities in self-sampling intervention usage between low- and middle-income countries (LMICs) and high-income countries (HICs), underscoring the need for universal health coverage and the potential of self-sampling to bridge STI healthcare access gaps. The systematic review and meta-analysis confirmed the diagnostic accuracy of self-collected specimens, supporting the scalability and effectiveness of self-sampling interventions in improving STI detection and reducing transmission. NGT sessions identified barriers to STI healthcare access, such as clinic distance, stigma, and limited STI knowledge. Key attributes for self-sampling included convenient access to self-collection kits, STI education, and youth-friendly healthcare environments. The DCE highlighted young women's preferences for self-sampling, emphasising enhanced access to self-collection kits,

comprehensive STI education, confidential results communication, autonomy in self-collection methods, and youth-friendly healthcare environments.

Conclusions

This pioneering study underscores the importance of user-centred, accessible, and inclusive STI healthcare services tailored to young women's needs. It addresses barriers to STI healthcare through the identified attributes and highlights young women's preferences, highlighting the significance of involving end-users in designing and implementing healthcare interventions. This research paves the way for more tailored, effective, and equitable healthcare interventions, contributing to improved sexual and reproductive health outcomes. It also contributes to advancing Sustainable Development Goals (SDG) 3 on health and well-being; SDG 5 on gender equity and empowerment of women and girls; SDG 10 for human rights to inequalities for all people, including underserved communities; and SDG 17 on collaborating with various stakeholders to achieve a common goal for improving STI healthcare management services.

Keywords: sexually transmitted infections; self-sampling; young women; healthcare access; diagnostic accuracy; user preferences

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Definition of terms

Acceptable – Acceptable refers to being able to be agreed on (1). In the current research, acceptable will be used to define men agreeing on a self-sampling intervention that is suitable for specimen collection.

Adolescent Girls and Young Women (AGYW) – Defined as a population group of females aged between 15–24 years (2). The same definition will be utilised for the current study.

Poor urban communities – defines urban poverty as a set of economic and social difficulties found in industrialised cities that are the result of a combination of processes (3). Additionally, urban poverty is seen as a type of poverty with the primary characteristic that it occurs in industrialised societies (3). In this study, poor urban communities were defined as communities in the eThekweni District municipality who have poor access to quality healthcare and other basic services.

Remote areas – remote are far from the city and where people live and, therefore, it is challenging to reach them (4). The same definition will be used in the correct study.

Self-sampling – self-sampling is when individuals can collect their own specimens for diagnostic enquiry at home, or clinics, or anywhere that is convenient for them (5). Also referred to as ‘self-collection’, ‘self-administered’, and ‘self-obtained’. This definition will be utilised in the current study.

Sexually transmitted infections (STIs) – refers to infections that are transmitted through sexual contact. For the purposes of this study, this term will be used to refer to such infections namely caused by *Chlamydia trachomatis*, *Neisseria gonorrhoea*, *Trichomonas vaginalis*, human papillomavirus, human herpes simplex virus, *Mycoplasma genitalium*, and *Treponema pallidum*.

Syndromic management – syndromic management relies on the identification of consistent groups of clinical symptoms and recognised signs, and the provision of treatment that is equipped to destroy the strongest pathogen known to cause or the most severe disease (6).

User-friendly – described as “easy to use” (7). Therefore, if something is easy to use then it means it is “user-friendly”.

Young women – In the current study, young women will be defined as the upper quadrant of the age group of AGYW, which is 18–24 years.

Acronyms and abbreviations

AC2	Aptima Combo 2
ATV	Aptima <i>Trichomonas vaginalis</i>
AHPV	Aptima human papilloma virus
BV	Bacterial vaginosis
CT	<i>Chlamydia trachomatis</i>
CI	Confidence interval
CC	Clinician-collected
CSW	Commercial sex worker
CIN2	Cervical intraepithelial lesion
DCE	Discrete choice experiment
FSW	Female sex workers
FCU	First-catch urine
FVU	First-void urine
HC2	Hybrid Capture II
HSIL	High-grade squamous intraepithelial lesion
HrHPV	High-risk human papillomavirus
HIC	High-income country
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
KZN	KwaZulu-Natal
LrHPV	Low-risk human papillomavirus
LMIC	Low- and middle-income countries
LCR	Ligase chain reaction
M. genitalium	<i>Mycoplasma genitalium</i>
mPCR/RLB	Multiplex polymerase chain reaction/reverse line blot
NG	<i>Neisseria gonorrhoea</i>

NGT	Nominal group technique
NPV	Negative predictive value
NAAT	Nucleic Acid Amplification Test
P-VSCT	Physician-collected specimen collection and transport
POCT	Point-of-care testing
PPV	Positive Predictive Value
PIS	Patient infected status
POC	Point-of-care
PCR	Polymerase chain reaction
PC-VS	Patient-collected vaginal swab
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
SDG	Sustainable Development Goal
STI	Sexually transmitted infection
SOVAS	Self-obtained vaginal swab
SCT	Self-collection and transport
S-VSCT	Self-collected specimen collection and transport
SIS	Single intravaginal swab
SVS	Self-collected vaginal swab
TCP	Tampon cellular pellet
TV	<i>Trichomonas vaginalis</i>
UPT	Urine preservative transport
USA	United States of America
UK	United Kingdom

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CHAPTER 1: INTRODUCTION

1.1. Thesis introduction

Despite substantial global efforts, sexually transmitted infections (STIs) remain a significant public health concern, particularly affecting young women in low- and middle-income countries (LMICs) (1, 2, 3). Syndromic management is the primary approach for STI management in many countries, especially in LMICs, where resources and access to diagnostic laboratories are limited (4, 5, 6, 7). This method relies on healthcare providers identifying a syndrome of clinical signs and symptoms and administering broad-spectrum treatment for the organisms commonly responsible for these symptoms (8, 9). While effective, this approach has notable limitations that likely contribute to the persistently high rates of STIs in LMICs (4, 6). This issue is particularly concerning given that infections are most prevalent among young women, who contribute towards building a healthy society and have the potential to be future leaders.

One of the main limitations of syndromic management is its reliance on symptomatic patients seeking care at healthcare facilities for diagnosis and treatment. This often results in underdiagnosis or missed diagnosis of asymptomatic infections, which are common among many STIs (2, 10), leading to unknowingly spread infections. Additionally, syndromic management can lead to overdiagnosis and overtreatment of infected individuals, potentially resulting in antimicrobial drug resistance (2, 5, 11). Fear of stigma associated with STIs and the invasive nature of genital examinations further contribute to untreated and undiagnosed infections (12, 13). This, ultimately, leads to delayed treatment, increasing the risk of long-term sexual and reproductive health complications such as infertility, heightened risk of human immunodeficiency virus (HIV) transmission, and progression to cervical cancer (14, 15). These challenges underscore the urgent need for an alternative approach that addresses the limitations of syndromic management and offers a more effective and user-friendly solution.

Recognising this urgent need, the present study proposes a paradigm shift to self-sampling for STI diagnosis in young women. Self-sampling allows individuals to collect their own specimens at a convenient location, whether at home or in a healthcare facility (16, 17). This method does not rely on the presence of clinical symptoms, enabling the screening and detection of asymptomatic infections (18, 19). According to Gupta et al. and Serrano et al. (20, 21), self-sampling increases STI screening among under-screened women in remote areas, who would otherwise not undergo screening. Studies have also shown that self-sampling is well accepted across diverse populations and has led to increased uptake of STI healthcare services (19, 22, 23). Privacy, convenience, reduced stigma, and a sense of empowerment to

manage one's sexual health are key factors contributing to its high acceptability (19, 23). Given that self-sampling offers a promising solution with the potential to overcome the barriers of syndromic management, it is crucial to explore this approach from various perspectives.

1.2. Thesis background

STIs are a global health concern, with the highest prevalence recorded in Sub-Saharan Africa (3, 24). Among countries in this region, South Africa bears the heaviest burden (24, 25). Within South Africa, the province of KwaZulu-Natal (KZN) has the highest prevalence of STIs, which is further exacerbated by the high prevalence of HIV infections in this province (26, 27, 28). Consequently, increased HIV infections are linked to a higher risk of other STIs such as syphilis, chlamydia, gonorrhoea, trichomonas, human papillomavirus, herpes simplex virus, and mycoplasma (25, 29). Global statistics indicate that the majority of STIs occur among young people, particularly adolescent girls and young women (30, 31, 32), a statistic that holds true in South Africa as well (25, 27, 28). Given the anatomical configuration of the female reproductive tract and the propensity of young women to have older sexual partners and engage in risky sexual behaviour (31, 33, 34), these findings are not surprising. Early exposure to STIs jeopardises young women's sexual and reproductive health (26) and increases the risk of developing long-term complications if infections are left untreated (6, 14, 15). Therefore, an effective STI management approach is crucial to improve STI healthcare service provision, particularly for this demographic.

To enhance STI healthcare, it is essential to understand the existing interventions, especially in LMICs. In resource-limited settings, where access to quality healthcare is constrained, syndromic management is the cornerstone approach used to manage and treat STIs (4, 5, 7, 15). It remains the most feasible and affordable option in LMICs, including South Africa (10), and has positively impacted STI prevalence by addressing 13% of symptomatic STIs in KZN between 1987 and 2004 (35). However, the majority of STIs are asymptomatic and thus go undiagnosed and untreated (2, 10, 36). This leads to the unknown spread of infections, perpetuating the burden of disease and increasing the sequelae of untreated infections (7, 15). Furthermore, research shows poor agreement between aetiological and syndromic diagnoses, especially in communities with high HIV prevalence (10). This can lead to overdiagnosis and overtreatment of patients, potentially resulting in the development of drug-resistant pathogens (2, 13). In KZN, where HIV infections are high, this is particularly concerning. Given the high STI prevalence among young women and the risk of complications due to non-treatment, a paradigm shift in STI healthcare beyond syndromic management is crucial to reduce the burden of disease, even in such settings.

One alternative intervention is self-sampling, which has been adopted in high-income countries (HICs) as an alternative to conventional clinic-based syndromic management (16, 37). By allowing individuals to conveniently collect their own specimens for STI diagnosis, it minimises dependency on physical access to healthcare facilities, addressing the challenges presented by syndromic management (16, 37, 38). Self-sampling enables laboratory testing to identify the specific causative pathogens, reducing the overdiagnosis of symptomatic individuals and the underdiagnosis of asymptomatic individuals. Ultimately, this leads to targeted treatment and potentially minimises the development of drug-resistant pathogens.

Considering the burden of STIs among young women in KZN and the challenges with syndromic management, implementing self-sampling as an alternative approach holds the potential to improve STI-related health outcomes. This necessitates the exploration of self-sampling as a more inclusive and accessible approach, aiming to reduce the burden of STIs and improve overall sexual health outcomes for young women in underserved communities. With a population of 3.9 million people, which is 34.7% of the overall population of KZN province, spread across approximately 2,555 km² (39), the eThekweni Metropolitan Municipality proved to be an ideal setting for the study. The main aim of this study was to collaborate with key stakeholders towards developing acceptable and user-friendly self-sampling interventions to diagnose STIs in young women residing in underserved communities in the eThekweni Metropolitan Municipality.

1.3. Problem statement

Despite global efforts to reduce the burden of STIs, infection rates remain disproportionately high among young women, particularly in LMICs (1, 2, 3, 40). The current syndromic management approach, widely used in these regions, presents significant challenges. These challenges include the underdiagnosis of asymptomatic infections (2, 10), deterrent invasive genital examinations (11, 12), and the overdiagnosis and overtreatment of infections, which can potentially lead to the development of drug resistance (2, 13). Additionally, young women in these areas face other obstacles, such as stigma associated with STIs, lack of awareness about STIs and their symptoms, and socioeconomic factors that impede access to healthcare facilities (12, 41, 42). The failure of local healthcare facilities to provide youth-friendly services that are non-judgmental towards sexually active young people also negatively impacts healthcare-seeking behaviours (43, 44).

In metropolitan municipalities, such as the eThekweni Metropolitan Municipality where our study was located, the pace of urban development often fails to keep up with growing populations (45, 46). This inadequacy results in the expansion of impoverished urban settlements, significantly impacting public health, poverty issues, and service provision, leading to restricted access to basic services in these communities (47). These challenges negatively affect healthcare-seeking behaviour, fostering undetected and untreated infections and the unintentional spread of infections within this population. The consequences of undiagnosed and untreated infections, including long-term sexual and reproductive health complications such as infertility and precancerous lesions (5, 14, 15), are particularly concerning for this young demographic (see Figure 1.1). Therefore, there is an urgent need for innovative alternatives that address the limitations of the syndromic approach to STI healthcare.

Self-sampling as an intervention for STI healthcare is a viable alternative to clinic-based syndromic management (48, 49). This approach is commonly used in HICs, but in LMICs, the STI management landscape remains predominantly reliant on syndromic management. There is a critical gap in STI management strategies in LMICs, particularly concerning the challenges faced by young women in underserved communities. Recognising this gap and the urgent need for an effective and accessible alternative, this study aimed to investigate and address some of the shortcomings of syndromic management. This was done through collaboration with key stakeholders, including young women and healthcare professionals, to develop an acceptable and user-friendly self-sampling intervention. The proposed shift to self-sampling as an alternative approach seeks to empower young women to actively manage their sexual health, facilitating the early detection of STIs, especially asymptomatic ones, and ensuring timely treatment within the selected study population.

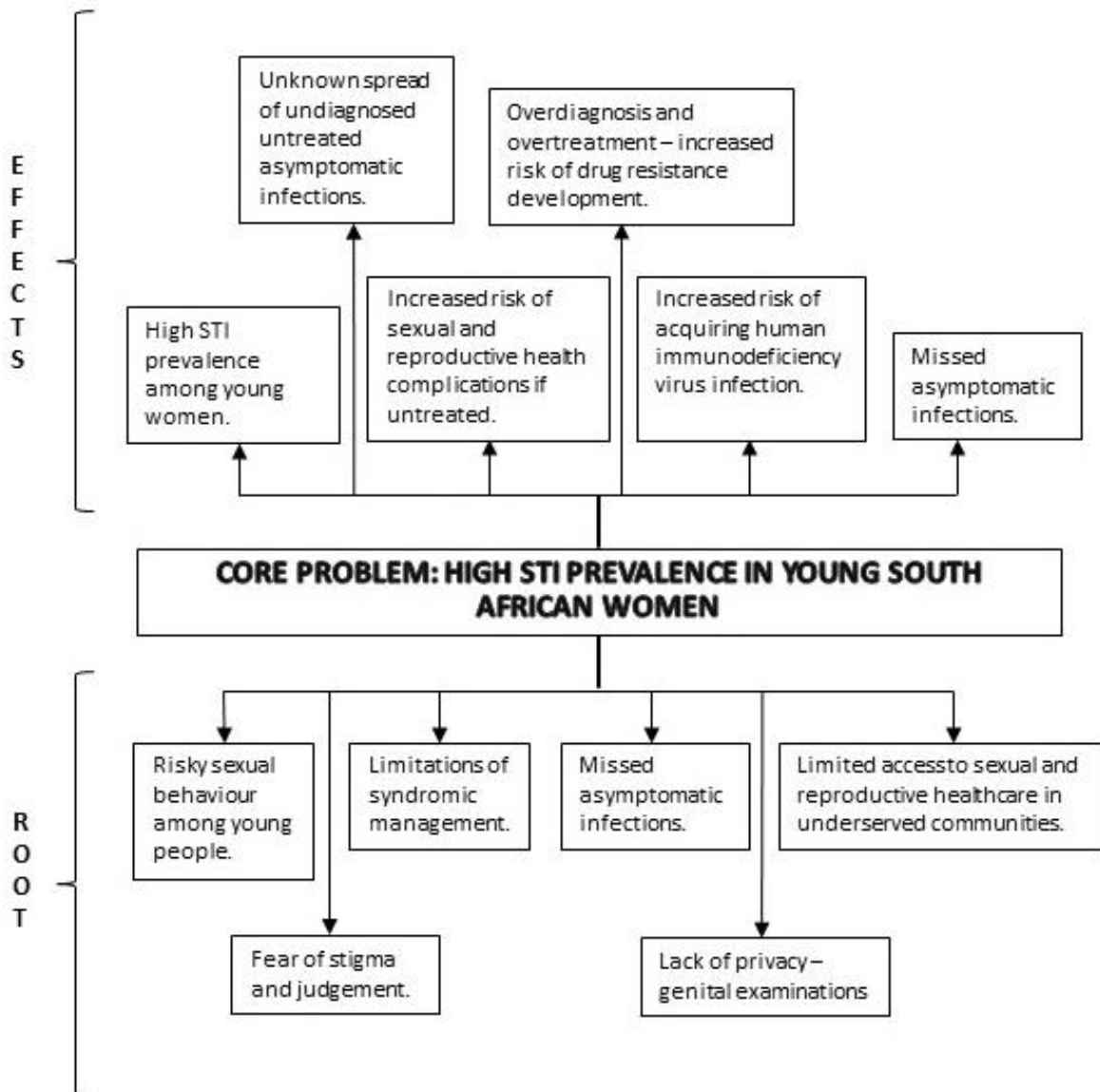


Figure 1.1: Problem analysis diagram

1.4. Study purpose

Syndromic management for STIs plays a significant role in combating these infections (2, 7, 50). Although it presents considerable challenges, it has been useful in addressing a portion of symptomatic individuals who present at their local healthcare facilities. However, given the high level of infections among young women in KZN and the long-term consequences of untreated infections, an alternative intervention like self-sampling is imperative. While the use, acceptability, and effectiveness of self-sampling are well understood, user preferences for self-sampling interventions and their attributes are not well documented.

For interventions to be effective and acceptable, it is crucial to conduct research in collaboration with prospective users to understand their preferences and develop tailored interventions. Therefore, this study proposed collaborating with young women and healthcare professionals to address the limitations of syndromic management and improve access to STI screening and diagnosis. It also aimed to contribute to the development of an acceptable and user-friendly self-sampling intervention for the target population, ultimately improving health outcomes for young women in KZN, particularly those in underserved communities.

1.5. Aim and objectives

The main aim of the study was towards developing a self-sampling intervention that is acceptable and user-friendly, based on user preferences, for the diagnosis of STIs in young women residing in underserved communities in eThekweni Metropolitan Municipality.

The following objectives were utilised to fulfil the study aim:

- An updated systematic review was conducted to determine the diagnostic accuracy of self-collected specimens compared to specimens collected by healthcare workers.
- A nominal group technique (NGT) was used to identify barriers to seeking STI healthcare and develop attributes for a self-sampling intervention for STI diagnosis through collaboration with young women, and healthcare workers.
- A discrete choice experiment (DCE) was conducted to understand young women's preferences for a self-sampling intervention to diagnose STIs that is both acceptable and user-friendly to them.

1.6. Study significance

This study sought to understand young women's preferences for self-sampling as an alternative intervention for STI healthcare management. Its significance lies in its potential to enhance STI-related healthcare service provision, leading to more accurate diagnoses and timely treatments within the context of KZN. By advocating for the early detection of infections through self-sampling, the study aims to minimise the risk of complications such as infertility and reduce the overall burden on healthcare systems.

Focusing on young women, who have the highest prevalence of STIs, and enabling them to actively participate in managing their health, the study seeks to improve healthcare-seeking behaviour within this population. This, in turn, will enhance the inclusivity and effectiveness of STI management approaches, particularly for young women in underserved communities. By

exploring an alternative STI management approach and providing evidence of user preferences for self-sampling interventions, the study offers new insights into STI management. This may enhance the focus on promoting preventive measures for STIs and influence STI healthcare management policies. The findings could benefit not only the target population in the eThekweni Metropolitan Municipality, but also similar populations globally.

In addition to improving STI healthcare management services and health outcomes, the study aligns with broader global goals, including Sustainable Development Goal (SDG) 3, which aims to ensure healthy lives for all by exploring alternative interventions to make STI healthcare more accessible for young women; SDG 5, which promotes gender equity in sexual and reproductive health by focusing on young women; SDG 10, which seeks to reduce inequalities by targeting underserved communities to ensure accessible STI healthcare; and SDG 17, which emphasises collaboration with various stakeholders, including young women and healthcare professionals, to improve STI healthcare management services (51). This study is pioneering in its approach and serves as an example for the global community, sharing insights on user preferences and contributing to the development of more effective and inclusive global policies for STIs.

1.7. Outline of the remaining chapters

This thesis consists of eight chapters. Chapter 1 presented the introduction and background, problem statement, aim, objectives, study purpose, and study significance. Chapter 2 presents the results of the literature review conducted in this study – a scoping review mapping evidence of self-sampling to diagnose STIs in women. Chapter 3 presents the theoretical and conceptual framework, which demonstrates the variables that were explored in the study. Chapter 4 presents the methodology used to conduct the study. Chapters 5 to 7 present the details of the three study objectives that were utilised to achieve the study aim. Chapter 8 presents the synthesis and discussion of the study findings and makes recommendations.

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CHAPTER 2: LITERATURE REVIEW

This chapter (Chapter 2) presents the literature review that was conducted as a scoping review, which aimed to map global evidence of self-sampling to diagnose sexually transmitted infections (STIs) in women. It presents a synthesised overview of existing evidence on self-sampling for STI diagnosis in women, which was obtained from multiple online databases and grey literature.

2.1 The findings of the scoping review were published in the *MDPI Diagnostics* journal with the title: “*Mapping Evidence for Self-sampling to Diagnose Sexually Transmitted Infections in Women: A Scoping Review*”

2.2 The scoping review revealed a limited number of studies investigating self-sampling for STI diagnosis in low-and-middle-income countries (LMICs). This is likely due to low adoption and uptake of such interventions. We present a literature review on the possible reasons for low adoption.

Systematic Review

Mapping Evidence of Self-Sampling to Diagnose Sexually Transmitted Infections in Women: A Scoping Review

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Abstract: Background: Sexually transmitted infections (STIs) are a major global healthcare burden, disproportionately affecting women. Self-sampling interventions for diagnostic purposes have the potential to improve STI healthcare management and expand STI services. However, there is currently no published evidence of the global use of self-sampling interventions to diagnose STIs in women. The main aim of this scoping review was to map evidence on the use of self-sampling interventions to diagnose STIs in women. Methodology: The methodology of this scoping review was guided by Arksey and O'Malley and Levac. A comprehensive literature search was conducted in PubMed, Scopus, Web of Science, Medline (EBSCO), ProQuest, and Cochrane. For grey literature, a search was conducted in Open Grey, World Health Organization, Google, and conference proceedings and dissertations. All search results were screened and assessed for eligibility. Thereafter data from eligible studies was extracted and analysed. The quality of these studies was appraised using the Mixed Methods Appraisal Tool 2018 version. Results: A total of 770 articles were retrieved from databases and grey literature sources. A total of 44 studies were eligible for data extraction following title, abstract and full-text screening. Of the included studies, 63% presented evidence of research conducted in high-income countries and 37% presented evidence in low- and middle-income countries. Studies presented evidence on the following: feasibility of self-sampling in remote areas; acceptance and ease of use of self-sampling interventions; types of self-sampled specimens; pooled samples for diagnosing STIs; laboratory diagnostic assays for STI using self-sampled specimens; and self-testing of self-sampled specimens. Conclusions: Self-sampling interventions are feasible and easy to use and, therefore, can improve STI management and treatment in women across various age groups and various access levels to good-quality healthcare. Despite this, there is a lack of evidence of self-sampling interventions designed according to user preferences. We recommend studies to collaborate with women to co-develop user-friendly self-sampling interventions to diagnose STIs in women.

Keywords: self-sample; sexually transmitted disease; women

1. Introduction

Sexually transmitted infections (STIs) are a global health challenge, with one million new cases diagnosed every day [1]. Although STIs affect both genders, women are at a higher risk due to the anatomy of their reproductive tract [2]. STIs are commonly diagnosed and treated based on the presentation of symptoms, particularly in low- and middle-income countries (LMIC) where access to technologically advanced diagnostic procedures are limited [3]. Often, STIs are treated using a syndromic management approach, where the patient is treated for a group of conditions that cause similar symptoms and often occur concomitantly. Although treating symptomatic STIs is effective, many asymptomatic infections are missed [4]. Not diagnosing or treating asymptomatic STIs may result in infections persisting or spreading. Diagnosing STIs mostly requires physically examining people who present to healthcare facilities [3], which may be challenging in remote areas where access to healthcare is limited [5,6]. Physical exams are unattractive to many people, due to the invasive nature of physical exam procedures and the social stigma associated with STIs [5,6]. Delayed diagnosis and treatment of STIs often increase the risk of STI-related long-term health complications, including chronic pelvic pain, fertility issues, and cervical cancer development [7].

Self-sampling to diagnose STIs is widely used in high-income countries (HIC) as an alternative to having healthcare workers collect samples [8]. Through self-sampling, people can collect their specimens, either at healthcare facilities or at home, in relative privacy [7,8]. Allowing people to self-sample at their convenience eliminates various barriers often associated with STIs, such as lack of privacy and stigmatization [7,9]. Self-sampling may also promote the diagnosis and management of STIs in remote areas and allow people who are skeptical and uncomfortable with conventional clinic-based practices to access treatment [5]. Self-sampling is also effective in screening for asymptomatic infections [6,7]. As a means of scaling up global STI services, the World Health Organization (WHO) recommends the expansion of self-sampling [10]. Despite this recommendation, self-sampling interventions to diagnose STIs in women are not very well documented.

The long-term effects of undiagnosed and untreated STIs, together with the difficulties associated with clinic-based management of STIs, contributes to the global challenges associated with STI management [11,12]. Self-sampling has the potential to facilitate STI management and expand STI services. The aim of this scoping review is to map evidence on the use of self-sampling interventions to diagnose STIs among women. Our findings may assist policymakers and healthcare practitioners involved in sexual healthcare and inform future research on self-sampling interventions for diagnosing STIs in women.

2. Materials and Methods

This scoping review was part of a larger study aiming to develop a user-friendly self-sampling intervention to diagnose STIs among young women in poor urban communities in eThekweni District Municipality, in KwaZulu-Natal, in South Africa. The scoping review was guided by recommendations from Arksey and O'Malley [13], Colquhoun Levac [14], and Godfrey Peters [15]. We present our methods and findings using the preferred reporting items for systematic reviews and meta-analyses extension for scoping reviews (PRISMA-ScR) guideline [16]. The scoping review protocol was registered prospectively on Open Science Framework and can be accessed via the link: <https://osf.io/tnbx6> (accessed on 20 June 2022).

2.1. Identifying the Research Question

We asked the research question: What is the evidence on self-sampling interventions to diagnose STIs among women?

We adopted the population, concept, and context (PCC) framework to effectively address the research question (see Table 1).

Table 1. PCC framework for defining eligibility of studies to address the research question.

Criteria	Determinants	Description
Population	Women	Women of sexual reproductive age
Concept	Self-sampling interventions	<ul style="list-style-type: none"> • Women collecting their own specimens for STI diagnosis, either at home or at a healthcare facility without the aid of a healthcare professional. • The self-sampling specimen collection kit. • Submission of self-collected specimens for diagnosis to a healthcare facility or directly to the laboratory. • Feedback on patient results. • Laboratory diagnostic techniques used for different specimen collection kits.
Context	STIs	STIs in women excluding Human Immunodeficiency Virus (HIV).

2.2. Identifying Relevant Studies

We conducted a systematic literature search of the following databases: PubMed, Scopus, Web of Science, Medline (EBSCO), ProQuest, and Cochrane. We used medical subject headings (MeSH) terms to define our searches with Boolean operators (AND/OR) between search terms. The search terms included (1) “self-sample” or “self-collect” or “self-administer” or “self-obtain”, (2) “sexually transmitted infections”, (3) “diagnostic specimens” or “diagnostic samples”, and (4) “women”. We searched the grey literature on the following websites: Open Grey, WHO, Google, and conference proceedings and dissertations. We adjusted keywords to suit different databases. We did not apply any time or language restrictions to ensure that we captured most of the literature. An experienced librarian conducted comprehensive database searches to ensure that the best search strategies were used for each database.

We included articles that fulfilled the following criteria:

- Peer-reviewed journal articles;
- Studies presenting evidence on self-sampling interventions for STIs;
- Studies presenting evidence on self-sampling in women for STI diagnosis;
- Studies of all designs with relevant information; and
- Studies focussing on the type, acceptability, feasibility, and effectiveness of self-sampling.

Articles were excluded if they:

- Focused on self-sampling interventions for HIV only; and
- Only presented evidence of specimens collected by healthcare workers for STI diagnosis.

2.3. Selection of Studies

Studies were selected in three stages. Firstly, article titles were screened according to their title in line with eligibility criteria. Eligible articles were exported to reference-manager software. In the second phase, two independent reviewers screened abstracts, using a screening tool that outlined the eligibility criteria. The screening tool was calibrated to ensure the accuracy and utility of screening questions. Calibration involved randomly selecting 21 (10%) articles from 211 articles, and then, pilot screening using the screening tool. The reviewers held extensive discussions to resolve any discrepancies and amend the screening tool accordingly. After the second stage of screening, eligible publications were exported to reference-manager software. The third stage included screening full texts using the screening tool. A third reviewer helped to resolve any discrepancies arising from full-text screening. Kappa statistics were used to determine the level of agreement between screeners.

2.4. Data Charting

We developed a data charting tool with variables relevant to the research question. Two independent reviewers then piloted the data-extraction tool, using seven (10%) of the included studies. The reviewers discussed the results of the extraction tool and updated the tool accordingly. Data were extracted from each article and thematically organised in a spreadsheet. Extracted data included: author, aim, study design, country, study population and sample size, type of self-collected specimen, diagnostic test used, key findings and conclusions.

2.5. Quality Appraisal of Included Articles

Included articles were critically appraised using the Mixed Method Appraisal Tool (MMAT), version 2018 [17]. Included articles were grouped according to study design, either qualitative or quantitative, and appraised using the relevant sections of the MMAT. Articles were scored as follows—low-quality studies had MMAT scores below 50%, average-quality articles had MMAT scores between 51–75%, and high-quality articles had MMAT scores ranging from 76–100%.

2.6. Collating, Summarising, and Reporting Results

The included articles were thematically analysed to demonstrate how they related to the research question. The following themes emerged from the included articles: feasibility, acceptance and ease of self-sampling interventions; types of self-collected specimens; diagnostic accuracy of self-collected specimens; agreement between physician-collected specimens and self-sampled specimens; pooled specimens for STI diagnosis; and self-testing of self-collected specimens. Our research findings were narratively summarised.

3. Results

3.1. Screening Results

Our search and screening strategy is outlined in the PRISMA flow diagram (Figure 1). We retrieved and screened 770 articles during title screening, of which 681 were from databases, nine were from Google, and 80 were from the WHO website. Databases search results are contained in Table 2. This was followed by abstract screening, after which 628 articles were excluded. We screened the full texts of the remaining 142 studies, of which 78 were excluded. At this stage, articles were excluded because they did not include self-sampling for STIs in women ($n = 20$), they did not focus on STIs ($n = 2$), and they did not assess the accuracy or validity of results of self-collected specimens ($n = 56$). The remaining 64 studies were eligible for data extraction. During data extraction, we excluded 20 articles because they compared laboratory diagnostic assays ($n = 16$), compared uptake of internet-based services versus in-person services ($n = 1$), and did not focus on STIs ($n = 1$) or on self-sampling in women ($n = 2$). Ultimately, 44 studies were included for review.

Reviewers showed moderate agreement following full-text screening ($k = 0.82, p < 0.05$). McNemar's chi-square statistic suggested that reviewers had similar proportions of yes/no answers ($p > 0.05$).

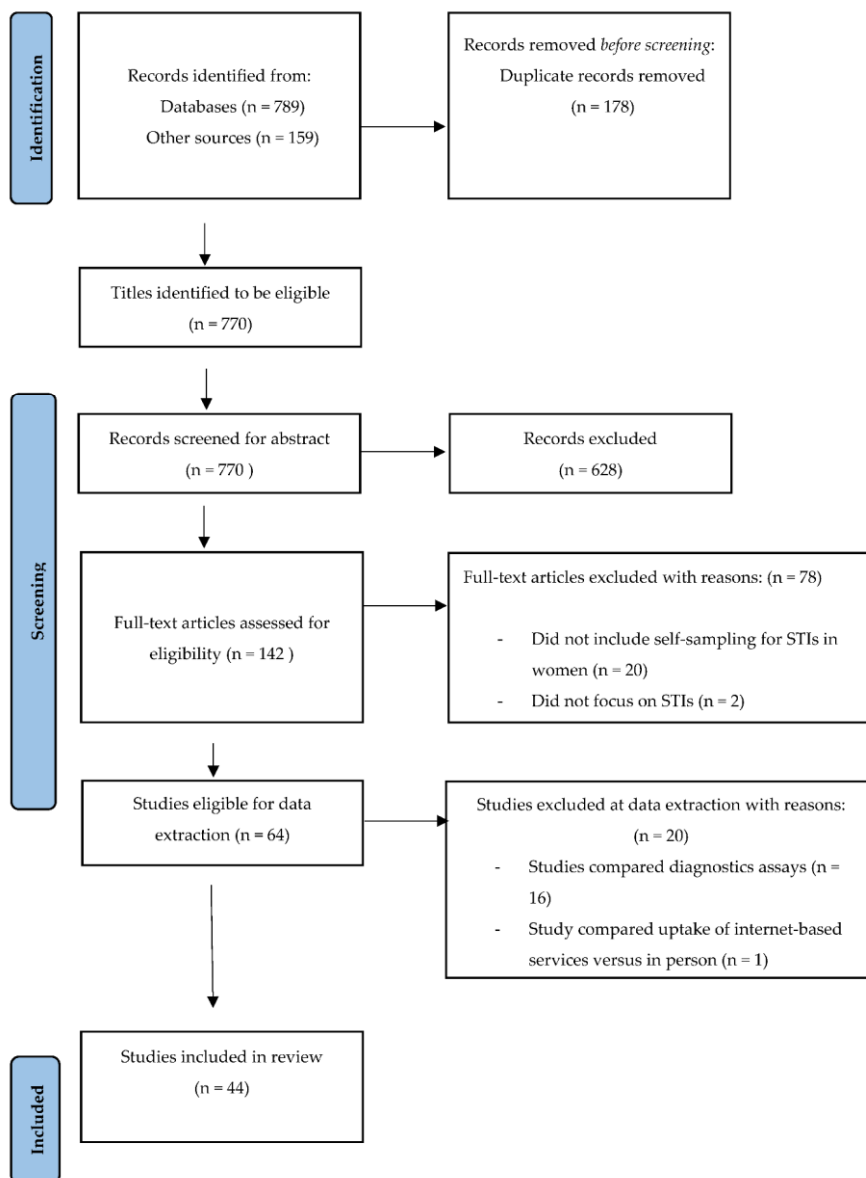


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram of the study selection process.

Table 2. Results of the database search.

Date	Database	Keywords	Number of Results Retrieved
14 July 2021	Scopus	(TITLE-ABS-KEY (sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test*" OR "self-collect*" OR "sexually transmitted disease testing*") AND TITLE-ABS-KEY ("Specimen Handling") AND TITLE-ABS-KEY ("Sexually Transmitted Disease*" OR "sexually transmitted infection*") AND TITLE-ABS-KEY (wom*n OR female* OR girl*) AND NOT TITLE-ABS-KEY (aids OR "HIV Infections" OR hiv OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome"))	117
15 July 2022	Cochrane	(sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test*" OR "self-collect*" OR "sexually transmitted disease testing*"):ti,ab,kw (Word variations have been searched)	26
19 July 2021	PubMed	((sampling[tw] OR sample[tw] OR "self sampling"[tw] OR "self sample"[tw] OR "sti testing"[tw] OR "sti diagnosis"[tw] OR "sexually transmitted infections test"[tw] OR "self-collect"[tw] OR "sexually transmitted disease testing"[tw] AND (female[Filter])) AND ("Specimen Handling/methods"[Mesh] OR "Specimen Handling"[tw] AND (female[Filter]))) AND ("Sexually Transmitted Diseases, Bacterial"[Mesh] OR "Sexually Transmitted Diseases, Viral"[Mesh] OR "sexually transmitted infection"[tw] OR "sexually transmitted disease"[tw])) NOT ("HIV Infections"[Mesh] OR "HIV Infections"[tw])	213
19 July 2022	Web of Science	((((ALL=(sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test*" OR "self-collect*" OR "sexually transmitted disease testing*")) AND ALL=("Sexually Transmitted Disease*" OR "sexually transmitted infection*" OR STI OR STD)) AND ALL=(wom*n OR female* OR girl*)) AND ALL=("Specimen Handling" OR "Specimen Collection" OR Specimen)) NOT ALL=(aids OR "HIV Infections" OR hiv OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome")	311
21 July 2022	Medline (EBSCO)	((((ALL=(sampl* OR "self sampl*" OR "sti test*" OR "sti diagnosis" OR "sexually transmitted infections test*" OR "self-collect*" OR "sexually transmitted disease test*")) AND ALL=() NOT ALL=()	140

3.2. Quality Appraisal

Of the 44 studies included in review, 36 studies were primary studies. The quality of these studies was appraised using the MMAT 2018 version [17]. The overall score of the studies ranged between 65% and 100%. Nine studies had an average score of 60–75% [18–26] and seven other studies scored an average score of 65%. The remaining 27 studies scored a high-quality score between 76–100% [6,27–53].

3.3. Characteristics of Studies

The characteristics of the 44 included studies are summarised in Table 3. Studies were conducted in various HICs and LMICs (Figure 2). Eleven (24%) studies were con-

ducted in the United States of America (USA) [20,22,28,29,33,35,37,45,47,54,55], five (11%) in Canada [21,52,53,56,57], three (7%) in Australia [32,41,58], two (5%) in the United Kingdom (UK) [25,38], and two (4%) in The Netherlands [44,59]. Two studies (4%) were conducted in South Africa [27,60], two (4%) in Lithuania [40,48], and two (4%) in Kenya [23,30]. Only one (2%) study was conducted in each of the following countries: Brazil [60], Sweden [46], Korea [42], Ghana [36], Japan [31], Uganda [34], Haiti [51], Thailand [49], Belgium [26], Denmark [24], India [43], and Chad [6]. In addition, four (8%) studies were systematic reviews and meta-analyses and were not assigned any specific study location [18,19,39,61].

Table 3. Summary of articles included in this scoping review on self-sampling interventions for diagnosing STIs in women.

Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Weisenfeld et al., 1996 [55]	USA	Agreement between physician-collected specimens and self-sampling in patients with urogenital CT.	$n = 300$ of which 200 self-samples and 100 samples from a pilot study	Vaginal introitus swab	Amplicor CT test	Vaginal introitus swabs, provider-collected to detect urogenital CT: sensitivity = 92% (95% coefficient of variation (CI), 83 to 100). Sensitivity of vaginal introitus swabs was greater than PCR, culture or enzyme immunoassay of the cervix or urethra. Self-sampling, PCR: sensitivity = 81%. Urine samples, PCR: sensitivity = 73%.
Ostergaard et al., 1996 [24]	Denmark	Self-sampling to collect urogenital samples at home, mailed to the laboratory for CT deoxyribonucleic acid (DNA) analysis. Diagnostic efficacy was compared to provider-collected urethral and endocervical swabs.	$n = 222$ aged 18–25 years	First-catch urine (FCU), vaginal pipette wash	Amplicor PCR	Prevalence of CT = 11.2% (23/205 women). Self-sampling, PCR: Sensitivity = 96%, specificity = 92.9%. Self-sampling, LCR: Sensitivity = 100%, specificity = 99.5%. Provider-collected: Sensitivity = 91%, specificity = 100%.
Tanaka et al., 2000 [31]	Japan	Compare vaginal swabs obtained by providers and self-sampling to screen for CT infection.	Group 1 = 193 men, 187 women Group 2 = 91 high-risk sex workers	Vaginal swab, FCU, endocervical sample	New generation amplified immunoassay IDEIA PCE chlamydia kit and PCR	Male urine samples and female endocervical swabs: IDEIA PCE performed similarly to the Amplicor PCR. Relative sensitivity of IDEIA (79.3%), IDEIA PCE (91.4%), and Amplicor PCR (100%) on male first-void urine specimens. Relative sensitivities of IDEIA (85%), IDEIA PCE (95%), and Amplicor PCR (100%) on female endocervical specimens. Self-sampled vaginal swabs (SVS), IDEIA PCE: positivity rate = 25.2%. Clinician-collected vaginal specimens, IDEIA PCE: positivity rate = 23.1%. Clinician-collected endocervical swabs, PCR and IDEIA PCE, positivity rate = 27.5%. Detection of CT, commercial assays similar to in-house PCR ($p = 0.68$, $p = 0.73$). Detection of NG, in-house PCR superior to Abbott LCR ($p = 0.0001$) but similar to Roche PCR ($p = 0.11$). Roche PCR and LCR similar detection of CT. LCR testing of extracted DNA did not increase sensitivity. CT, self-sampling, PCR vs. cell culture: Sensitivity = 100%. Vaginal samples, PCR: Sensitivity = 100%, >PCR and cell culture on cervical samples. Single vaginal sampling, PCR: Sensitivity = 100%. Self-samples, mailed vaginal specimens are feasible for PCR-testing for genital CT. Self-sampling would help to reach a section of the population in which pelvic examination and cervical sampling are not routinely performed.
Tabrizi et al., 2000 [32]	Australia	Evaluate two commercial amplification systems detecting CT and NG from tampon specimens	$n = 400$ tampon specimens	Tampon specimens	In-house PCR assay, Abbott LCR, Roche cobas [®] Amplicor	
Domeika et al., 2000 [48]	Lithuania	Using self-sampled and mailed specimens to detect genital CT	$n = 94$	Vaginal introital sample	PCR (AMPLICOR CT, Roche Diagnostic Systems, Inc., Branchburg, NJ)	

Table 3. Cont.

Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Macmillan et al., 2000 [38]	UK	The feasibility of using self-sampled vulval swabs, instead of FCU to diagnose female genital CT infection in a family planning population.	$n = 103$ younger than 25 years old	vulval swab, urine	LCR	Prevalence of CT = 11.7%. Vulval swabs had 100% sensitivity, 100% specificity, and 100% Positive Predictive Value (PPV) and Negative Predictive Value (NPV). FCU had 91.7% sensitivity, 100% specificity, and PPV = 100% and NPV = 98.9%. Women found both tests to be acceptable.
Rompalo et al., 2001 [35]	USA	Evaluate a single intra-vaginal swab (SIS) for simultaneous detection of NG, CT, Trachomatis vaginalis (TV), and HPV infections among military women on active duty.	$n = 793$	Intravaginal swab (a Dacron SIS from the AMPLICOR collection kit)	A combination test that uses PCR combined with DNA probe hybridization in a colorimetric detection assay.	NG culture: sensitivity = 70.8%, specificity = 100%. NG PCR: sensitivity = 95.8%, specificity = 97.8%. CT enzyme immunoassay: sensitivity = 72.8%, specificity = 90%. CT PCR: sensitivity = 94.6%, specificity = 99.3%. Self-sampling with an SIS accurately detects multiple STIs.
Alary et al., 2001 [53]	Canada	Evaluate a modified sanitary napkin as a self-sampling device to detect CT infection in women. Self-sampled specimens vs. endocervical and FCU from the same women.	$n = 246$	Modified sanitary napkin, FCU	cobas [®] Amplicor PCR	Modified sanitary napkin, PCR: sensitivity = 93.1% (95% CI, 83.3 to 98.1%), specificity = 98.9% (95% CI, 97.4 to 99.6%). FCU, PCR: sensitivity = 81.0% (95% CI, 68.6 to 90.1%), specificity = 100% (95% CI, 99.2 to 100%). Modified sanitary napkin: PPV = 91.5% (54 of 59), NPV = 99.1% (447 of 451). Urine samples: PPV = 100% (47 of 47), NPV = 97.6% (451 of 462). Modified sanitary napkins may be an effective non-invasive device for self-sampling to detect urogenital CT infection.
Harper et al., 2002 [20]	USA	Compare the detection of high-risk HPV using tampons with longer exposure times in the cervicovaginal vault vs. self-sampling swabs. Women's acceptance of sampling with a tampon for longer periods.	$n = 103$ aged 16 years and older.	Tampon	PCR	309 tampons vs. 618 self-sampled swabs, 83% were returned. Among women, the 10-s tampon detected fewer with normal histology and high-risk HPV (HR-HPV) relative to swabs ($p = 0.0412$). The 1 h, 4 h, and overnight tampons had similar detection rates to swabs. In women with cervical intraepithelial neoplasia (CIN), tampons and swabs similarly identified HR-HPV. Self-sampling and endocervical testing yielded similar results for NG (K: 0.614, $p = 0.001$), CT (K: 0.865, $p = 0.001$). Self-sampling and vaginal microscopy yielded similar results for TV (K: 0.627, $p = 0.001$).
Holland-Hall et al., 2002 [54]	USA	The use of self-sampling to screen female adolescent detainees for three organisms in a setting where speculum exams are not feasible.	Sample size not indicated	Vaginal swab	PCR	All participants supported the practice of self-sampling using a vaginal swab. All participants stated willingness to perform self-testing in between their regular pelvic exams. Detection rate, PCR: CT = 11.5%, NG = 11.8%, TV = 24.6%. PCR significantly more sensitive than microscopy and culture in detecting NG and TV.
Knox et al., 2002 [41]	Australia	Compared FCU, SVS, self-sampled tampon and practitioner-collected endocervical swab specimens to detect NG, CT and TV.	$n = 318$	Vaginal swab, urine, tampon, endocervical swab	Culture, wet prep and Nucleic Acid Amplification Test (NAAT) PCR	CT, PCR: Sensitivity, tampons = 100%; FCU = 72.7%. NG, PCR: Sensitivity, tampons = 97.2%, endocervical swab = 92.6%, self-sampled swab = 71.9%, FCU = 31.2%. Sensitivity of urine PCR for detecting NG improved with freezing of urine specimens and shorter transport time. TV, PCR: Sensitivity, tampons = 100%, TV = 87.7%.

Table 3. Cont.

Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Chandeying et al., 2003 [49]	Thailand	Compared several specimen types to detect CT infection. Assess the acceptability of self-sampling.	$n = 953$	urine, vaginal swab, tampon	PCR	CT prevalence = 17.6% amongst female sex workers (FSWs) and 5.7% amongst outpatient women. Acceptability: Tampon = 72.6%, self-sampled vaginal swab = 74.2%. In FSWs: Sensitivity, tampon = 95.9%, SVS = 89.2%, more sensitive than either urine or endocervical swabs. In outpatient women: Sensitivity, endocervical swabs = 100%, tampons and SVS = 85.7%. Specificity was >98% for all sampling methods for both groups.
Shafer et al., 2003 [33]	USA	Compare FCU, self-collected vaginal swabs and physician-collected endocervical specimens to detect CT and NG in a large cohort of young women upon entering the military. Meta-analysis comparing the accuracy of patient-collected vaginal specimens with clinician-collected specimens for detecting HPV-DNA.	$n = 2157$	FCU and vaginal swab	NAAT—LCR	SVS: best detection of CT and NG. CT, detection rate: FCU = 72%, endocervical specimen = 64%, FCU/vaginal swab = 94. Women preferred self-sampling to routine pelvic examinations.
Ogilvie et al., 2005 [61]	n/a	Agreement physician obtained cervical and SVS to detect HPV DNA. Women's preferences for collection method according to age	$n = 106$ studies	Multiple specimen types, Dacron, cotton swab, cytobrush, tampons	PCR, Hybrid Capture II (HCII)	Self-sampling vs. clinician-collected specimens: sensitivity = 0.74, specificity = 0.88. Self-sampling in referral settings: sensitivity = 0.81, specificity = 0.90. Tampons offered sensitivity between 0.67–0.94 ($n = 4$ studies). PCR and HC-II offered similar sensitivity.
Karwalajitys et al., 2006 [57]	Canada	Agreement physician obtained cervical and SVS to detect HPV DNA. Women's preferences for collection method according to age	$n = 543$ women aged 15 to 49 years and a group of 50 years and older	SVS	HC-II assay for carcinogenic HPV	$n = 307$ women, aged 15–49 years. Prevalence of HPV: vaginal swabs = 20.8% (64/307), cervical specimens = 17.6% (54/307). Prevalence of HPV, women older than 50 years, vaginal swabs = 9.9% (15/152), cervical specimens = 8.6% (13/152). Vaginal swabs vs. cervical specimens: Agreement $\kappa = 0.54$ (younger women) and $\kappa = 0.37$ (older women) (both $p < 0.001$), indicating fair agreement. Nearly half of women preferred self-sampling or had no preference.
Van de Wijgert et al., 2006 [27]	South Africa	Self-sampling using vaginal swabs or tampons compared to physician-obtained swabs	$n = 450$	Tampon, vaginal swab	cobas® Amplicor CT/NG test, TV by MDM culture, bacterial vaginosis (BV) by Nugent scoring of a Gram-stain slide, 22 Candida species by Sabdex culture, and high-risk HPV types by the Digene HC-II for hrHPV DNA Test.	Self-sampling (tampons and swabs): satisfactory validity for NG, CT, BV, and Candida species. Self-sampling (swabs): satisfactory validity for HR-HPV. Self-sampling was not suitable for diagnosing TV by culture. Self-sampling was feasible and acceptable, but some women preferred speculum examinations, which allowed the clinician to view the vagina and cervix. PCR tests for HPV show high test sensitivity and reliability. PCR tests for HPV could be adopted as a stand-alone test, and, if positive, other tests such as p16INK4a or cytology could be used to increase specificity. Women can self-sample and send samples to laboratories. Self-sampling is convenient and easy. Suited to the lifestyles and busy schedules of the modern woman.
Morris and Rose 2007 [18]	Not indicated	HPV detection as primary cervical cancer screening	Sample size not indicated	Tampons, vaginal swabs	PCR NAAT	

Table 3. Cont.

Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Kucinskiene et al., 2007 [40]	Lithuania	The utility of self-sampling and pooling of samples for screening for CT among sexually active students.	$n = 424$	Vaginal swabs	Digene HC-II CT/NG Test	<p>CT was present in 30 (5.6%) of 533 vaginal samples.</p> <p>Out of the 177 pools (three samples per pool), 29 pools were positive for CT/NG. 26 positive pools contained at least one positive CT sample and two contained two positive CT samples. The remaining CT/NG positive pool was only positive for NG.</p> <p>HC-II, pooled vaginal samples: Sensitivity = 100%, specificity = 100%. 30 (7.1%) sexually active students (20–24 years old, $n = 424$) tested positive for CT.</p> <p>Prevalence in high schools ranged from 0 to 1%.</p> <p>Prevalence in college students was as high as 14.2%.</p>
Winer et al., 2007 [29]	USA	SVS vs. physician-collected cervical vs. physician-collected vulvovaginal swabs in women. Compared ability of mailed samples and in-clinic self-collected samples to detect HPV DNA.	$n = 374$	Vaginal swab	HPV PCR analysis	<p>HPV detection: physician-collected cervical/vulvovaginal > clinician-collected vulvovaginal > self-sampled vaginal > clinician-collected cervical</p> <p>Agreement between sampling modalities: women (25 to 30 years) = 86.5–95.7% (κ 0.65–0.92); women (18 to 25 years) = 94.9–98.8% (κ 0.84–0.96).</p> <p>More than 86% of women complied with self-sampling, only 51% accepted a pelvic examination.</p> <p>HR-HPV, prevalence = 19% (self-sampling and physician-collected samples)</p> <p>Self-sampling vs. physician-collected sampling: agreement = 92% ($\kappa = 0.75$), HIV-positive ($\bar{K} = 0.71$), HIV-negative ($\bar{K} = 0.75$).</p> <p>$n = 342$ adolescents</p> <p>CT positivity rate = 26.6 per 100 women</p> <p>NG positivity rate = 11.7 per 100 women</p> <p>Vaginal swab: Sensitivity, CT = 97.3%, NG = 100%</p> <p>FCU: Sensitivity, CT = 89.2%, NG = 88.6%</p> <p>Provider-collected sample (PES): Sensitivity, CT = 90.1%, NG = 95.5%</p> <p>Specificities: 94.7%–99.7% for CT and NG.</p> <p>Agreement, CT: SVS vs. PES ($\bar{K} = 0.89$), SVS vs. FCU ($\bar{K} = 0.88$) and PES vs. FCU ($\bar{K} = 0.91$) ($p < 0.0001$)</p> <p>Agreement, NG: SVS vs. PES ($\bar{K} = 0.91$), SVS vs. FCU ($\bar{K} = 0.87$) and PES vs. FCU ($\bar{K} = 0.91$) ($p < 0.0001$).</p>
Safaian et al., 2007 [34]	Uganda	Compare SVS and physician-collected cervical swabs in their ability to detect HPV DNA.	$n = 2223$	Vaginal swab	HC-II determined carcinogenic HPV. PCR to determine HPV genotypes.	<p>Self-sampling vs. physician-collected sampling: agreement = 92% ($\kappa = 0.75$), HIV-positive ($\bar{K} = 0.71$), HIV-negative ($\bar{K} = 0.75$).</p> <p>$n = 342$ adolescents</p> <p>CT positivity rate = 26.6 per 100 women</p> <p>NG positivity rate = 11.7 per 100 women</p> <p>Vaginal swab: Sensitivity, CT = 97.3%, NG = 100%</p> <p>FCU: Sensitivity, CT = 89.2%, NG = 88.6%</p> <p>Provider-collected sample (PES): Sensitivity, CT = 90.1%, NG = 95.5%</p> <p>Specificities: 94.7%–99.7% for CT and NG.</p> <p>Agreement, CT: SVS vs. PES ($\bar{K} = 0.89$), SVS vs. FCU ($\bar{K} = 0.88$) and PES vs. FCU ($\bar{K} = 0.91$) ($p < 0.0001$)</p> <p>Agreement, NG: SVS vs. PES ($\bar{K} = 0.91$), SVS vs. FCU ($\bar{K} = 0.87$) and PES vs. FCU ($\bar{K} = 0.91$) ($p < 0.0001$).</p>
Fang et al., 2008 [45]	USA	Concordance of two self-sampling methods (FCU vs. vaginal swab) and provider-collected endocervical samples for detecting CT and NG	$n = 350$ aged 12–18 years	FCU and self-sampled vaginal swabs	BDProbeTec ET Amplified DNA Assay	<p>Gel-based urine sample vs. neat urine: Sensitivity = 94.6–100%, specificity = 100%</p> <p>No PCR inhibition or reduced analytical sensitivity using gel-based samples.</p>
Bialasiewicz et al., 2009 [58]	Australia	A novel, super-absorbent polymer-based method for self-collection and ambient temperature transport of urine. Evaluate ability to detect CT.	52 urine specimens	Urine	PCR for CT (cobas® TaqMan 48 rtPCR)	<p>172 of 318 women tested positive for CT. 19 (16.8%) of asymptomatic women ($n = 113$) had discordant tests (FCU vs. self-sampling) and 7 (12.1%) of symptomatic women ($n = 58$) had discordant tests (FCU vs. self-sampling).</p> <p>CT, sensitivity: endocervical specimens = 97.1% (166/171), self-sampled specimens = 96.5% (165/171) and self-sampled vaginal/FCU specimens = 95.3% (163/171), FCU = 87.7% (150/171), which was significantly lower.</p>
Falk et al., 2010 [46]	Sweden	Sensitivity of self-sampled vaginal specimens, FCU, self-sampled specimens/FCU and endocervical specimens to detect genital CT in asymptomatic women.	$n = 318$	Vaginal swab, FCU, endocervical specimens	cobas® Amplicor CT Test, LightMix 480HT PCR OLBIO GmbH, (Berlin, Germany) on a LightCycler 480	<p>172 of 318 women tested positive for CT. 19 (16.8%) of asymptomatic women ($n = 113$) had discordant tests (FCU vs. self-sampling) and 7 (12.1%) of symptomatic women ($n = 58$) had discordant tests (FCU vs. self-sampling).</p> <p>CT, sensitivity: endocervical specimens = 97.1% (166/171), self-sampled specimens = 96.5% (165/171) and self-sampled vaginal/FCU specimens = 95.3% (163/171), FCU = 87.7% (150/171), which was significantly lower.</p>

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Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
van Dommelen et al., 2011 [59]	The Netherlands	Performance of SVS/FCU combination compared FCU or vaginal swabs alone.	$n = 791$	SVS, first-catch urine (FCU)	NAAT: Strand Displacement Amplification (SDA) assay and PCR	CT detection rate: SVS = 94% (89%–99%), FCU = 90% (84%–96%), SVS/FCU = 94% (89%–99%) (NAAT by SDA and PCR) Detection rates were similar across sample types. SVS vs. FCU, agreement = 98% ($p = 0.61$) SVS vs. SVS/FCU, agreement = 99% ($p = 1$) FCU vs. SVS/FCU, agreement = 98.8% ($p = 0.51$) Culture: sensitivity = 81% Clinician taken endocervical NAATs: sensitivity = 96% Self-sampled vulvovaginal NAATs: sensitivity = 99% AC2 tests were significantly more sensitive than culture ($p < 0.001$). Endocervical vs. vulvovaginal swabs: No difference. Therefore, the specificities and PPV of all tests in all sites were 100%, and NPV of all tests were 99% or greater. Culture: sensitivity = 84%. Clinician-taken endocervical AC2: sensitivity = 100%. Self-sampled vulvovaginal swab AC2: sensitivity = 100%. AC2 assays were significantly more sensitive than culture ($p = 0.004$) for both endocervical and endocervical swabs.
Stewart et al., 2012 [25]	UK	Accuracy of self-sampled vulvovaginal swabs vs. clinician-taken urethral and endocervical swabs for detecting NG in women attending a sexual health clinic in an urban setting	$n = 3973$ older than 16 years	Self-sampled vulvovaginal swab	NAAT—Aptima Combo 2 (AC2)	NG/CT detection: urine samples for men, self-sampled vaginal swabs in women.
Levy et al., 2012 [39]	Not indicated	Specimen collection and test characteristics of NAATs at different anatomical sites.	Sample size not indicated	Self-collection: urethra, cervicovaginal, rectum and pharynx.	NAATs	Only seven of 75 women infected with TV reported symptoms. Self-sampling; Sensitivity = 97.2%, specificity = 97.6% FCU: Sensitivity = 41.7%, specificity = 100%. Dacron swab: Sensitivity = 92.3%, specificity = 98.8%. Flocked-nylon swab: Sensitivity 92.3%, specificity = 99.2%. Specificity for self-testing using the rapid TV test was high in both settings. South Africa: sensitivity = 83.3%; Brazil: sensitivity = 68.4% (non-significant, z test $p = 0.2$). Pooled sensitivity = 76.7% (95% CI, 61.4 to 88.2%). Pooled specificity = 99.1% (95% CI, 98.2 to 99.6%). Self-sample, PCR: specificity = 99.1%, 95% CI, 98.2 to 99.6%, sensitivity = 76.7%; 95% CI, 61.4 to 88.2%. Sensitivity was higher among symptomatic women (87.5%; 95% CI, 47.3 to 99.7%) than asymptomatic women (80%; CI, 51.9 to 95.7%). Rectal swabs: High concordance rates for detecting CT and NG ($\geq 96\%$) using the cobas [®] 4800 and the Abbot m2000 real-time [™] assay. κ coefficients > 0.75 , indicating excellent agreement. Self-sampled vaginal swabs: High concordance rate ($\geq 99\%$) using the cobas [®] 4800 and Abbot m2000 real-time [™] assays for detecting CT and NG.
Jang et al., 2012 [19]	Not indicated	Compare SVS and FCU to diagnose TV	$n = 530$	Dacron swab taken from an APTIMA collection kit, nylon-flocked swab, FCU	Transcription-mediated amplification analyte-specific reagents using a cutoff of 50 000 relative light units.	
Jones et al., 2013 [60]	Brazil, South Africa	Evaluated the XenoStrip TV test, now the OSOM Trichomonas rapid test in two developing countries. Compared home- and clinic-based screenings. The home arm required two self-sampled vaginal swabs.	Sample size not indicated, Women aged 14–25 in South Africa. Women aged 18 to 40 years in Brazil	SVS	PCR and rapid point-of-care test (POCT)	
Geelen et al., 2013 [44]	Netherlands	Clinical performance of rectal and self-sampled vaginal swabs for detecting of CT and NG	$n = 921$	Rectal swab, self-sampled vaginal swabs	Roche cobas [®] 4800 CT/NG assay and Abbott m2000 real-time [™] CT/NG	

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Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Ting et al., 2013 [30]	Kenya	Compare APTIMA HR-HPV mRNA testing of physician-collected and self-sampled specimens for detecting high-grade cervical lesions in high-risk FSWs in Kenya. Identify risk factors for HR-HPV mRNA in our population of FSWs	$n = 350$ aged 18 to 49 years	self-sampled specimen using the APTIMA Cervical Specimen Collection and Transport cytobrush	Aptima HPV (AHPV), AC2, Aptima TV (ATV)	Prevalence: hrHPV mRNA, physician collected samples = 30%, self-sampled specimens = 29%. Prevalence high-grade squamous intraepithelial lesion (HSIL) = 4% ($n = 15$). HSIL, HR-HPV testing: Sensitivity, physician-collected samples = 86% (95% CI, 62%–98%), self-sampled specimens = 79% (95% CI, 55–95%). HSIL, HR-HPV testing: Specificity, physician-collected samples = 73% (95% CI, 68%–79%), self-samples specimens = 75% (95% CI, 70%–79%). Risk factors for HPV: age < 30 years, TV or Mycoplasma genitalium (MG) infection, more than eight years of educational cbasattainment.
Van Der Pol et al., 2013 [28]	USA	Patient infection status derived from vaginal swab specimens compared with other sample types	$n = 4279$	FCU; a single vaginal swab, Self-collected or clinician-collected using the cobas [®] collection kit	NAAT, cobas [®] CT/NG (c4800) Test (Roche Diagnostics, Indianapolis, IN) performed on the cobas [®] 4800 system	Detection rates: CT = 248, NG = 65 CT, self-collected vs. other samples, agreement = 98.8% to 99.2%, $\kappa = 0.88$ NG, Self-collected vs. other samples, agreement = 99.8% to 99.9%, $\kappa = 0.92$ Cervical SCT vs. PreservCyt samples: agreement = 91.1%; $J = 0.82$, AHPV assay Cervical SCT vs. SurePath samples: agreement = 86.7%; $J = 0.72$, AHPV assay. Self-sampled vaginal SCT vs. physician-collected SCT: agreement = 84.7%; $J = 0.68$, $p = 0.014$, 3.35 times more extra positives in self-sampled vaginal SCT Self-sampled vaginal SCT vs. cervical SCT samples: agreement = 82.0%; $J = 0.63$, $p = 0.046$, similar extra positives Women found the kit easy to use and comfortable for self-sampling 37/287 women tested positive for CT. All samples were detected by the Aptima swab, the flocked swab in the Aptima specimen transport medium and the ESwab in ESwab medium. Aptima swabs in Aptima specimen transport uniquely detected CT in three swabs. Flocked swabs in Aptima specimen transport medium uniquely detected CT in two swabs. CT, FCU: Sensitivity = 100%. 84.3% of women were comfortable with collecting specimens. 87.4% of women, 25 years and older, were comfortable with self-sampling 78.8% of women, younger than 25, were comfortable with self-sampling. CT, agreement: S-VSCT vs. P-VSCT 99.6% ($\kappa = 0.93$).
Chernesky et al., 2014 [21]	Canada	Compared self-sampled cervical collection and transportation (SCT) samples to PreservCyt and SurePath cervical samples	$n = 580$	Self-collected vaginal sample using SCT	Aptima HPV assay, a target NAAT	$p = 0.014$, 3.35 times more extra positives in self-sampled vaginal SCT Self-sampled vaginal SCT vs. cervical SCT samples: agreement = 82.0%; $J = 0.63$, $p = 0.046$, similar extra positives Women found the kit easy to use and comfortable for self-sampling 37/287 women tested positive for CT. All samples were detected by the Aptima swab, the flocked swab in the Aptima specimen transport medium and the ESwab in ESwab medium. Aptima swabs in Aptima specimen transport uniquely detected CT in three swabs. Flocked swabs in Aptima specimen transport medium uniquely detected CT in two swabs. CT, FCU: Sensitivity = 100%. 84.3% of women were comfortable with collecting specimens. 87.4% of women, 25 years and older, were comfortable with self-sampling 78.8% of women, younger than 25, were comfortable with self-sampling. CT, agreement: S-VSCT vs. P-VSCT 99.6% ($\kappa = 0.93$).
Li et al., 2014 [22]	USA	Compare AC2 performance on combinations of vaginal swabs, transportation media and FCU samples.	$n = 287$	flocked swab, Aptima vaginal swab, FCU	AC2	87.4% of women, 25 years and older, were comfortable with self-sampling 78.8% of women, younger than 25, were comfortable with self-sampling. CT, agreement: S-VSCT vs. P-VSCT 99.6% ($\kappa = 0.93$).
Chernesky et al., 2014 [56]	Canada	Compare a specimen collection and transport (SCT) kit for detecting CT and TV from SVS and physician-collected vaginal and cervical samples	$n = 708$	vaginal swab using the SCT kit Self-vaginal: S-VSCT Physician-collected vaginal (P-VSCT) Physician-collected cervical: (P-CSCT)	CT: AC2, TV: ATV	S-VSCT vs. CSCT 99.4% ($\kappa = 0.91$), S-VSCT vs. PC L-Pap 99.4% ($\kappa = 0.91$), S-VSCT vs. P L-Pap 99.3% ($\kappa = 0.88$), TV, agreement: S-VSCT vs. P-VSCT 99.9% ($\kappa = 0.97$), S-VSCT vs. P-VSCT 99.7% ($\kappa = 0.94$), S-VSCT vs. PC L-Pap 99.6% ($\kappa = 0.91$), S-VSCT vs. SP L-Pap 98.8% ($\kappa = 0.78$).

Table 3. Cont.

Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Boggan et al., 2015 [51]	Haiti	Feasibility of HPV screening as primary testing for cervical cancer. Compare vaginal self-sampling to physician-administered cervical screening methods	$n = 1845$ aged between 25–65 years.	Vaginal swabs	HR-HPV genotyping using the HC-II HPV assay pool.	HR-HPV screening is a feasible tool for primary cervical cancer screening in a low-resource, Haitian population. Women volunteered to participate in vaginal self-screening for HPV. Sensitivity of HPV screening for detecting \geq CIN-II: vaginal samples = 87.5%, cervical samples = 96.9%. Cervical vs. vaginal samples: High agreement. Vaginal self-sampling sample can be implemented in this under-screened and high-risk population. Respondents (97.1%) reported that the HerSwab instructions were easy to follow. 80.9% of respondents preferred self-collection over physician collection. 79.7% (137/172) of respondents would consider self-sampling at home. 96.2% (177/184) of respondents found it easy or very easy to insert and withdraw the device. 93.4% (171/183) of respondents found it easy and very easy to turn the device handle while inside the vagina. Agreement: self-sampling vs. provider collected specimen, CT: 94.7% (90.2%–97.3%; $\kappa = 0.64$ (0.43–0.85)) Agreement: self-sampling vs. provider-collected specimen, NG: 98.4% (95.1–99.6; $\kappa = 0.56$ [0.13–1]). HPV: agreement between self-collected and clinician-collected samples = 94.2% ($\kappa = 0.88$, $p \leq 0.0001$) HIV seropositive: agreement between self-collected and Clinicia-collected samples, $\kappa = 0.84$ ($p < 0.0001$) HIV seronegative: agreement between self-collected and clinician-collected samples, $\kappa = 0.86$ ($p < 0.0001$) self-collected vs. clinician-collected: sensitivity = 92.6% (95% CI: 85.3–97.0%), specificity = 95.9% (95% CI: 89.8–98.9%). Detection rate: 193 of 284 women were at high risk for HPV, irrespective of sampling and cytology. Self-sampling: Detected high-risk HPV in all cases of HSIL and CIN-II + TV, detection: Self-sampling = 10.2%, Physician = 10.8% MG, detection: Self-sampling = 3.3%, Physician = 5.5% CT, detection: Self-sampling = 1.1%, Physician = 2.1% NG, detection: Self-sampling = 0%, Physician = 0.5%. High-risk HPV: Self-sampling $\kappa = 0.56$, Physician $\kappa = 0.66$ TV: Self-sampling $\kappa = 0.86$, Physician $\kappa = 0.91$. MG: Self-sampling $\kappa = 0.65$, Physician $\kappa = 0.83$. Most participants understood self-collection instructions (93.6%) and were willing to use self-collection in the future (96.3%).
Arias et al., 2016 [52]	Canada	Survey opinions of young sexually active women on ease and comfort of self-sampling using HerSwab. Agreement between self-sampling and provider-collected swabs for detecting CT and NG.	$n = 189$ aged 16–41 years	Vaginal swab collected with a HerSwab device	AC2	
Obiri-Yeboah et al., 2017 [36]	Ghana	The performance of self-collected cervico-vaginal samples for detecting HPV compared to clinician collection	$n = 333$	vaginal swab using careHPV brush	careHPV assay	
de Marais et al., 2018 [47]	USA	Clinical performance of self-sampling cervico-vaginal specimens for detecting CIN-II in US women at risk of cervical cancer due to underscreening. Compare self-sampled specimens and physician-collected specimens to detect CT, NG, TV, and MG	$n = 284$	Cervico-vaginal swab, using Viva brush	AHPV, AC2 assay for CT and NG, the ATV assay and the Aptima analyte-specific reagent-based assay for MG	

Table 3. Cont.

Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Lockhart et al., 2018 [23]	Kenya	The agreement of SCT for CT, NG, TV and MG screening using self-versus physician-collected specimens. The acceptability of self-sampling for female sex workers (FSWs) over 18 months.	ages 18 to 49 years, sample size not indicated	self-sampled cervico-vaginal sample using the Aptima Cervical Specimen Collection and Transport cytobrush	CT, NG: the Aptima Combo 2 assay TV, MG: the ATV assay	Prevalence, SCT: NG = 2.9%, CT = 5.2%, TV = 9.2%, MG = 20.1%. Prevalence, physician-collected: NG = 2.3%, CT = 3.7%, TV = 7.2%, MG = 12.9%. Agreement between samples was consistently strong (κ range, 0.66–1.00) for all STIs, except for MG which had a moderate agreement (κ range, 0.50–0.75). Most participants found self-collection easy (94%) and comfortable (89%). SCT was effective for STI screening in a clinic-based, less-developed country setting.
Khan et al., 2019 [43]	India	Reliability of self-sampled vaginal swabs vs. physician-collected swabs to diagnose fungal (Candida albicans or non-albicans Candida species) bacterial vaginosis (BV) and parasitic TV aetiology of vaginal discharge and prevalence of various infections and coinfections.	$n = 550$	Vaginal swabs	Gram staining, wet mount, and culture	Prevalence: Bacterial vaginosis ($n = 79$, 14.4%), vulvovaginal candida (VVC) ($n = 144$, 26.2%) and TV ($n = 3$, 0.5%) VVC coexisted with BV in 58 (10.5%) patients. No coinfection of TV with BV or VVC. Candida albicans was isolated in 84 (58.3%) VVC cases. Self-sampling, BV: sensitivity = 91.1%, specificity = 100%, PPV = 100%, NPV = 98.5%. Self-sampling, Candida albicans VVC and TV: sensitivity (100%), specificity (100%), PPV (100%) and NPV (100%). Self-sampling vs. physician, agreement: $\kappa = 0.95$ (BV), $\kappa = 0.99$ (VVC), $\kappa = 1.0$ (TV). With specific instructions and guidance, self-collected swabs can approximate physician-collected swabs. HR-HPV prevalence = 13.5% ($n = 174$) All physician-collected specimens were sufficient for detecting HPV. 15 (27%) of tampon specimens were of poor quality. 1 (2%) of vaginal swabs were of poor quality. Vaginal swabs were similar to physician-collected specimens, while tampons were of poor quality.
McLarty et al., 2019 [37]	USA	Compare tampons, self-sampled vaginal swabs and physician-collected specimens to diagnose HPV.	$n = 174$	Tampons, swabs (Eve Medical HerSwab)	Roche cobas® HPV method	Genital mycoplasmas detected in 54.2% of samples. Ureaplasma parvum detected in 42.6% of samples. Self-sampling performed similarly to physician-collected samples in detecting genital microorganisms. Sensitivity = 97% (95%CI: 92.5–99.2%), specificity = 88.0% (95%CI: 80.7–93.3%).
Nodjikoombaye et al., 2019 [6]	Chad	Performance of a novel genital veil (V-Veil-Up Gyn Collection Device, V-Veil-Up Pharma Ltd., Nicosia, Cyprus) for self-sampling to diagnose STIs as compared to physician-collected specimens.	$n = 271$	Self-sampling with veil	IVD-marked multiplex real-time PCR Allplex STI Essential Assay	$n = 489$ patients, prevalence: CT = 6.5% (95% CI 4.5% to 9.1%), NG = 3.5% (95% CI 2.0% to 5.5%), CT and NG coinfections = 1.4% 42 patients tested positive on at least one non-pooled sample. Only five tested negative in the pooled sample. CT: Sensitivity = 94% (95% CI 79% to 99%). NG: Sensitivity = 82% (95% CI 57% to 96%). Missed pooled samples derived from single-site infections with low bacterial loads. Testing only vaginal samples would have missed 40% of CT infections and 60% of NG infections.
Verougstra et al., 2020 [26]	Belgium	The feasibility of molecular testing for CT and NG in pooled versus single site samples in a large cohort of FSWS.	$n = 501$	a pharyngeal swab, a self-collected vaginal swab and a self-collected rectal swab	NAAT using Abbott Real Time	

Table 3. Cont.

Author	Country	Aim	Population and Sample Size	Self-Sampling Intervention	Diagnostic Test	Key Findings
Kim et al., 2021 [42]	Korea	Do self-sampled vaginal specimens contain enough DNA to detect HPV. Compare self-sampled specimens with physician-collected cervical samples. Investigated ease, comfort and reliability of a self-sampling to obtain a vaginal sample.	n = 151	vaginal swab—(using G+ Kit®; DocTool)	PCR: the Anyplex II HPV28 Detection assay, Real-time PCR using CFX96.	Prevalence HPV: PCR: self-sampling = 67.5%, physician-collected = 57.4%. Prevalence, high-risk (HR) HPV: PCR: self-sampling = 58.7%, physician-collected = 48.6%. Sensitivity, HR HPV: self-sampling = 100% (95% CI 0.09 to 0.32) for high-grade squamous intraepithelial lesion, 78% (95% CI -0.09 to 0.13) for atypical squamous cells, 95% (95% CI -0.01 to 0.25) for low-grade squamous intraepithelial lesion. Self-sampled specimens contained enough DNA to detect HPV. Self-sampled vs. physician-collected samples had similar sensitivity and specificity. Self-sampling is feasible for detecting abnormal cervical cytology. Self-sampling is easy and reliable.

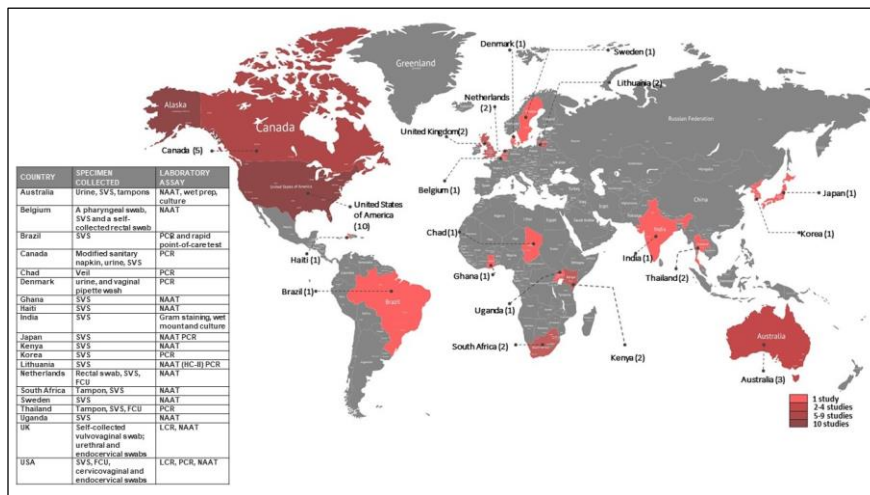


Figure 2. World map showing global evidence on self-sampling interventions for diagnosing STIs in women.

Nucleic acid amplification-based tests (NAATs) were used to diagnose STIs in 95% ($n = 42$) of studies [6,18–21,23–40,42,44,45,47–49,51–55,57–60,62–64], while only one study used a NAAT, conventional culture, and wet mount techniques [41]. The NAAT tests included Aptima Combo 2, Polymerase Chain Reaction (PCR), IVD-marked multiplex real-time PCR Allplex STI Essential Assay, Digene Hybrid Capture II (HCII) *Chlamydia trachomatis/Neisseria gonorrhoea* (CT/NG) Test, PCR for CT (cobas® TaqMan 48 real time PCR), cobas® Amplicor CT/NG test, the Anyplex II Huma papillomavirus (HPV)28 Detection assay, Real-time PCR using CFX9, care HPV Assay, Ligase Chain Reaction (LCR), and Strand Displacement Amplification. One study used only conventional wet mount and culture techniques to diagnose STI [43]. Only one study used NAAT and point-of-care (POC) devices to detect infection [61].

3.4. Summary of Findings

We reviewed studies that presented evidence on using self-sampled specimens for diagnosing STIs in women across the globe. The following themes emerged from the included studies: feasibility, acceptance and ease of self-sampling interventions; types of self-sampling specimens; diagnostic accuracy of self-sampled specimens; agreement between physician-collected specimens and self-sampled specimens; pooled samples for STI diagnosis; and self-testing of STIs using self-collected specimens.

3.4.1. Feasibility, Acceptance, and Ease of Self-Sampling Interventions

Nine studies reported on acceptance, ease of use, and feasibility of self-sampled specimens in settings where pelvic examinations were not routinely conducted and healthcare access was limited [23,27,33,38,42,51,52,54,56]. In Haiti, Boggan et al. [51] reported good feasibility of self-sampling for cervical cancer screening. Similarly, Korean women also found that self-sampled vaginal swabs were feasible for detecting HPV DNA and cervical cancer screening [42]. In South Africa, some women preferred pelvic examinations conducted by attending healthcare workers, even though self-sampling was feasible and acceptable [27]. In contrast, Arias et al. [52] and Morris and Rose [18] found that women preferred self-sampling and avoided pelvic examination by healthcare workers. Similarly, women in the USA [54], Canada [56], Kenya [23], and the UK [38] reported that self-sampling was easy. Although most women preferred self-sampling, there is relatively limited evidence for interventions tailored to patients' preferences, in terms of specimen type, place of specimen collection, communication of results, and management and treatment of infected individuals.

3.4.2. Types of Self-Sampled Specimens

Studies in the review investigated the use of different types of self-collected specimens to diagnose various STIs, including NG, CT, TV, HPV and genital mycoplasmas. Self-sampled specimens were collected using vaginal swabs, cervicovaginal swabs, rectal swabs, pharyngeal swabs, urine and tampons. Thirty-three studies used vaginal swabs [18,19,21,22,25–29,31,33–36,38–46,48,49,51,52,54–57,59–61], four studies used cervicovaginal swabs [23,30,47,61], 12 studies used urine specimens [22,24,28,33,38,39,41,45,46,51,53,58,59], nine studies used tampons [18,20,27,32,37,41,49,51,61], three studies used rectal swabs [26,39,44], two studies used pharyngeal swab [26,39], one study used a modified sanitary towel [53], one study used a vaginal wash specimen [24], and one study collected genital specimens using a veil collection device [6]. Of the 33 studies that collected vaginal swabs, 18 studies used multiple types of self-sampled specimens including vaginal swabs, rectal swabs, pharyngeal swabs, tampons, and urine.

Two studies in the USA [33,35] and one study in Japan [31] concluded that self-sampled vaginal swabs were accurate and suitable for diagnosing STIs. Self-sampled vaginal swabs also showed high sensitivity and specificity in Brazil and South Africa [60], Canada [53], the USA [45], Japan [31], and the UK [38].

In the USA, Fang et al. [45] demonstrated that urine was the least sensitive method for diagnosing STIs. In Australia, urine specimens transported from remote settings were least sensitive [41]. In the Netherlands, STIs were similarly detected by self-sampled vaginal swabs and by a combination of vaginal swabs and first-catch urine [59]. Levy et al. [39] reported that urine was the preferred self-sampling specimen type for men.

Self-sampling was also conducted using tampons. In the USA, tampons were highlighted as a sampling technique that could collect a bigger cell sample than vaginal swabs and, therefore, had the potential to rapidly diagnose women [20]. Chandeying et al. [49] in Thailand reported that tampons were sensitive in detecting infections. However, another study conducted in USA, indicated that a high proportion of tampons were insufficient for STI testing [37].

Two Kenyan studies [23,30], one USA study [47], and a meta-analysis by Ogilvie et al. [61] investigated the use of self-sampled cervicovaginal swabs. In these studies,

self-collected cervicovaginal swabs were deemed acceptable and valid for self-sampling even in places where pelvic examinations are not done routinely [23,47,48]. In Chad, one study investigated the use of a specimen collection device called a veil, which was reported as a convenient and gentle way to collect cervicovaginal secretions for STI testing [6].

3.4.3. Diagnostic Accuracy in Self-Collected Specimens

Of the 44 included studies, 25 studies reported on the accuracy of laboratory diagnostic results [6,18,19,22,25,31,34–38,41–45,48,49,51,53,55,58,60,61]. In Canada, Alary et al. [53] reported that a self-collected modified sanitary towel had a sensitivity and specificity of 93.1%. In Thailand, Chandeying et al. [49] reported diagnostic accuracy of tampons (sensitivity = 95.9%, specificity = 98.4%), urine (sensitivity = 70.3%, specificity = 99.7%), endocervical swabs (sensitivity = 59.5%, specificity = 99.7%), and vaginal swabs (sensitivity = 89.2%, specificity = 99.2%). In Lithuania, Domeika et al. [48] reported that vaginal swabs had 100% sensitivity and specificity, when analysed with a PCR assay. Similarly, Jang et al. [19] reported that vaginal swabs had a sensitivity and specificity of 97.2% and 97.6% respectively. Geelen et al. [44] also reported that rectal swabs and vaginal swabs had a sensitivity and specificity of 87.1% and 100%, respectively. Irrespective of self-sample type, our findings highlight that diagnostic testing on self-collected specimens yields fairly accurate results.

3.4.4. Agreement between Physician-Collected and Self-Sampled Specimens

We reviewed 19 studies that compared physician-collected and self-sampled specimens [6,19,21,23,28–31,34,36,37,39,43,45,47,51,55–57,59]. Boggan et al. [51] reported 91.4% agreement between self-sampled vaginal swabs and physician-collected cervical specimens. In Canada, Chernesky et al. [21] reported 82% agreement between self-collected vaginal swabs and physician-collected cervical specimens. De Marais et al. [47] reported strong agreement between self-samples collected at home and in the clinic, and between self-samples collected at home and physician-collected specimens. According to Boggan et al., [51] the strong agreement between vaginal swabs and cervical specimens suggests that self-sampled vaginal swabs could be used to improve access to STI healthcare services in high-risk populations.

3.4.5. Pooled Specimens for STI Diagnosis

Two studies explored the use of pooled specimens to diagnose STIs [26,65]. In both instances, pooled specimens reportedly saved costs, and enabled more patients to be tested which increased the rate of STI detection [26,65]. Pooling samples may thus be useful for detecting STIs. Our review reveals a large knowledge gap on the use of pooled patient specimens to diagnose STIs.

3.4.6. Self-Testing of Self-Collected Specimens

Only one USA study reported on the use of self-testing assays on self-collected samples [54]. This study describes self-testing of STIs using self-collected specimens in adolescent females [54]. Young women found self-testing and self-sampling to be acceptable, more so than having to undergo a pelvic exam [54]. These findings highlight the need for innovative and convenient diagnostic tools to diagnose STIs beyond healthcare to improve STI treatment and management services.

4. Discussion

This scoping review presents global evidence on self-sampling interventions used to diagnose STIs in women. Our findings show that 23% of included studies were conducted in the USA and 95% ($n = 42$) of the included studies used NAAT to diagnose or detect STIs. We found few studies describing participant-tailored self-sampling interventions that could be used for routine STI management at local healthcare facilities. Most studies investigated the use of self-sampled vaginal swabs to diagnose STIs [18,19,21,25–29,31,33–36,38–46,48,49,51,52,54–57,59–61] compared to urine, tampons, and sanitary napkins,

similar to results reported elsewhere [62]. We also found limited evidence of testing self-collected specimens using rapid near-patient diagnostic assays for diagnosing STIs. The WHO World Health Day 2019 Campaign Essentials [66] emphasizes the drive for universal health coverage through primary healthcare services. All people should have access to good-quality healthcare that is centred on their needs and preferences [66].

Despite receiving verbal and/or written instructions for specimen self-collection, studies found that self-sampling interventions to diagnose STIs in women were feasible [7,51,60,61]. Similarly, participants who received verbal and written instructions for specimen self-collection reported ease and comfort in collecting their own specimens at their convenience [23,27,33,38,42,51,52,54,56]. This further highlights the ease with which self-sampling for STIs can be used as an alternative to clinic based STI healthcare management services. Based on these findings, the usefulness of self-sampling for STIs in resource-limited settings across the globe cannot be ignored. However, there is limited evidence of the uptake and adoption of such interventions in public STI healthcare-management services. Additionally, 63% of the included studies were conducted in HICs, and only 37% of the studies were conducted in LMICs. Similarly, Flowers et al. [63] reported increased uptake of self-sampling in the UK. The lack of evidence on the uptake of such interventions in LMICs is concerning. Much effort is still required from relevant stakeholders to fulfil goal 3.3 of the Sustainable Development Goals 2030 which aims to end epidemics of various communicable diseases [64].

Only two of the reviewed studies reported on the use of pooled samples to diagnose STIs and highlighted a gap in the use of pooled specimens. Pooling of specimens from the genital tract and extragenital tract has proven successful in detecting infections in individuals who practice oral and anal sex [62]. The lack of evidence on the use of pooled specimens for diagnosing STI is concerning in cases of anal and oral sex which may contribute to the spread of STI-causing pathogens to areas beyond the genital tract [67].

We reviewed studies reporting on the accuracy of diagnostic results when using self-sampled specimens. We found that self-sampled specimens result in fairly accurate diagnoses [50,68]. Self-sampled vaginal swabs, in particular, yielded similar results to physician-collected specimens [69,70]. The overall findings of the review highlighted that the diagnostic results on self-collected specimens were fairly accurate.

When considering high global STI statistics [1] and limited access to good-quality healthcare and laboratory services in LMIC [71,72], this lack of rapid POC testing is concerning. By providing services closer to patients, POC testing has the potential to improve the turn-around time for the management and treatment of disease which will improve disease outcomes [71,73].

Although STIs have been of great interest among the medical population, the level of public knowledge of such is not well known. It has been proven that sufficient knowledge about STIs has an effect on minimizing the spread of infection [74]. A study conducted in Italy about knowledge of STIs among young individuals reported that they had insufficient knowledge [75]. In South Africa knowledge about STIs was relatively good among women of childbearing age but there were gaps in knowledge [76]. Another study in Ethiopia reported low levels of good knowledge of STIs [77]. This highlights the need to make more efforts to educate individuals across the globe among different population age groups.

4.1. Strengths and Limitations

We conducted extensive searches on various databases and websites to retrieve all relevant studies. We used the PRISMA guidelines to guide the recording and reporting of our results thereby ensuring transparency. We did not have any language restrictions or study design limitations. We systematically identified relevant studies and charted and analysed data. Although we made every attempt to ensure a rigorous search strategy, we may have missed relevant studies. Our screening tool may not have been rigorous enough, resulting in the inclusion of 44 studies.

4.2. Implications for Practice

Most of the studies included in this review were conducted in HICs where there is equitable access to good-quality healthcare services. In HICs, the use of advanced innovative healthcare practices is normal. Few studies on self-sampling interventions were conducted in LMICs where access to good-quality healthcare services still poses a challenge for ordinary citizens. In LMICs, healthcare systems are far behind in terms of the services they provide to their people. As such, LMICs continue to struggle with health issues that are no longer a burden in HICs. Our review highlights the ease and usefulness of self-sampled vaginal swabs, which may prove feasible and adaptable in LMICs.

The coronavirus disease of 2019 (COVID-19) pandemic has led to the minimization of human interaction and movement to reduce and prevent the spread of COVID-19.

According to Pinto et al. [78], COVID-19 restrictions do not only affect the way people interact with each other, but also the way humans interact with healthcare and STI management services. Thus, adding to the previously stated restrictions already posed by clinic based STI healthcare services. Furthermore, it is well known that COVID-19 restrictions also increased the acceptability of home-based healthcare services to ensure that patients continue to receive relevant healthcare services. As such, the use of self-sampling interventions to diagnose STIs would play an integral role as alternatives to clinic-based STI healthcare management services while observing COVID-19 restrictions and regulations. When considering the current burden of STIs in sub-Saharan Africa, the convenience of self-sampling during the COVID-19 pandemic, and the potential to improve STI management in this region, cannot be disregarded.

Despite the potential benefit of self-sampling in LMICs, we found no evidence for self-sampling interventions that had been developed according to the needs and preferences of women. There is a need to develop self-sampling interventions for STI diagnosis which are tailored to the preferences of the user.

4.3. Recommendations for Future Research

We found that most of the research on self-sampling for STIs was conducted in HICs. We recommend that future studies be conducted in LMICs. Self-sampling seems to largely rely on self-collected vaginal swabs and there is opportunity to investigate different types of self-sampling including tampons, sanitary pads, and urine, which may promote the development of a self-sampling intervention tailored to the preferences of women. Since only two studies reported on the use of pooled samples for diagnosing STI, we recommend future research investigating the use of pooled specimens to diagnose STIs present in extragenital areas. We also found that self-sampling and POC testing was rare in primary healthcare practice. Future research should explore the use of POC tests and self-sampling to bring healthcare services closer to users who have limited access to healthcare.

5. Conclusions

This scoping review shows that despite self-sampling interventions having the potential to improve STI management and treatment there is a need for self-sampling interventions tailored to the needs of users. Self-sampled vaginal swabs have the potential to increase access to healthcare. In LMIC settings, having women collect their own samples in private settings may save time and resources in primary care settings.

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Abbreviations

AC2	Aptima Combo 2
ATV	Aptima Trichomonas vaginalis
AHPV	Aptima Human Papilloma Virus
BV	Bacterial vaginosis
CT	<i>Chlamydia trachomatis</i>
CI	Confidence interval
CIN-II	Cervical intraepithelial lesion
FSW	Female sex workers
FCU	First-catch urine
HC-II	Hybrid Capture II
HSIL	High-grade squamous intraepithelial lesion
HR-HPV	High-risk human papilloma virus
HIC	High-Income Country
HPV	Human Papilloma Virus
LMIC	Low- and middle-income countries
LCR	Ligase chain reaction
MG	Mycoplasma genitalium
mPCR/RLB	Multiplex polymerase chain reaction/reverse line blot
NG	<i>Neisseria gonorrhoea</i>
NPV	Negative predictive value
NAAT	Nucleic Acid Amplification Test
P-VSCT	Physician-collected specimen collection and transport
POCT	Point-of-care testing
PPV	Positive predictive value
POC	Point-of-Care
PCR	Polymerase Chain Reaction
PC-VS	Patient-collected vaginal swab
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
STI	Sexually Transmitted infections
SCT	Self-collection and transport
S-VSCT	Self-collected specimen collection and transport
SIS	Single intravaginal swab
SVS	Self-collected vaginal swab
TV	Trichomonas vaginalis
USA	United States of America
UK	United Kingdom
VVC	Vulvovaginal Candida

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2.2 On adoption of self-sampling interventions for diagnosing STI in LMICs

Research evidence supports the acceptability of self-sampling interventions for diagnosing STIs among women across the globe. This evidence also highlights the potential benefits of self-sampling on the health outcomes of infected individuals (1). Despite this, the scoping review we conducted yielded a large portion of studies using self-sampling in high-income countries compared to studies in LMICs. Thus indicating low uptake of self-sampling for STI diagnosis in LMICs. This review will discuss various challenges that may negatively impact and hinder the adoption of such interventions in LMICs including socio-cultural issues, scepticism, cost-implications, and integration into health systems.

Socio-cultural issues around taboos of discussing sexual reproductive health and stigma associated with STIs remain prominent deterrents for engaging STI healthcare services in LMICs. According to Watara et.al. (2), young people, particularly young women do not seek sexual reproductive healthcare due to embarrassment and fear of being judged for being sexually active, an act that is against cultural beliefs at their age. STI associated stigma also remains a challenge for engagement of services (2). Although evidence of acceptability and usefulness of self-sampling presents a strong case for its advocacy, societal and cultural issues, which negatively impact the use of conventional STI healthcare approaches, may also continue to negatively impact adoption of this intervention. Thus, addressing socio-cultural issues is paramount to the adoption of self-sampling in LMICs.

While there is evidence of the positive impact of self-sampling on health outcomes and high user acceptability, some scepticism may still exist among stakeholders including healthcare providers. A study on awareness and attitudes towards self-sampling conducted on healthcare providers revealed hesitation and scepticism. The main concern highlighted in this study was the lack of confidence in patients' competence to collect their own specimens was highlighted as a potential barrier to adoption of self-sampling in various settings (3). In another study investigating acceptability of self-sampling, some women expressed preference for specimens collection to be done by clinicians (4).

Integrating interventions that are suitably innovative and cost effective for various settings including those with limited resources in LMICs, would contribute immensely towards achieving the desired universal health coverage of the World Health Organization (5). With self-sampling holding the potential to improve access and screening of disease, this

intervention is an ideal option towards achieving universal health coverage. Self-sampling is also holds the potential to bring relief to the overburdened healthcare system in LMICs. However, it is important to understand the associated cost implications for adoption. Some studies report on cost reduction associated with reduced treatment cost because when self-sampling is utilised for screening there is a reduced risk of disease and spread thereof (6, 7). However, there are limited studies that expand on the actual cost implications of adopting self-sampling. In resource-limited settings with overburdened healthcare systems, this lack of information about adoption costs may partially contribute to low adoption of the intervention.

Although understanding the cost implications for adopting self-sampling interventions is important, the question of integrating interventions into existing health systems is of even greater significance. For successful integration, it is important for all stakeholders to fully grasp the concept of self-sampling as an alternate STI healthcare intervention. A study investigating healthcare personnel perspectives on self-sampling for cervical cancer screening revealed enthusiasm to adopt (8). However, study participants in this study expressed reluctance to implement due to lack of knowledge about the actual process and how it would integrate into existing health system (8). Coupled with infrastructure and structural shortcomings including transportation (9, 10), common in LMICs, integration of these interventions would prove challenging and as such hinder adoption. Insufficient integration of self-sampling into national and local healthcare strategies may hinder its adoption.

In conclusion, successful adoption of self-sampling interventions in LMICs is contingent upon addressing multiple interconnected barriers. Socio-cultural norms related to STI-associated stigma can significantly discourage participation. Scepticism about the accuracy of self-collected samples may result in reliance on healthcare provider collected specimens instead. Logistical concerns including limited infrastructure and limited information on cost implications, further complicate adoption. Although self-sampling is well known and understood in high-income countries, insufficient knowledge and understanding of self-sampling and healthcare strategies to integrate this intervention limits scalability and sustainability in various setting. As such, addressing these factors is essential to ensure successful adoption of self-sampling interventions in various settings including LMICs.

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CHAPTER 3: METHODOLOGY

This chapter (Chapter 3) outlines the theoretical and conceptual frameworks used to guide this research, demonstrating their application and relevance to each research objective. This chapter also presents the research methodology for the study. Since the intricate details of the research methods used to achieve each objective are discussed in the article or manuscripts presented for each objective, only the study design and study setting will be presented in the research methodology section.

3.1. Theoretical and conceptual frameworks

3.1.1. Introduction to theoretical and conceptual frameworks

Applying theoretical and conceptual frameworks plays a crucial role in providing a structured lens through which to examine and understand complexities in research. These frameworks guide the methodology of a study, from data collection to data analysis, grounded in existing theories (1, 2). We used these frameworks to investigate the complexities of sexually transmitted infections (STIs), syndromic management, and self-sampling as an intervention for STIs among young women in underserved communities.

We utilised the Theoretical Domains Framework (TDF), because it provides a structure to explore behaviours and social influences that affect the acceptance and uptake of an intervention (3, 4). The intervention of interest in our study was self-sampling as an alternative to clinic-based syndromic management. Conceptual frameworks, on the other hand, provide a roadmap to understand, evaluate, and implement certain interventions within a real-world setting (2, 3). In our study, we employed the Consolidated Framework for Implementation Research (CFIR), which combines constructs from existing implementation theories to evaluate different factors and the context in which an intervention exists (5). We integrated both frameworks to enable a holistic and nuanced examination of the interplay between the various factors influencing STI healthcare provision in the study context.

The following sections provide an in-depth exploration of these frameworks to illustrate how they guide our understanding of STI healthcare, behavioural and social determinants, and intervention characteristics.

3.1.2. Theoretical framework: TDF

The TDF served as the lens through which we investigated barriers to accessing existing clinic-based interventions for STIs and how they influence seeking medical assistance for STI-related concerns. Using this framework, we delved into individual-level factors and societal norms that influence healthcare-seeking behaviour, which would, in turn, affect the acceptance and uptake of self-sampling as an alternative intervention for young women. This was a crucial step in understanding social dynamics to address potential barriers to the acceptance of a new intervention.

3.1.3. Conceptual framework: CFIR

In our study, it was imperative to understand how self-sampling is viewed and perceived by healthcare workers and prospective users; thus, we utilised CFIR as our conceptual framework. This framework complemented TDF by providing a structure to evaluate the implementation process and the various factors that may influence the overall implementation of a self-sampling intervention. CFIR is composed of five domains: intervention characteristics, outer settings, inner settings, characteristics of individuals, and the process (5).

We considered the characteristics of self-sampling, including convenience, acceptance, diagnostic accuracy, and overall advantage over syndromic management. The outer setting pertains to understanding the environment or context in which the intervention would be implemented, allowing the development of strategies tailored to community challenges. The inner setting seeks to understand organisational factors such as support, organisational culture, and resources that can support the intervention (5). We considered the characteristics of healthcare providers and young women, as they would impact the implementation process of the intervention. This aligns with the TDF's exploration of individual factors. The process domain of CFIR guides the steps involved in implementing the self-sampling intervention (see Figure 3.1) (5). However, for the purposes of this study, we did not investigate the implementation process.

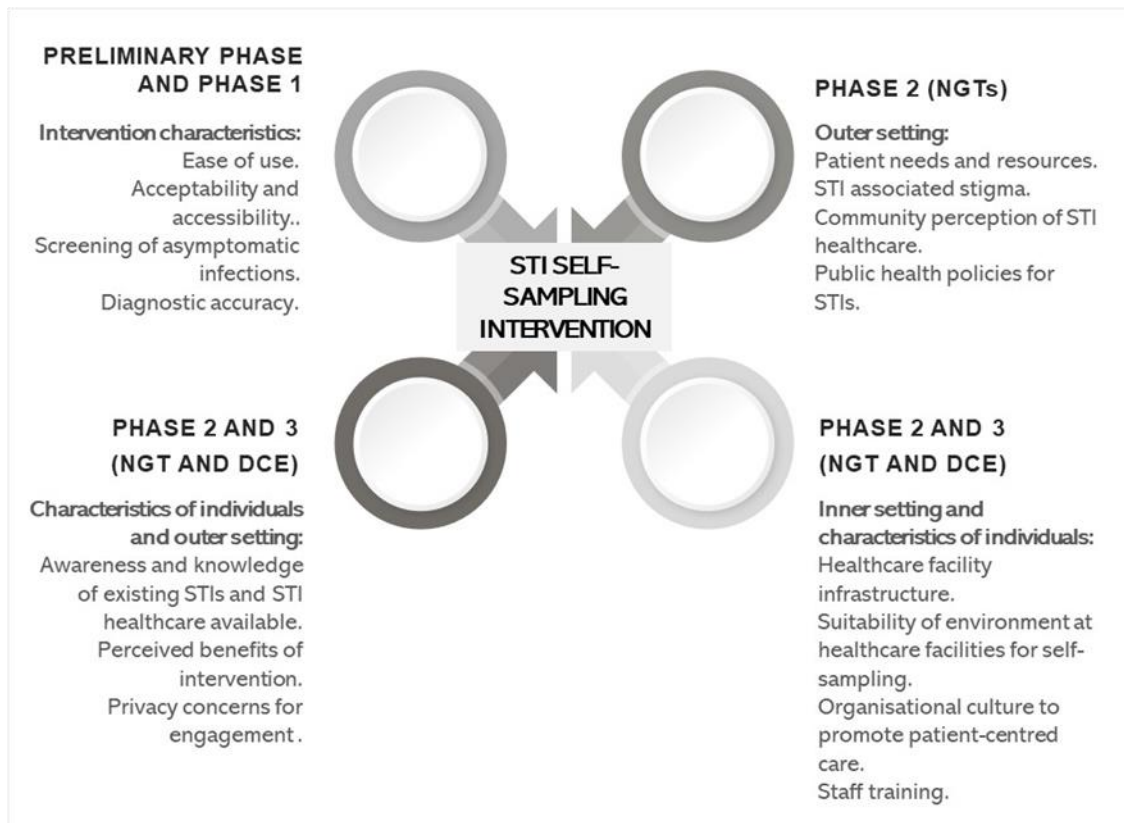


Figure 3.1: Consolidated framework for the co-creation of a user-friendly self-sampling intervention for STI diagnosis in young women

3.1.4. Integration of TDF and CFIR

Our study adopted a comprehensive approach by integrating both the TDF and CFIR frameworks. TDF facilitated a nuanced exploration of individual and social determinants impacting behaviour, while CFIR offered a systematic examination of the implementation context, enriching our understanding of the broader contextual landscape of our investigation. This dual-framework approach ensured thorough consideration of all factors potentially influencing the challenges and successes of an alternative STI management intervention, specifically in self-sampling.

3.1.5. Application and relevance of TDF and CFIR for study objectives

Conducted in iterative phases where each objective informed the next, our study heavily relied on TDF across multiple phases. We initially conducted a scoping review to map evidence on the use of self-sampling interventions to diagnose STIs in women. Thereafter, a systematic review into the diagnostic accuracy of self-collected specimens versus those collected by healthcare workers for STI diagnosis in women was conducted. This investigation was guided by TDF. Subsequently, in the identification of barriers to access and attribute development

using the NGT, TDF facilitated the exploration of individual factors influencing access barriers and intervention attribute development, in collaboration with young women and healthcare workers. Finally, in the discrete choice experiment (DCE) objective, TDF aided in uncovering individual preferences crucial for understanding acceptance and user-friendliness of the self-sampling intervention. The integration of CFIR complemented TDF by providing insights into organisational and contextual factors. In the systematic review, CFIR explored organisational practices relevant to self-sampling intervention implementation. When identifying barriers and developing attributes, CFIR highlighted organisational and contextual influences on intervention acceptance among young women, as well as how the broader implementation context shapes decision-making processes regarding the intervention.

3.1.6. Conclusion

Theoretical and conceptual frameworks serve as essential foundations guiding research conduct. Investigating interventions necessitates the examination of various factors influencing use and implementation, encompassing individual, organisational, and contextual realms. Integrating TDF by focusing on individual and social factors, with CFIR addressing organisational and contextual factors, was indispensable for providing a holistic investigative framework to achieve our study aim. These frameworks formed the scaffolding upon which our study was constructed, facilitating meaningful, evidence-based conclusions.

3.2. Methods

3.2.1. Study design

STI healthcare is complex and involves diverse real-world settings, making the successful implementation of healthcare-related interventions dependent on multiple factors beyond their efficacy. Therefore, evaluating interventions in diverse settings is essential to ensure their relevance and applicability in the intricate landscape of STI healthcare. Our study aimed to assess the effectiveness of self-sampling, while simultaneously exploring factors that would influence its implementation. To achieve this aim, we employed a multi-methods research design, conducting our research objectives in consecutive phases (6).

Regarding the study design, it was necessary to adopt a design that aligned with the study goals. The effectiveness-implementation hybrid type 3 (E-IHt3) study design was suitable, as it accommodates both effectiveness and implementation research objectives. This design allows for the evaluation of intervention effectiveness, while also assessing factors that influence implementation (7, 8). We conducted a scoping review to map evidence on the use

of self-sampling interventions. Based on the findings of the scoping review, we then performed a systematic review to determine the diagnostic accuracy of self-collected specimens compared to healthcare worker-collected specimens for diagnosing STIs. Following the systematic review, we conducted nominal group technique (NGT) sessions with key stakeholders, including young women and healthcare workers, to co-create attributes of an acceptable and user-friendly self-sampling intervention for STIs. The findings from the NGT sessions were utilised to design a DCE survey, which was used to understand young women's preferences for a self-sampling intervention to diagnose STIs.

3.2.2. Study setting

The study was carried out in the eThekweni Metropolitan Municipality, located in one of South Africa's largest provinces, KwaZulu Natal (KZN). This province is disproportionately afflicted with the highest prevalence of human immunodeficiency virus (HIV) infections in all South Africa (9, 10), which is particularly concerning, given the overall global burden of STIs. Approximately 3.9 million people, representing 34.7% of the overall population of the KZN Province, live in this municipality, which spans approximately 2,555 km² (11). Considering the impact of urbanisation due to the influx of people into cities for better employment opportunities, the dense population in this municipality is not surprising. Overpopulation contributes to the emergence of impoverished communities, both within and around cities, providing a fertile environment for the spread of communicable diseases (12, 13). The rapid influx of people into cities leads to a failure to accommodate the increasing number of residents, resulting in a scarcity of essential resources and restricted access to basic services for only a privileged few (14). Consequently, managing health risks in poorer communities becomes exceptionally challenging.

The high prevalence of HIV in KZN, combined with overpopulation that facilitates the rapid spread of infections and the heightened risk of untreated STIs, creates an ideal research site. The overpopulated, underserved communities within the urban core of the eThekweni Metropolitan Municipality, specifically, offered favourable conditions for our investigation (see Figure 3.2 below). We strategically selected wards characterised by extreme poverty or those with the highest prevalence of households with no monthly income to ensure our study captured the unique challenges and dynamics present in the poorest areas. This approach aimed to provide valuable insights into the impact of limited access to basic healthcare services on STI healthcare within these communities.

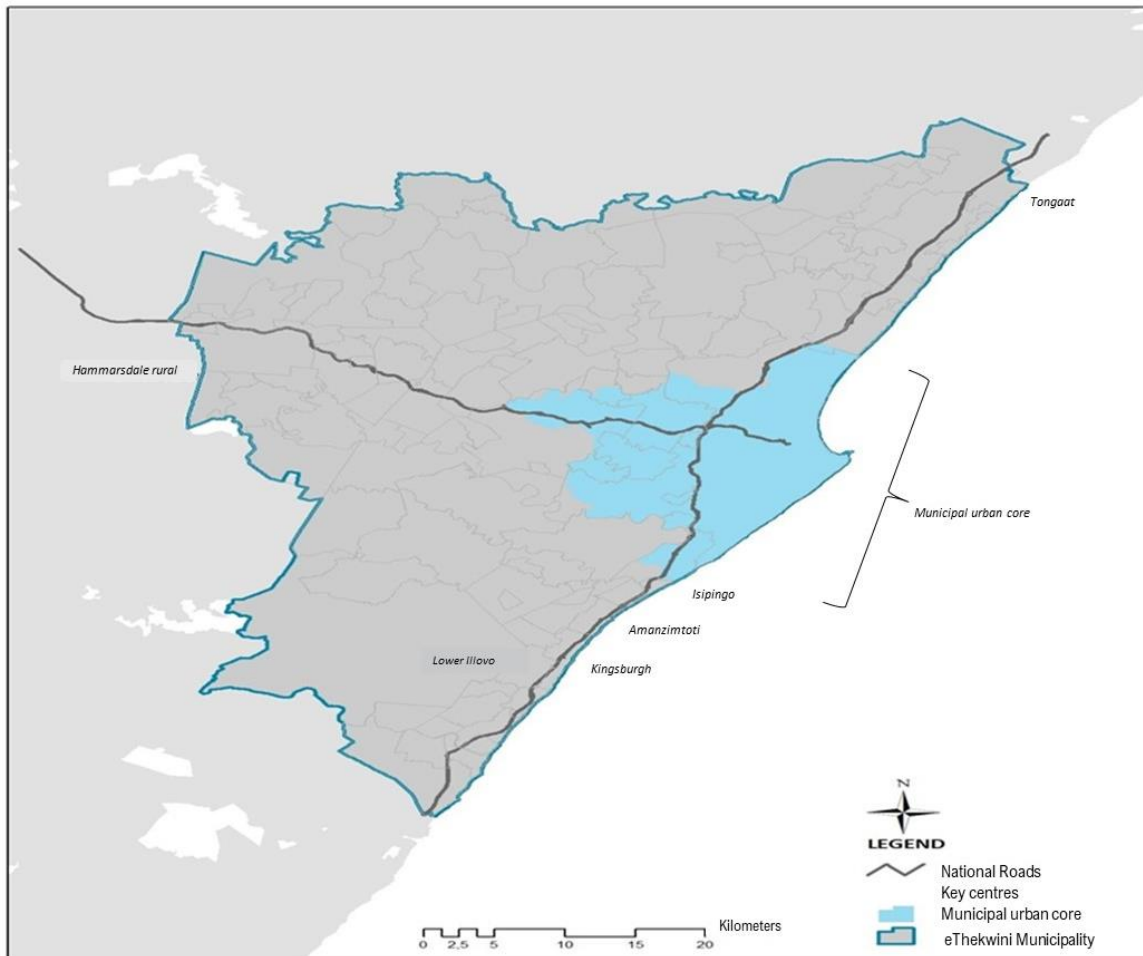


Figure 3.2: Map depicting urban core of eThekweni Metropolitan Municipality (15)

3.2.3. Phase 1: Systematic review

Objective 1: To conduct a systematic review and meta-analysis to determine the diagnostic accuracy of STI diagnostic assays.

Design: Systematic review and meta-analysis according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (16).

Data Source: A comprehensive search of relevant articles for the systematic review was conducted in the following databases: PubMed, Cochrane, Web of Science, Scopus, ProQuest, Medline (EBSCO), and AfricaWide. A search for grey literature was also conducted on Google, the World Health Organization (WHO) website, and Department of Health websites. Eligibility criteria were developed to facilitate the screening process for articles and grey literature. A data extraction tool was used to collect data from eligible articles and grey literature.

Data Analysis: The Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) tool for primary diagnostic accuracy studies was utilised to assess the quality of all included primary studies (17). For included studies that assessed and reported sensitivity and specificity, a meta-analysis of diagnostic accuracy was performed. The Review Manager (RevMan) software was used for statistical analysis. RevMan was also used to calculate pooled sensitivity, specificity, and diagnostic odds ratio with a 95% confidence interval. Cochran's Q statistics were used to determine heterogeneity among the included primary studies. Statistical significance was indicated by a p-value of <0.05.

Outcome Measure: Diagnostic accuracy of self-collected specimens compared to healthcare provider-collected specimens.

3.2.4. Phase 2: Mixed method – nominal group technique

Objective 2: To co-create a user-friendly self-sampling intervention for the diagnosis of STIs through collaboration with healthcare workers and young women.

Study Design: Nominal group technique (NGT)

Sampling and Recruitment: Systematic purposive sampling was used to recruit healthcare workers and young women. One NGT included young women aged between 18- and 24-years visiting healthcare facilities for family planning and STI healthcare services. Individuals who expressed interest in participating were screened for eligibility. Once eligibility was determined, eligible individuals were contacted with details of the co-creation workshop. NGT requires between 8–12 participants (18); eight young women participated. Another NGT was conducted among eight healthcare workers involved in STI healthcare service provision.

Data Source: Two NGTs were conducted: one with young women and another with healthcare workers at local primary healthcare (PHC) facilities. The same questions were used in both NGTs. The first question identified barriers hindering young women from accessing current STI healthcare services. The second question developed key attributes for a self-sampling intervention to diagnose STIs in young women. The principal investigator (PI) explained the study, aim, and NGT process to participants before splitting them into two groups of four. Each NGT session involved silent generation of ideas, a round-robin sharing of responses, note-taking by the research team, and thematic grouping of responses. Participants then prioritised and ranked contributions on a scale from 1 (low priority) to 7 (high priority).

Data Analysis: Quantitative data from the first question was used to calculate a total importance score for each barrier by summing individual participant scores. To develop self-sampling intervention attributes, the total importance score for each attribute was calculated

to reflect perceived efficacy, allowing participants to reach a consensus. Thematic content analysis was used to analyse qualitative data and identify emerging themes.

Outcome Measure: Identification of barriers hindering young women from accessing STI healthcare services and identification of attributes for a self-sampling intervention through participant consensus. The attributes identified during the NGTs served as the basis to understand young women's preferences for a user-friendly self-sampling intervention for STI diagnosis in the third phase of the study.

3.2.5. Phase 3: Quantitative method

Objective 3: To determine STI self-sampling interventions that are acceptable and preferable to young women.

Study Design: Discrete choice experiment (DCE)

Sampling and Recruitment: Participant recruitment was based on stratified random sampling, with underserved communities stratified into three subpopulations: core informal settlement, fringe informal settlement, and core township (19). Community selection also considered socioeconomic classification based on household monthly income. The eThekweni Metropolitan Municipality online database was used to identify eligible communities (20). Young women aged between 18–24 years residing in underserved urban communities in the chosen study location were randomly recruited. Interested participants provided written informed consent before completing the survey. Non-consenting individuals were excluded. A walkthrough of the survey questions was conducted to ensure understanding and ease of completion.

Data Source: Attributes for the self-sampling intervention developed during the NGT sessions were used to develop a DCE survey. The survey collected data from young women randomly selected in the chosen communities. Participants completed a series of choice tasks with hypothetical scenarios for self-sampling intervention attributes. Each scenario presented two different alternatives of attribute configurations. The survey also collected demographic details and participant experiences. For safety reasons, participants completed a paper-based survey, and the collected information was later transferred to an Excel spreadsheet.

Data Analysis: The demographic and socioeconomic characteristics of respondents were described using absolute and relative frequencies (n and %). Bivariate logistic regression modelled participant preferences for self-sampling attributes. Binary outcome variables indicating preference or non-preference for each attribute level were analysed alongside

predictor variables. Regression coefficients, odds ratios, and statistical significance of predictor variables were determined. Model fit was assessed using the log-likelihood ratio (LLR) test, Akaike Information Criterion (AIC), and Bayesian Information Criterion (BIC). Model selection criteria, including AIC and BIC, were reported. Additionally, the kappa coefficient measured agreement on the ease of understanding the survey tool.

Outcome Measure: Understanding young women's preferences for an acceptable and user-friendly self-sampling intervention for STI diagnosis.

3.3. Ethical considerations and data sharing

The collection and processing of participants' personal information complied with Processing of Personal Information Act, which outlines the conditions for the lawful processing of personal information. Prior to study participation, participants were informed about the study, its aims, and the data collection process, and they had the opportunity to ask questions for clarification. Participants were screened for eligibility before participation, and those who consented provided written informed consent. This process was conducted by the principal investigator and a research assistant. Participants were informed that participation was voluntary and that they could withdraw at any point during the data collection process. Participant confidentiality was maintained by using codes, and no identifying information was shared at any stage of the results dissemination. COVID-19 regulations were strictly followed according to the latest guidelines.

Stakeholders, including community members, PHC clinics, and the Department of Health, were engaged throughout data collection to ensure that the cultural dimensions of the community were understood and respected by the research team. Full ethical approval was obtained from the University of Pretoria's Research Ethics Committee (Reference no. 136/202) (see Appendices A and B) and the KZN Department of Health (Reference no. KZ_202208_005) (see Appendices C and D). The results of each objective were disseminated through article publications in peer-reviewed journals and at local and international conferences. The study findings will also be shared with various key stakeholders, including the Department of Health and PHC facilities included in the study.

3.4. Strengths and limitations of the study

Utilising a multi-methods research design ensured that each objective served as an evidence-based foundation for subsequent objectives. The systematic review enriched evidence on the

accuracy of self-collected specimens compared to healthcare worker-collected specimens by integrating insights from diverse studies with different methodologies. The NGT fostered collaboration with young women and healthcare service providers, leading to comprehensive attribute development for self-sampling STI diagnosis. This collaboration ensured diverse perspectives while minimising bias by ranking high-priority attributes from each key stakeholder.

Involving young women and healthcare workers in the NGT and DCE provided a holistic understanding of STI healthcare utilisation, ensuring that the developed interventions were user-centred and tailored to specific user preferences. Additionally, the study's rigorous consent process and adherence to ethical guidelines enhanced its credibility and reliability.

However, the study had some limitations. Reliance on self-reported data introduced potential recall and social desirability biases. The focus on young women from underserved urban communities means the findings might not apply to those in other settings, such as rural or more affluent urban areas. The paper-based survey method, while necessary for safety, may have led to data entry errors during transfer to the Excel spreadsheet.

3.5. Study timeline

- **Systematic review and meta-analysis:** Database searching, screening, analysis, synthesis, and manuscript development commenced in January 2022 and was completed in June 2022.
- **NGT data collection:** Conducted with PHC healthcare workers and young women in February 2023.
- **NGT manuscript completion:** April 2023 (healthcare workers) and May 2023 (young women).
- **DCE protocol preparation:** Completed in January 2024.
- **DCE data collection:** Commenced on 1 February 2024, and completed on 6 March 2024.
- **DCE results manuscript development:** Commenced in February 2024 and completed in May 2024.

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CHAPTER 4: ARTICLE ADDRESSING OBJECTIVE 1

The scoping review, which was presented in Chapter 2, highlighted a gap in existing literature. Previous systematic reviews had only focused on specific STIs, such as chlamydia and gonorrhoea, or chlamydia only. However, there was no comprehensive review that focused on a wide range of STIs, including those caused by *Chlamydia trachomatis*, *Neisseria gonorrhoea*, human papillomavirus, *Mycoplasma genitalium*, *Trichomonas vaginalis*, and *Treponema pallidum*. Recognising this gap, this chapter (Chapter 4) addresses the first objective of this thesis – to provide a thorough understanding of the diagnostic landscape in relation to self-sampling for STI diagnosis and facilitate improved insight and evidence-based recommendations for diverse STIs in women.

Chapter 4 is presented in manuscript form in accordance with the target journal requirements. It was published in *Scientific Reports*, a Springer Nature journal, and is titled: “*Accuracy of self-collected versus healthcare worker collected specimens for diagnosing sexually transmitted infections in females: an updated systematic review and meta-analysis*”

scientific reports



OPEN Accuracy of self-collected versus healthcare worker collected specimens for diagnosing sexually transmitted infections in females: an updated systematic review and meta-analysis

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The use of self-collected specimens as an alternative to healthcare worker-collected specimens for diagnostic testing has gained increasing attention in recent years. This systematic review aimed to assess the diagnostic accuracy of self-collected specimens compared to healthcare worker-collected specimens across different sexually transmitted infections (STIs) including *Chlamydia trachomatis* (CT), human papillomavirus (HPV), *Mycoplasma genitalium* (MG), *Neisseria gonorrhoea* (NG), *Treponema pallidum* and *Trichomonas vaginalis* (TV) in females. A rigorous process was followed to screen for studies in various electronic databases. The quality of included studies was assessed using the Quality Assessment of Diagnostic Accuracy Studies 2 tool. There were no studies on syphilis that met the criteria for inclusion in the review. A total of six studies for chlamydia, five studies for HPV, four studies for MG, and seven studies for gonorrhoea and trichomoniasis were included in the review. However, not all studies were included in the sub-group meta-analysis. The analysis revealed that self-collected specimens demonstrated comparable diagnostic accuracy to healthcare worker-collected specimens across most STIs. This indicates that the diagnostic accuracy of self-collected specimens can provide accurate results and enhance access to diagnostic testing, potentially improving healthcare service delivery. Future research should further explore the diagnostic accuracy of self-collected specimens in larger and more diverse populations.

Keywords Self-collect, Sexually transmitted infections, Diagnostic specimens, Females, Women

Abbreviations

CT	<i>Chlamydia trachomatis</i>
CIN2	Cervical intraepithelial neoplasia 2
DOR	Diagnostics Odds Ratio
DoH SA	Department of Health South Africa
FP	False positive
FN	False negative
HPV	Human papilloma virus
HSIL	High grade squamous intraepithelial lesion
LMICs	Low-and-middle-income countries

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MeSH	Medical subject headings
MG	<i>Mycoplasma genitalium</i>
NAAT	Nucleic acid amplification test
NG	<i>Neisseria gonorrhoea</i>
NPV	Negative predictive value
PCR	Polymerase chain reaction
PI	Principal investigator
PIS	Patient infected status
PICO	Population intervention comparison outcome
PPV	Positive predictive value
PRISMA	Preferred reporting items for systematic review and meta-analyses
QUADAS-2	Quality assessment of diagnostic accuracy studies 2
RevMan	Review manager
STI	Sexually transmitted infections
SROC	Summary receiver operating characteristic
TN	True negative
TP	True positive
TV	<i>Trichomonas vaginalis</i>
WHO	World Health Organization

Sexually transmitted infections (STIs) are a major global health concern that causes symptomatic and asymptomatic infections^{1,2}. Most STIs caused by bacteria and parasites are curable if diagnosed and treated accordingly but all viral STIs are incurable^{3,4}. The largest portion of STIs occurs in females across the globe⁵. In females, the consequence of undiagnosed and untreated STIs can result in reproductive health complications that include infertility, stillbirths, cancer development and increased susceptibility to HIV^{1,2,4,6,7}. Considering this, our study focused on STIs in females.

Governments across the globe, particularly in low-and-middle-income countries (LMICs) continue to use syndromic management of STIs due to a scarcity of resources and restricted access to diagnostic laboratories^{8,9}. This approach relies on reported signs and symptoms, and physical examinations for diagnosis and then treatment is issued for the most common STIs^{8,10}. In light of this, it deters infected individuals who fear invasive genital examinations and stigmatization associated with STIs¹¹. Additionally, this approach cannot address asymptomatic infections because these individuals may not seek care^{8,12}. As such, asymptomatic individuals continue to spread infection and become susceptible to long term STI complications. Syndromic management often promotes over-diagnosing and over-treating because treatment is issued often targeting the most common STI causative pathogens instead of a specific pathogen^{13,14}. As such Murewanhena et al.¹⁴ suggest a shift from syndromic management of STIs to a more pathogen specific diagnosis and treatment of STIs. The development of innovative alternative interventions, such as self-sampling, is key to improving STI healthcare service provision^{15–17}. Self-sampling enables individuals to self-collect specimens for STI diagnosis either at home or healthcare facilities, providing convenience and accessibility in testing¹⁸. This intervention can be used to screen for asymptomatic infections¹¹, and screen infections in remote areas where access to quality healthcare is limited^{19,20}. Based on this, self-sampling can address the challenges linked to the syndromic management of STIs^{19,21}. However, self-sampling may jeopardise specimen quality since the collection is performed by inexperienced individuals.

Since the potential of self-sampling interventions for STI diagnosis is evident, it is imperative to determine their diagnostic accuracy and reliability. A scoping review conducted by Jaya et al.²² in 2021 presented evidence that supports self-sampling interventions as appropriate alternatives to physician collected specimens for STI diagnosis. A meta-analysis conducted in 2005 proved that self-collected swabs were suitable alternatives to clinician-collected specimens for the diagnosis of human papillomavirus (HPV)²³. A systematic review and meta-analysis conducted in 2015 on *Neisseria gonorrhoea* (NG) and *Chlamydia trachomatis* (CT) also reported that self-collected specimens were reliable for diagnostic testing¹⁵. Considering the potential impact of the self-sampling intervention on sexual and reproductive healthcare there is a need for an updated systematic review and meta-analysis sexual and reproductive healthcare. This is to foster improvements in clinical decision-making pertaining to sexual and reproductive healthcare provision. As such, the current study is an updated systematic review and meta-analysis on the accuracy of self-collected specimens compared to healthcare worker-collected specimens for STI diagnosis. This study will evaluate the diagnostic accuracy of self-sampling for STI diagnosis in studies conducted from 2015 onwards because a systematic review of a similar nature included studies up to 2015. The overarching aim of an updated systematic review is to ensure that the best evidence to inform clinical decision making and healthcare policy development for STI healthcare is provided.

Methods

Protocol and registration

The protocol for this study was submitted to the International Registration of Systematic Reviews (PROSPERO), with the registration number CRD42022341462. This study was guided by the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA)²⁴.

Eligibility criteria

The Population, Intervention, Comparison, and Outcome (PICO) framework for determining the research question eligibility was followed. Studies were included if they: (a) assessed the accuracy of self-collected specimens against healthcare worker-collected specimens for STI diagnosis in women were included, (b) studies that used

healthcare worker collected specimens as the reference or gold standard, (c) the study population comprised of specimens that had been tested for STIs including HPV, NG, CT, *Treponema pallidum* (syphilis), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG), (d) examined self-collected versus clinician-collected samples using different diagnostic assays including nucleic-acid-based assays, and manual methods that included wet mount, culture, and gram stain peer-reviewed studies published in 2015 and onwards to diagnose STIs. Data on investigations conducted on females was extracted from studies that include people of another gender. There were no language restrictions applied and studies with different study designs were included. Studies were excluded if: (a) the time of self-sampling and healthcare worker specimen collection exceeded three weeks due to the window period for seroconversion, (b) presented information on combined specimen results, (c) self-sampling was not conducted in females, (d) self-sampling and healthcare worker collected specimen was collected from different individuals.

Index test

The diagnostic accuracy of self-collected specimens to diagnose STIs was evaluated against healthcare worker specimens. Self-collected specimens for STI diagnosis included vaginal swabs, urine, cervical swabs and tampons. The sensitivity and specificity of each diagnostic assay for each STI were evaluated.

Reference standard

Healthcare worker-collected specimens for the diagnosis of STIs were used as the gold reference standard in this study.

Search strategy

A systematic search of data was conducted in Cochrane, Medline, Scopus, Web of Science, and PubMed electronic databases (see Table 1). The search was limited to studies from 2015 onwards. The Principal Investigator (PI) developed the search strategy with an experienced librarian at the University of Pretoria. Medical Subject Headings (MeSH) terms were used to define our searches with Boolean operators (AND/OR) between search terms. The search terms used included but were not limited to (1) "Self-sampling" or "self-collected" or "self-administered" or "self-obtained" (2) "sexually transmitted infections" (3) "diagnostic specimens" or "diagnostic samples" (4) "women" or "females". A hand search for grey literature was also conducted on the WHO website, the Department of Health South Africa (DoH SA), and the Open Grey website.

Study selection

Screening of studies suitable for inclusion in the systematic review and meta-analysis was conducted on the studies between 2015 and 2022. Since this systematic review stems from the findings of a scoping review which was conducted in 2021. Studies which had been screened for the scoping review from 2015 to 2021 were re-screened using eligibility criteria for the systematic review. To ensure the inclusion of studies conducted in 2022, the assisting librarian conducted a new search for studies that were published in 2022. An EndNote library was then created for all studies that were eligible for full-text screening. Thereafter, ZNJ and TD performed full-text screening of all studies that fulfilled the eligibility criteria of the systematic review and meta-analysis. NT resolved discrepancies that arose during full-text screening by ZNJ and TD. Thereafter, ZNJ and NT extracted data from studies found eligible for inclusion at the full-text screening stage. Thereafter, any disagreements were resolved by discussion until an agreement was reached. Study selection for the systematic review was guided by the PRISMA flowchart.

Data extraction

ZNJ and NT independently extracted data from eligible studies using a data extraction tool that was designed to extract data from the included primary studies. The tool was piloted using 10% of the included studies and amended accordingly before final use. The extracted data was divided into two separate sections namely a section for basic qualitative information and another section for the quantitative outcomes of interest. Basic information extracted included author name(s) and year of publication, study title, study aims, study population, study design, sample size, eligibility criteria, reference standard specimen, type of self-collected specimen, type of laboratory assay, main findings, and conclusions. Data extracted for the section on the outcome of primary studies true positive, true negative, false positive, false negative, sensitivity and specificity, positive predictive value, negative predictive value, and evidence of agreement or concordance between self-collected and healthcare worker collected specimens. In some instances, the true negative, true positive false positive and false negative results were not available, and the relevant data was requested from the authors. A 2 × 2 table was produced based on the collected data. Any discrepancies that arose between the reviewers were discussed until a unanimous resolution was reached.

Assessment of methodological quality

The Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) tool for primary diagnostic accuracy studies, was utilised to assess the quality of all the included studies²⁵. This tool consists of four main domains that include patient selection, index test, reference standard, and flow and timing²⁵, which were adapted to the current study accordingly. To determine the risk of bias, signalling questions answered as "yes" "no" or "unclear", were used in each phase²⁵.

Date	Database	Keywords	Number of results retrieved
14 July 2021	Scopus	(TITLE-ABS-KEY (sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test" OR "self-collect" OR "sexually transmitted disease testing") AND TITLE-ABS-KEY ("Specimen Handling") AND TITLEABS-KEY ("Sexually Transmitted Disease" OR "sexually transmitted infection") AND TITLE-ABS-KEY (wom*n OR female* OR girl*) AND NOT TITLE-ABS-KEY (aids OR "HIV Infections" OR hiv OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome"))	117
15 July 2021	Cochrane	(sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test" OR "selfcollect" OR "sexually transmitted disease testing");ti,ab,kw (Word variations have been searched)	26
19 July 2021	PubMed	((sampling[tw] OR sample[tw] OR "self sampling"[tw] OR "self sample"[tw] OR "sti testing"[tw] OR "sti diagnosis"[tw] OR "sexually transmitted infections test"[tw] OR "self-collect"[tw] OR "sexually transmitted disease testing"[tw] AND (female[Filter])) AND ("Specimen Handling/ methods"[Mesh] OR "Specimen Handling"[tw] AND (female[Filter]))) AND ("Sexually Transmitted Diseases, Bacterial"[Mesh] OR "Sexually Transmitted Diseases, Viral"[Mesh] OR "sexually transmitted infection"[tw] OR "sexually transmitted disease"[tw]) NOT ("HIV Infections"[Mesh] OR "HIV Infections"[tw])	213
19 July 2021	Wb of Science	((((ALL = (sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test" OR "self-collect" OR "sexually transmitted disease testing")) AND ALL = ("Sexually Transmitted Disease*" OR "sexually transmitted infection*" OR STI OR STD)) AND ALL = (wom*n OR female* OR girl*)) AND ALL = ("Specimen Handling" or "Specimen Collection" OR Specimen)) NOT ALL = (aids OR "HIV Infections" OR hiv OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome")	311
21 July 2022	MEDLINE (EBSCO)	((((ALL = (sampl* OR "self sampl*" OR "sti test*" OR "sti diagnosis" OR "sexually transmitted infections test*" OR "self-collect*" OR "sexually transmitted disease test*")) AND ALL = () NOT ALL = ()	140
26 Aug 2022	PubMed	((sampling[tw] OR sample[tw] OR "self sampling"[tw] OR "self sample"[tw] OR "sti testing"[tw] OR "sti diagnosis"[tw] OR "sexually transmitted infections test"[tw] OR "self-collect"[tw] OR "sexually transmitted disease testing"[tw]) AND ("Specimen Handling/methods"[Mesh] OR "Specimen Handling"[tw])) AND ("Sexually Transmitted Diseases, Bacterial"[Mesh] OR "Sexually Transmitted Diseases, Viral"[Mesh] OR "sexually transmitted infection"[tw] OR "sexually transmitted disease"[tw]) NOT ("HIV Infections"[Mesh] OR "HIV Infections"[tw]) Filters: Female, from 2021—2022	8
26 August 2022	Web of Science	((((ALL = (sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test" OR "self-collect" OR "sexually transmitted disease testing")) AND ALL = ("Sexually Transmitted Disease*" OR "sexually transmitted infection*" OR STI OR STD)) AND ALL = (wom*n OR female* OR girl*)) AND ALL = ("Specimen Handling" or "Specimen Collection" OR Specimen)) NOT ALL = (aids OR "HIV Infections" OR hiv OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome")	28
26 August 2022	MEDLINE (EBSCO)	(sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test" OR "self-collect" OR "sexually transmitted disease testing") AND ((MH "Sexually Transmitted Diseases +") OR "Sexually Transmitted Disease" OR "sexually transmitted infection" OR STI OR STD) AND ("Specimen Handling" OR (MH "Specimen Handling +")) NOT ((MH "HIV") OR (MH "Acquired Immunodeficiency Syndrome") OR aids OR "HIV Infections" OR hiv OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome")	12
26 August 2022	Scopus	(TITLE-ABS-KEY (sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test" OR "self-collect" OR "sexually transmitted disease testing") AND TITLE-ABS-KEY ("Specimen Handling") AND TITLEABS-KEY ("Sexually Transmitted Disease" OR "sexually transmitted infection") AND TITLE-ABS-KEY (wom*n OR female* OR girl*) AND NOT TITLE-ABS-KEY (aids OR "HIV Infections" OR hiv OR "human immunodeficiency virus" OR "acquired immunodeficiency syndrome"))	7
26 August 2022	Cochrane	(sampling OR sample OR "self sampling" OR "self sample" OR "sti testing" OR "sti diagnosis" OR "sexually transmitted infections test" OR "selfcollect" OR "sexually transmitted disease testing");ti,ab,kw (Word variations have been searched)	0

Table 1. Database search.

Statistical analysis and data synthesis

For included studies in which sensitivity and specificity had been assessed and reported a meta-analysis of diagnostic accuracy was performed. The Review Manager (RevMan) software was used to conduct statistical analysis. The RevMan software was also used to calculate the pooled sensitivity, specificity, and diagnostic odds ratio with a 95% confidence interval. Cochran's Q statistics were utilised to determine heterogeneity among the included primary studies. Statistical significance in all the analyses was calculated using the *p*-value where a *p*-value of < 0.05 indicated statistical significance.

Ethical approval

Ethical clearance for the study was obtained from the University of Pretoria's Faculty of Health Sciences Research Ethics Committee. The reference number is 136/2022. Participant consent was not applicable.

Results

Study selection and characteristics of included studies

Sixteen studies conducted in 2015, which were retrieved during a database search for the scoping review underwent title screening using the relevant eligibility criteria for the systematic review. For the new database search conducted by the librarian to ensure the inclusion of studies in Aug 2022, forty-eight search results were retrieved. Nine were duplicates, which left only thirty-nine eligible for title screening. The abstract screening was then conducted on fifty-five studies (thirty-nine plus sixteen studies). Post abstract screening, thirty-seven studies

were excluded and only eighteen studies were eligible for data extraction. Reasons for exclusion were studies presenting data on pooled specimens, studies not presenting data on self-collected and healthcare worker collected specimens, and studies not about self-sampling STIs. Post full text screening of the studies only fourteen were eligible for inclusion in the systematic review. Four studies were excluded for being conducted before 2015, studies not about self-sampling, not about STIs, and a study presenting data on pooled specimens. Ultimately, data extraction was conducted on a total of fourteen studies (see Fig. 1 below). There was moderate agreement between the reviewers at full-text screening ($kappa = 0.5$).

Characteristics of included studies

The characteristics of included studies are all depicted in Table 2. Fourteen studies were included in the systematic review but not all of them were included in the meta-analysis. A large portion of the studies, five studies, were from the United States of America (USA)^{26–30}, one study in Canada³¹, one in Haiti³², one in France³³, one study in Saudi Arabia³⁴, one in India³⁵, one in the Republic of Korea³⁶, one study in Kenya³⁷, one in Chad¹⁹, one study in Ghana³⁸. See Table 3 for quantitative characteristics of included studies. It is important to note that some of the sensitivity and specificity measurements were obtained from the articles as calculated by the authors. However, where the measurements were not available, the researchers calculated using data that was already available on the manuscripts and original data obtained from authors of some of the included studies. Furthermore, for studies where this information was not available at all, it was not reported.

The characteristics of the included studies were further divided into sub-groups for meta-analysis for each STI as outlined in the following sections:

Chlamydia

A total of six studies compared the diagnostic accuracy of self-collected specimens to healthcare worker collected specimens in females^{19,27,30,31,33,37}. Five of the studies were conducted in a clinic^{19,27,31,33,37}, and study location was not reported for one of the studies³⁰. Of these six studies, three of them compared healthcare worker collected vaginal swabs to self-collected vaginal swabs^{30,31,33}. In two of the studies healthcare workers collected cervical swabs were compared to self-collected cervicovaginal swabs^{27,37}. Only one study compared healthcare worker collected endocervical swabs to self-collected veil specimens¹⁹. STI testing was performed using automated NAAT based assays. All six studies were cross-sectional studies. In five of the studies, research participants had received instructions on how to self-collect specimens for testing^{19,27,31,33,37}, and in one study the research participants did not receive any instructions³⁰. The number of research participants in the studies ranged from 189 to 3860. Only four of the six studies were included in the subgroup meta-analysis^{19,30,31,33}. Out of the two excluded studies, one

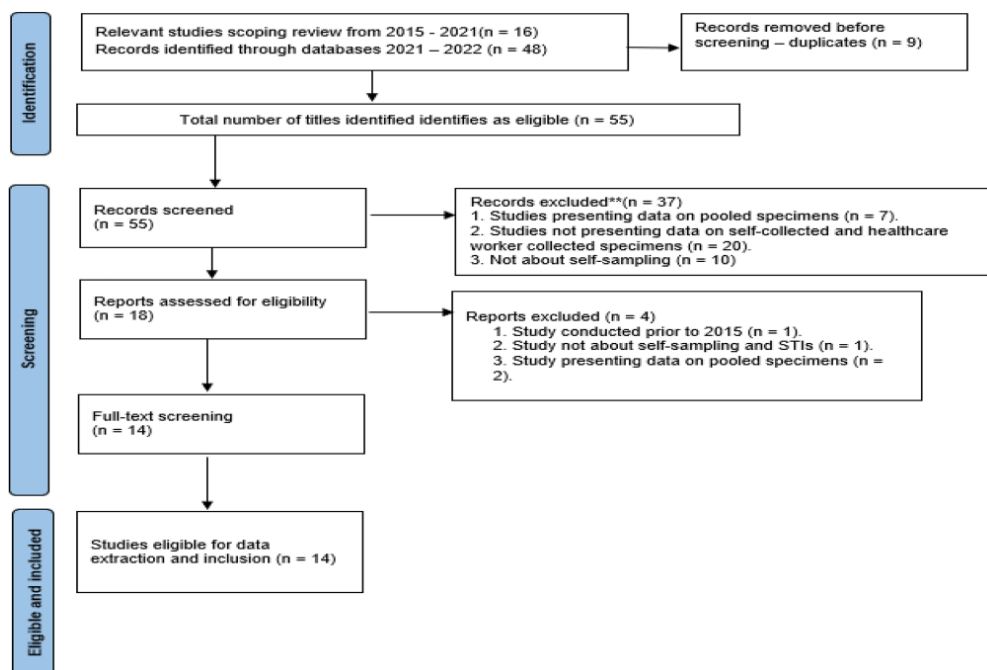


Figure 1. PRISMA flow diagram of the selection process of relevant studies.

Disease	Author, year published	Country of study	Study design	Study population (sex) and samples size	Mode of instruction for self-collection	Location of self-collection	Specimen and testing		
							Specimen (healthcare worker collected/self-collected)	Diagnostic platform Automated (run on instrument)/ manual (manual method used)	Assay type
CT	Arias et al. 2016 ³¹	Canada	Cross sectional	Female - 189	Demonstration of collection method and self-collection had collection instructions	Study clinic	Vaginal swab/ vaginal swab	Automated	NAAT Aptima Combo 2
	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal/cervical classical sampling/vaginal swab	Automated	COBAS—Roche Diagnostics Kits
	De Marais et al. 2018 ²²	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima Combo2
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoambaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Allplex STI Essential Assay
	Van Der Pol et al. 2019 ³⁵	USA	Cross sectional	Female = 3860	Not indicated	Not indicated	Vaginal swab/ vaginal swab, urine	Automated	NAAT—COBAS NG/CT test—the BD ProbeTec CT Qx and GC Qx amplified DNA assay; Aptima Combo 2 CT/NG; and the Abbott m2000 RealTime CT/NG assay
HPV	Boggan et al. 2015 ³²	Haiti	Cohort	Female = 1836	Orientation by a study nurse	Study clinic	Cervical swab/ vaginal swab	Automated	Hybrid Capture 2 High-Risk HPV DNA Test
	De Marais et al. 2018 ²²	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima HPV assay
	Kim et al. 2020 ³⁶	Korea	Cross sectional	Female = 151	Digital and written instructions provided	Study clinic	Cervical swab/ vaginal swab	Automated	multiplex real-time PCR Anyplex II HPV28 Detection assay
	McLarty et al. 2019 ³⁸	USA	Cross sectional	Female = 174	Individual instructions were provided	Home and study clinic	Cervical swab/ tampon, vaginal swab	Automated	Roche Cobas HPV method
	Obiri-Yeboah et al., 2017 ³⁸	Ghana	Cross sectional	Female = 333	Instructed on how to obtain a specimen	Study clinic	Cervical swab/ vaginal swab	Automated	careHPV assay
MG	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal/cervical classical sampling/vaginal swab	Automated	TIB MOLBIOL LightMix—PCR Roche Diagnostics
	De Marais et al. 2018 ²²	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima analyte-specific reagent-based assay
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoambaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Allplex STI Essential Assay

Continued

Disease	Author, year published	Country of study	Study design	Study population (sex) and samples size	Mode of instruction for self-collection	Location of self-collection	Specimen and testing		
							Specimen (healthcare worker collected/self-collected)	Diagnostic platform Automated (run on instrument)/ manual (manual method used)	Assay type
NG	Arias et al. 2016 ³¹	Canada	Cross sectional	Female = 189	Demonstration of collection method and self-collection had collection instructions	Study clinic	Vaginal swab/ vaginal swab	Automated	NAAT Aptima Combo 2
	Barbee et al. 2021 ²⁸	USA	Cross-sectional	Female = 89	Not indicated	Study clinic	Endocervical swab/vaginal swab	Manual and automated	Culture and NAAT Aptima Combo 2
	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal/cervical classical sampling/vaginal swab	Automated	COBAS—Roche Diagnostics Kits
	De Marais et al. 2018 ²⁷	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima Combo2
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoombaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Allplex STI Essential Assay
	Van Der Pol et al. 2019 ³⁰	USA	Cross sectional	Female = 3860	Not indicated	Not indicated	Vaginal swab/ vaginal swab, urine	Automated	NAAT—COBAS NG/CT test—the BD ProbeTec CT Qx and GC Qx amplified DNA assay; Aptima Combo 2 CT/ NG; and the Abbott m2000 Real-Time CT/ NG assay
TV	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal and cervical swabs/ vaginal swab	Automated	TIB MOLBIOL LightMix—PCR Roche Diagnostics
	De Marais et al. 2018 ²⁷	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima TV assay
	Hawash et al. 2021 ³⁴	Saudi Arabia	Cross sectional	Female = 174	Instructions were provided and sample collection was done in the presence of medical personnel	Study clinic	Vaginal swab/ vaginal swab	Manual, and automated	OSOM TV rapid test, wet prep, TV DNA PCR
	Khan et al. 2019 ³⁵	India	Cross-sectional	Female = 550	Participants were given instructions	Study clinic	Vaginal swab/ vaginal swab	Manual	Trichomonas culture
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoombaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Allplex STI Essential Assay
	Schwebke et al., 2018 ²⁹	USA	Cross sectional	Female = 1867	Not indicated	Study clinic	Cervical swab/ vaginal swab	Manual, and automated	In Pouch TV broth culture and Aptima NAAT for TV

Table 2. Characteristics of included studies. CT = *Chlamydia trachomatis*; NG = *Neisseria gonorrhoea*; TV = *Trichomonas vaginalis*; HPV = Human papillomavirus; DNA = Deoxyribonucleic acid; PCR = Polymerase Chain Reaction; Veil sample = self-collection device for cervicovaginal fluid collection.

study was excluded because only agreement data was reported and the other parameters were not reported³⁷. Similarly, the other study only reported sensitivity and specificity data²⁷. Figure 2 presents research findings for the subgroup analysis of four studies, where the summary estimate for sensitivity was 0.85 (95% Confidence

Disease	Author, year published	TP	FP	TN	FN	PPV (%)	NPV (%)	Cohen's kappa/concordance (%)	Healthcare worker Vs self-collected		Self-collected only		Healthcare worker collected only	
									Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
<i>Chlamydia trachomatis</i>	Arias et al. 2016 ³¹	5	10	159	6	33	96	98.4	50	94.4	–	–	–	–
	Camus et al. 2021 ³³	33	1	994	0	97.06	100	99.9%	100 (NA)	99.9 (99.7–100)	–	–	–	–
	Nodjik-ouambaye et al. 2019 ¹⁹	126	12	90	4	91	95	92.8%	97 (80.7–93.3)	88 (80.7–93.3)	–	–	–	–
	Van Der Pol et al. 2019 ³⁰	119	17	1769	1	87.5	99.9	–	–	–	99.2 (95.4–99.4)	99 (99.4–99.9)	98.6 (95.2–99.6)	99.1 (98.6–99.4)
Human papilloma virus	De Marais et al. 2018 (HSIL) ²⁷	–	–	–	–	–	–	0.66	–	–	100 (NA)	88.9 (83.6–93.0)	100 (NA)	90 (84.8–93.9)
	De Marais et al. 2018 (CIN 2) ²⁷	–	–	–	–	–	–	0.66	–	–	100 (NA)	91.1% (86–94.8)	100 (NA)	92.2% (87.3–95.7)
	Obiri-Yeboah et al., 2017 ³⁸	–	–	–	–	–	–	94.2	92.6 (85.3–97.0)	95.9 (89.8–98.8)	–	–	–	–
<i>Mycoplasma genitalium</i>	Camus et al. 2021 ³³	14	0	0	1014	100	100	100%	100 (NA)	100 (NA)	–	–	–	–
	Nodjik-ouambaye et al. 2019 ¹⁹	126	12	90	4	91	95	–	97 (80.7–93.3)	88 (80.7–93.3)	–	–	–	–
<i>Neisseria gonorrhoea</i>	Arias et al. 2016 ³¹	0.8	4	180	1	17	99	98.4%	40	98.4	–	–	–	–
	Camus et al. 2021 ³³	7	1020	1021	1	0.68	99.9	99.9%	85.7 (59.9–100)	100 (NA)	–	–	–	–
	Nodjik-ouambaye et al. 2019 ¹⁹	126	12	90	4	91	95	86%	97 (80.7–93.3)	88 (80.7–93.3)	–	–	–	–
	Van Der Pol et al. 2019 ³⁰	28	0	1903	5	84.5	100	–	–	–	100 (87.9–99.9)	99.7 (99.3–99.9)	100 (87.9–100)	99.7 (99.4–99.9)
Trichomoniasis vaginalis	Camus et al. 2021 ³³	9	1015	1015	0	0.88	100	99.8%	100 (NA)	99.8 (99.5–100)	–	–	–	–
	Hawash et al. 2021 ³⁴	15	2	127	5	88.2	100	97.9%	–	–	83.3 (58.5–96.4)	98.4 (94.5–99.8)	88.8 (65.2–98.6)	100 (97.1–100)
	Khan et al. 2019 ³⁵	3	0	547	0	100	100	100%	100	100	–	–	–	–
	Nodjik-ouambaye et al. 2019 ¹⁹	126	12	90	4	91	95	92.8	97 (80.7–93.3)	88 (80.7–93.3)	–	–	–	–
	Schwebke et al., 2018 ²⁹ (InPouch)	156	37	1593	5	80.8	99.7	–	96.90 (92.9–99.9)	97.70 (96.9–98.4)	–	–	–	–
	Schwebke et al., 2018 ²⁹ (Aptima assay)	186	5	1593	7	96.4	99.7	–	97.4 (94.0–99.1)	99.6 (99.1–99.8)	–	–	–	–
	Schwebke et al., 2018 ²⁹ (PIS)	186	7	1591	7	96.4	99.6	–	96.4 (92.7–98.5)	99.6 (99.1–99.8)	–	–	–	–
	Schwebke et al., 2018 ²⁹ (Xpert vs PIS)	186	7	1591	7	96.4	99.6	–	96.4 (92.7–98.5)	99.6 (99.1–99.8)	–	–	–	–

Table 3. Quantitative characteristics of included studies. TP = True positive; FN = False positive; TN = True negative; FN = False negative; PPV = Positive predictive value; NPV = Negative predictive value; PIS = patient infected status.

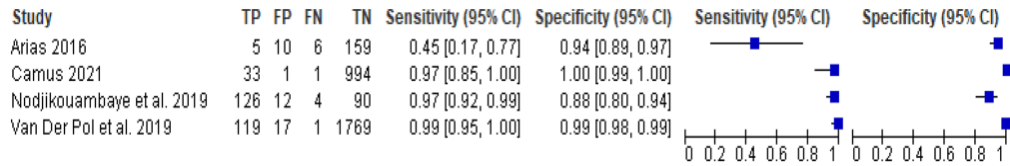


Figure 2. Forest plot of chlamydia studies that compared self-collected vaginal swabs with healthcare worker collected cervical and vaginal specimens.

Interval 0.77–0.92), while specificity was 0.95 (95% Confidence Interval 0.91–0.98). The SROC plot (Fig. 3) is a depiction of the pooled sensitivity and specificity of the studies.

The studies show statistical significance in the studies, but there is moderate evidence of heterogeneity among the studies. The diagnostic tests have a good discriminatory ability to differentiate between individuals with and without chlamydia (Table 4).

Human papilloma virus

Five studies compared the diagnostic accuracy of healthcare worker collected specimens with self-collected specimens to diagnose HPV^{27,28,32,36,38}. Three of the studies compared healthcare worker collected cervical swabs were compared to self-collected vaginal swabs^{32,36,38}, while one study compared healthcare worker collected

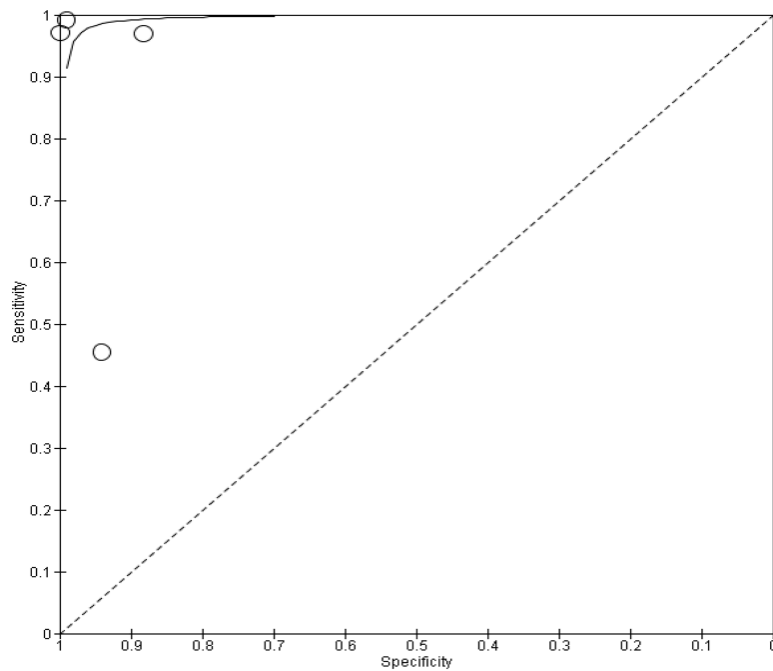


Figure 3. SROC depicting diagnostic accuracy of included studies for chlamydia.

Item	Result
P value	0.02. The result is significant at $p < 0.05$
Cochran's Q (heterogeneity)	9.82
DOR	7.78

Table 4. Heterogeneity and statistical significance for CT.

cervical swabs with self-collected tampons and vaginal swabs²⁸, and another study compared healthcare worker collected cervical swab with self-collected cervicovaginal swabs²⁷. All the studies were conducted in a research clinic. The sample size of the studies ranged from 151 to 1836 study participants. Study participants received instructions on how to self-collect their specimens for STI diagnosis, prior to specimen collection. NAAT based diagnostic assays were used in all the studies. Four of the studies were cross-sectional studies^{28,32,36}, and only one was a clinical trial²⁷. In one study, the sensitivity and specificity of self-collected specimens was 100 and 88.9% respectively, while healthcare worker collected diagnostic result sensitivity and specificity were 100 and 90% respectively²⁷. In another study, the sensitivity and specificity of self-collected specimens compared to healthcare worker collected specimens were 92.6 and 95.9% respectively³⁸. One study reported the sensitivity of self-collected specimens as 100%³⁶. Another study reported the sensitivity and specificity of only self-collected swab as 86 and 94% respectively, while for the self-collected tampon it was 77 and 100% respectively²⁸. Another study reported sensitivity results of self-collected specimens as 89.1% and sensitivity of healthcare workers collected specimens as 87.9%³². However, a sub-group meta-analysis was not performed because the relevant data for TN, FN, TP and FP was not available.

Mycoplasma genitalium

Out of the four studies that investigated MG infection, two studies compared self-collected cervicovaginal swabs with healthcare worker collected cervical swabs^{27,37}; one study compared healthcare worker collected vaginal and cervical swabs with self-collected vaginal swabs³³, and another one compared healthcare worker collected endocervical swabs with self-collected veil specimens¹⁹. Diagnostic testing was performed using NAAT based assays in all the studies. All the studies were conducted in clinics. In all the studies, research participants received instructions on how to self-collect specimens before collecting their own specimens. The sample size ranged from 193 to 1028 participants. All studies were cross-sectional. Only two of the included studies had sufficient data for a meta-analysis for this subgroup^{19,33}. Figure 4 presents the analysis of the two studies where the summary estimate for sensitivity was 0.49 (95% Confidence Interval 0.39–0.58) and for specificity was 0.88 (95% Confidence Interval 0.81–0.94).

Presented below in Fig. 5 is the SROC plot depicting the diagnostic accuracy of the studies in this subgroup. The sub-group meta-analysis suggests that the accuracy of the diagnostic test may vary across studies, with poor sensitivity in one study and poor specificity in the other. However, overall, the test shows a moderate to high diagnostic accuracy, as indicated by the high DOR value (Table 5).

Gonorrhoea

Seven studies investigated the diagnostic accuracy of self-collected specimens in comparison to healthcare worker collected specimens in diagnosing NG. Six of these studies were cross-sectional^{19,26,30,31,33,37}, and only one was a clinical trial²⁷. The sample size of the studies ranged from 89 to 3860. Laboratory diagnosis was performed using automated NAAT based assays in all the studies, and one of the studies also used manual diagnostic methods²⁶. Six studies reported that specimen collection had occurred at research clinics^{19,26,27,31,33,37}, and one study did not indicate³⁰. In six of the studies, research participants received instructions before specimen collection^{19,26,27,31,33,37}, but in one study there was no report about whether research participants had been instructed how to self-collect their specimen³⁰. Two studies compared diagnostic accuracy in healthcare worker collected vaginal swabs to self-collected vaginal swabs^{30,31}. One study compared self-collected vaginal swabs to cervical and vaginal swabs collected by healthcare workers³³. Two studies compared diagnostic accuracy in self-collected cervicovaginal swabs and healthcare worker collected cervical swabs^{27,37}. In one study diagnostic accuracy is compared between healthcare worker collected endocervical swabs with self-collected vaginal swabs²⁶. Another study compared diagnostic accuracy in self-collected veil specimens with healthcare worker collected endocervical swabs¹⁹. Figure 6 below presents summary estimates for the sensitivity and specificity of diagnostic accuracy of healthcare worker collected specimens compared to self-collected specimens. The summary estimate for sensitivity and specificity is 0.59 (95% Confidence Interval 0.49–0.68) and 0.84 (95% Confidence Interval 0.76–0.91).

Presented below in Fig. 7 is the SROC plot depicting the diagnostic accuracy of the studies in this subgroup. The Cochran's Q test shows significant heterogeneity among the studies at 17.156. The diagnostic odds ratio of 2.579 suggests that the overall accuracy of the diagnostic test is low to moderate. The *p*-value indicates statistical significance (Table 6).

Trichomoniasis

Seven studies investigated the diagnostic accuracy of self-collected specimens in comparison to healthcare worker collected specimens in diagnosing trichomoniasis. Six of the studies were cross-sectional^{19,29,33–35,37}, and one study was a clinical trial²⁷. Four studies utilised automated NAAT-based assays^{19,27,33,37}, one study used manual testing methods³⁵, while two studies used both automated NAAT assays and manual methods for TV diagnosis^{29,34}. Study

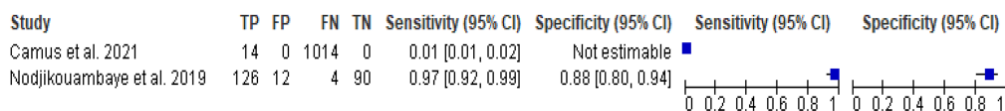


Figure 4. Forest plot of MG studies that compared self-collected vaginal swabs with healthcare worker collected cervical and vaginal specimens.

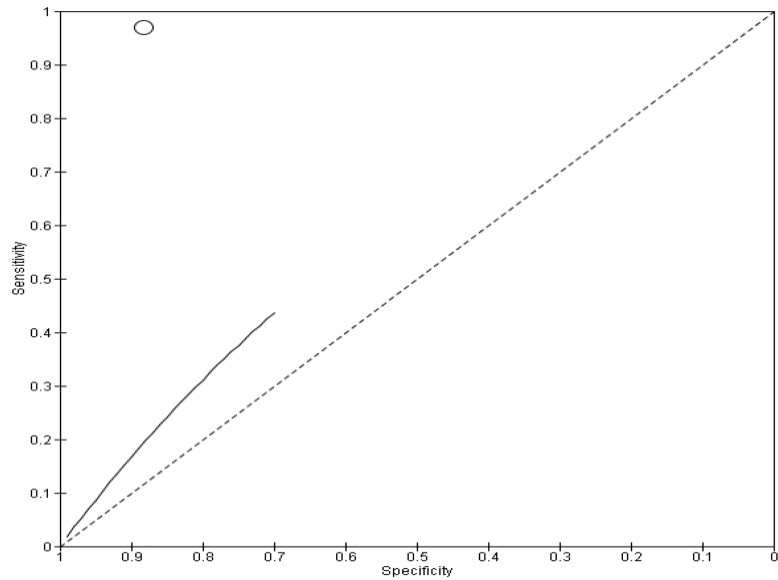


Figure 5. SROC depicting diagnostic accuracy of MG in included studies.

Item	Result
P value	0.001. The result is significant at $p < 0.05$
Cochran's Q (heterogeneity)	15.50
DOR	21.7

Table 5. Heterogeneity and statistical significance for MG.

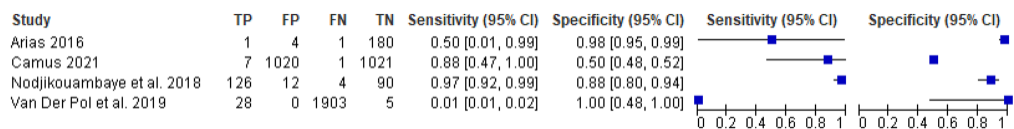


Figure 6. Forest plot of gonorrhoea studies that compared self-collected vaginal swabs with healthcare worker collected cervical and vaginal specimens.

participants in all the studies collected their specimens at the research clinics. In five of the studies the participants received instructions on how to self-collect specimens before collecting their specimens^{19,27,33–35,37}, and in one study this was not reported²⁹. The sample size of research participants ranged from 174 to 1867. One study compared the diagnostic accuracy of healthcare worker collected vaginal and cervical swabs with self-collected swabs³⁵. Two studies compared healthcare worker collected cervical swabs with self-collected vaginal swabs^{29,37}. One study compared endocervical swabs collected by healthcare workers with self-collected veil specimens¹⁹. Two studies compared diagnostic accuracy between self-collected vaginal swabs with healthcare worker collected vaginal swabs^{34,35}. Only one study compared healthcare worker collected endocervical swabs with self-collected vaginal swabs¹⁹. Figure 8 below presents summary estimates for the sensitivity and specificity of diagnostic accuracy healthcare worker collected specimens compared to self-collected specimens.

The summary estimate for sensitivity and specificity is 0.94 (95% Confidence Interval 0.89–0.98) and 0.91 (95% Confidence Interval 0.85–0.96) respectively and it is depicted on the SROC in Fig. 9 below. Additionally, Fig. 9 depicts the diagnostic accuracy of the studies in this subgroup.

The Cochran's Q test result shows that there is significant heterogeneity among the studies and the diagnostic test is moderately accurate in identifying patients with disease (Table 7).

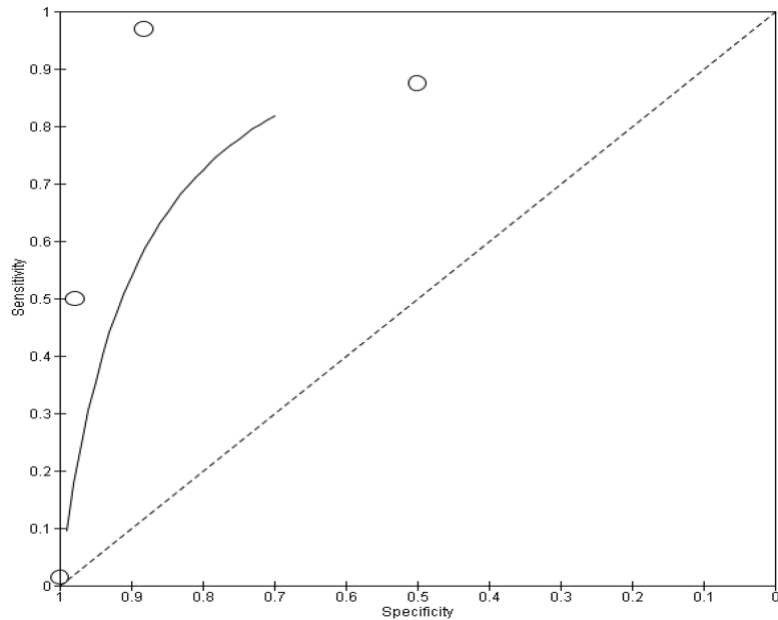


Figure 7. SROC depicting diagnostic accuracy of NG in included studies.

Item	Result
P value	0.0006. The result is significant at $p < 0.05$
Cochran's Q (heterogeneity)	17.156
DOR	2.579

Table 6. Heterogeneity and statistical significance for NG.

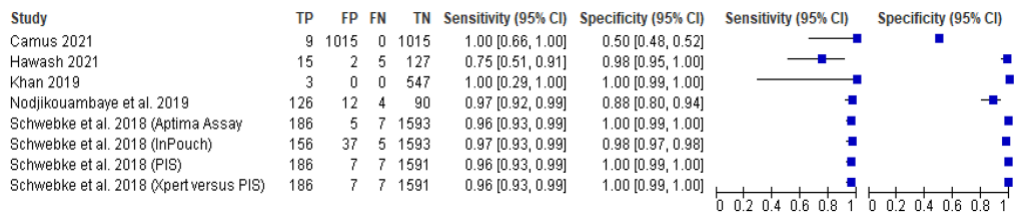


Figure 8. Forest plot of TV studies that compared self-collected vaginal swabs with healthcare worker collected cervical and vaginal specimens.

Methodological quality of studies

Table 8 below depicts the risk of bias and applicability assessment of included studies using the QUADAS-2 tool used to assess quality²⁵. The domains of the QUADAS-2 tool are patient selection, index test, reference standard, and flow and timing. Patient selection outlines the process of selecting study participants in the primary studies which includes setting, presentation, prior testing, and intended use of index test; index test describes how the test of interest was conducted and interpreted; reference standard describes how the standard test was conducted and interpreted, and flow and timing describe excluded studies and intervals between the index and reference

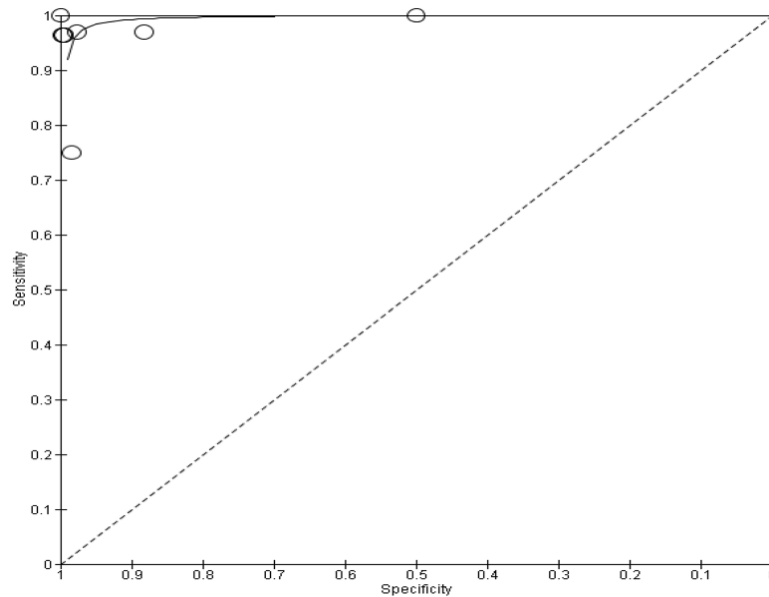


Figure 9. SROC depicting diagnostic accuracy of TV in included studies.

Item	Result
<i>P</i> value	0.001. The result is significant at $p < 0.05$
Cochran's Q (heterogeneity)	25.15
DOR	20.02

Table 7. Heterogeneity and statistical significance for TV.

tests²⁵. For the current study, the index test is designated as the self-collected specimens, while the reference test refers to the healthcare worker collected specimens.

For the majority of the studies, the sampling approach utilised was convenience sampling and not random or consecutive sampling which are the options available in the patient selection domain. Although convenience sampling was used for most of the studies and therefore introduced a high-risk bias, that is unlikely to interfere with the diagnostic accuracy of self-sampling and healthcare worker collected specimens. The reference standard domain and flow and timing domains were found to mostly be at low risk of bias in all the studies. Concerning applicability, all studies were at low risk of bias. However, regarding the applicability of the reference standard, it was unclear for most studies. The graphical results of the included studies from the QUADAS-2 quality assessment tool are indicated in Fig. 10.

Discussion

This study compared the diagnostic accuracy of self-collected specimens to healthcare worker collected specimens for diagnosing CT, HPV, MG, NG, syphilis, and TV in females. No studies on syphilis fulfilled the eligibility criteria for inclusion in this review. For CT, six studies were included in the analysis, out of which four were included in the subgroup meta-analysis. The summary estimate for sensitivity was 0.85 (0.77–0.92), while specificity was 0.95 (0.91–0.98). For HPV, five studies were included, and there was insufficient data to perform a sub-group meta-analysis. However, the sensitivity and specificity of self-collected specimens of the individual studies compared to healthcare worker collected specimens varied between studies, with sensitivity ranging from 86 to 100%, and specificity ranging from 88.9% to 100%. For MG, four studies investigated diagnostic accuracy, and two studies had sufficient data for a sub-group meta-analysis. The summary estimate for sensitivity was low at 0.49 (0.39–0.58), while specificity was 0.88 (0.81–0.94). For NG, seven studies were included in the analysis, and four studies were included in the sub-group meta-analysis. The pooled sensitivity and specificity estimate was 0.59 (0.49–0.68) and 0.84 (0.76–0.91) respectively.

Study	RISK OF BIAS				APPLICABILITY CONCERNS		
	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD
Arias et al 2016	☹️	😊	😊	😊	😊	😊	😊
Barbee et al 2021	☹️	😊	😊	😊	😊	😊	😊
Boggan et al 2015	☹️	😊	😊	😊	😊	😊	?
Camus et al 2021	😊	😊	😊	😊	😊	😊	?
De Marais et al 2018	☹️	😊	😊	😊	😊	😊	?
Hawash et al 2021	☹️	😊	😊	😊	😊	😊	?
Lockhart et al 2018	?	😊	😊	😊	😊	😊	?
Khan et al 2019	😊	😊	?	😊	😊	😊	?
Kim et al 2020	☹️	😊	😊	😊	😊	😊	?
McLarty et al 2019	☹️	😊	😊	😊	😊	😊	😊
Nodjikuumbaye et al 2019	☹️	😊	😊	😊	😊	😊	?
Obiri-Yeboah et al 2017	☹️	😊	?	😊	😊	😊	?
Schwebke et al 2017	☹️	😊	?	😊	😊	😊	?
Van Der Pol et al 2019	☹️	😊	😊	😊	😊	😊	?

Table 8. QUADAS-2 summary of methodological assessment.

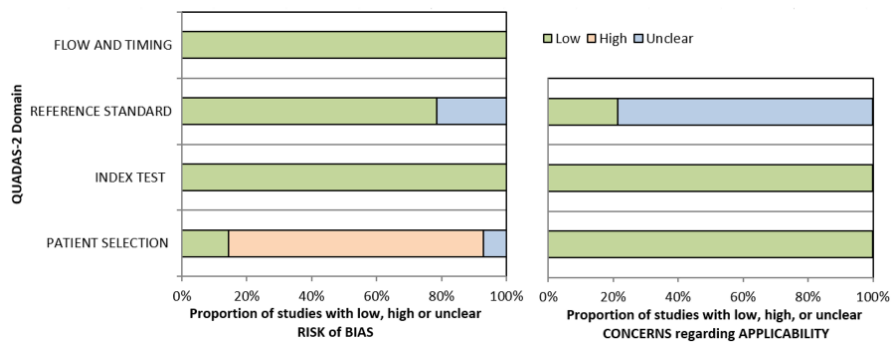


Figure 10. Assessment of included studies using QUADAS-2.

In the case of CT and NG, it is important to note that the low sensitivity and high specificity are comparable to previous findings¹⁵. For TV, seven studies investigated diagnostic accuracy, and four studies were included in the sub-group meta-analysis. The results of the meta-analysis showed that self-collected specimens have high sensitivity and specificity for the diagnosis of trichomoniasis, with a summary estimate for sensitivity and specificity of 0.94 (0.89–0.98) and 0.91 (0.85–0.96), respectively.

The study found that there was significant heterogeneity among the studies. This may be attributed to differences in the methods used to collect and test specimens across the different studies. The DOR results indicated that the diagnostic tests used in the studies had a good ability to differentiate between individuals with and without CT, HPV, NG, MG and TV. The study also presented a SROC curve to visualize the sensitivity and specificity of all included studies, with most points falling between 0.9 and 1.00 on the y-axis (sensitivity), indicating better performance in distinguishing between the presence and absence of infection.

The QUADAS-2 tool was used to assess the quality of the included studies, and it showed that a majority of them used convenience sampling to select patients. Although this sampling method can increase the risk of bias, it did not appear to affect the diagnostic accuracy of self-collected specimens and specimens collected by

healthcare workers. Most of the included studies had a low risk of bias in the index test, reference standard, flow, and timing domains. Overall, the included studies introduced minimal bias, which enhances the quality of the research findings. Study screening, selection, and data extraction were conducted systematically to ensure the most suitable studies were included in the review. A comprehensive approach to reviewing existing evidence on the diagnostic accuracy of self-collected specimens versus those collected by healthcare workers was employed. Only peer-reviewed and published studies were included to ensure reliable results. Some of the included studies utilized convenience sampling, which may have introduced bias in the patient selection process.

Since we classified healthcare worker collected specimens as the gold-standard diagnostic accuracy was presumed to be 100%. For CT the healthcare worker collected sensitivity ranged between 50 and 100%, while specificity was 88 and 99.2%; for MG sensitivity ranged between 97 and 100%, while specificity was 88 and 100%; NG sensitivity ranged between 40 and 97%, while specificity was 88 and 100%; and TV sensitivity ranged between 96 and 100%, while specificity was 88 and 100%.

The results indicate that self-collected specimens are a comparative alternative to healthcare worker collected specimens for STI testing. This is in keeping with previous studies that advocate for the use of self-sampling interventions as alternative tools to enable and promote screening of STIs even in asymptomatic patients and resource-limited settings^{15,39}. These findings have important implications for STI testing, particularly in settings where access to healthcare workers may be limited or where stigma and embarrassment may prevent individuals from seeking testing.

Limitations

The lack of eligible studies for syphilis and insufficient study data for meta-analysis in HPV limits the comprehensiveness of the review. There was significant heterogeneity among included studies, likely due to varying specimen collection and testing methods, which introduced variability and challenges with generalizability of the findings. Despite efforts to minimise bias during data analysis, the use of convenience sampling in most studies introduced potential bias in patient selection. Assuming the accuracy of the gold standard of healthcare worker-collected specimens may not fully capture variability in sensitivity and specificity among these samples. Conversely, the wide range of sensitivity and specificity values across individual studies underscores the complexity of interpreting overall diagnostic accuracy. Lastly, it is important to consider that the findings of this study may not be generalizable to resource-limited settings where access to healthcare workers and testing facilities differs.

Conclusion

This study presents evidence of the accuracy of self-collected specimens when used to diagnose STIs in females. The meta-analysis findings highlight that the diagnostic accuracy of self-collected specimen to diagnose STIs in females is comparable with that of healthcare worker collected specimens. When considering the global burden of STIs on the public health system, such findings are an indication of how self-sampling for STI diagnosis could be used to improve STI management services across the globe. Although much evidence exists on the use of this intervention in high-income countries²², the researchers hope that the findings of this study will capture the attention of governments in LIMCs and cause them to see their need for it. Furthermore, the potential of self-sampling interventions to improve screening of asymptomatic STIs must be recognized and utilized as a tool to fulfil goal 3 of the sustainable development goals which is targeted at treating and improving access to quality healthcare for all people across the globe. The study is limited in that the investigation of diagnostic accuracy of self-collected specimens was only conducted on females. Therefore, the findings are not representative of self-collected specimens among a broader and more diverse population. We, therefore, recommend a future study to investigate the accuracy of self-collected specimens for diagnosing a wide range of STIs in a more diverse and broader population.

Data availability

All data generated or analysed during this study are included in this manuscript [and its supplementary information files].

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Author contributions

Conceptualization, Z.N.J. and T.M.-T.; developing and conducting the search strategy, K.K.; screening, Z.N.J., T.D., and NT; writing—original draft, Z.N.J.; writing—reviewing and editing, T.M.-T., W.M., T.D.; supervision, T.M.-T and W.M. All authors have read and agreed to the current version of the manuscript.

Competing interests

The authors declare no competing interests.

Additional information

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CHAPTER 5: ARTICLE ADDRESSING OBJECTIVE 2

For an intervention to be implemented effectively, it is imperative to understand the environment in which it would exist, including with individuals and at organisational level. We recognised the need to conduct such an investigation for self-sampling as an alternative intervention for STI diagnosis. The second objective was to utilise a nominal group technique (NGT) to collaborate with young women and healthcare workers to investigate barriers to accessing sexually transmitted infection (STI) healthcare and develop attributes of an acceptable self-sampling intervention. We collaborated with young women in underserved communities and healthcare providers working in primary healthcare facilities located in these underserved communities in the selected municipality.

This chapter (Chapter 5) presents the two NGTs conducted as follows:

5.1. Presents the article on the NGT conducted with healthcare workers, which was published in Biomed Central Health Services journal under the title: *“Nurses’ perspectives on user-friendly self-sampling interventions for diagnosis of sexually transmitted infections among young women in eThekweni district municipality: a nominal group technique”*.

5.2. Presents the manuscript on the NGT conducted with young women, formatted according to Biomed Central Women’s Health journal requirements, where it was submitted. The manuscript is titled: *“Young women’s perspectives on a user-friendly self-sampling intervention to improve the diagnosis of sexually transmitted infections in underserved communities in KwaZulu-Natal, South Africa”*

5.1. Published article presenting the NGT with healthcare workers

Jaya et al. *BMC Health Services Research* (2024) 24:106
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BMC Health Services Research

RESEARCH

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Nurses' perspectives on user-friendly self-sampling interventions for diagnosis of sexually transmitted infections among young women in eThekweni district municipality: a nominal group technique

Ziningi N. Jaya^{1,2*}, Witness Mapanga¹, Boitumelo Moetlhoa¹ and Tivani P. Mashamba-Thompson³

Abstract

Background Syndromic management is the main non-laboratory-based management approach for sexually transmitted infections (STI) in most low- and middle-income countries (LMICs) but it has limitations. Self-sampling has been proven as a suitable alternative approach to help improve management STIs by improving access to diagnosis among vulnerable populations. We sought to determine health workers' perspectives on user-friendly self-sampling interventions for STIs among young women in eThekweni District Municipality.

Methods Healthcare workers providing STI healthcare services in the study location participated in a nominal group technique (NGT) workshop. The NGT workshop was aimed enabling collaboration with key health providers in identifying user-friendly self-sampling interventions for diagnosis of STIs among young women. Data collection was conducted in two phases: phase 1 determined barrier that hinder young women from accessing current STI healthcare services and phase 2 focused on determining the key strategies for self-sampling interventions to diagnose STIs in young women. Thematic analysis and percentage form analysis were used to examine qualitative and quantitative data respectively.

Results The following barriers were identified: negligence; myths about STIs; fear of judgement; denial; operating hours; lack of knowledge of STI symptoms and safe sex practices; and stigma associated with STIs. The following strategies were suggested: hand out self-sampling kits at popular restaurants; collect self-sampling kits from security guard at primary healthcare clinics (PHCs); receive STI diagnostic results via SMS or email or the clinic for treatment; improve youth friendly services at PHCs; educate the public on proper use of the kits. Education about STIs and handing out self-sampling kits at clinics, universities, schools, pharmacies or via outreach teams were ranked high priority strategies.

Conclusions The findings highlight the need to address stigma and fear of judgment and provide comprehensive education to improve healthcare-seeking behaviour in young women. Additionally, the study also indicates that using eHealth solutions could significantly enhance the accessibility and efficiency of STI healthcare services in LMICs.

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Keywords Barriers, Sexually transmitted infections, Self-sampling, Strategies, eHealth solutions

Background

The burden of sexually transmitted infections (STIs) remains a major public health challenge throughout the globe [1, 2], and the associated mortality and morbidity remain high [3]. Effective management of STIs is essential to reduce the burden of infections and associated complications. However, in many parts of the globe, including low-and-middle-income-countries (LMICs), healthcare infrastructure is often limited in providing quality affordable STI healthcare services [4]. The current research explores and presents barriers faced by young women residing in underserved communities in accessing STI healthcare services and identifies strategies for self-sampling interventions to improve access.

Diagnosis and management of STIs often relies on syndromic management, particularly in resource-limited settings due to cost implications [5]. This approach involves treating patients based on their clinical presentation instead of specific laboratory diagnoses [6–8]. While it has proven valuable and effective in treating and managing STIs, it presents several limitations. The limitations include failure to identify asymptomatic infections and thus prevent timely diagnosis and treatment of infected individuals [6, 9]. Furthermore, since the issuing of treatment is not based on confirmed laboratory diagnoses, it often leads to over-diagnosis and over-treatment of patients which increases costs of healthcare and development of antibiotic resistance [5]. Several researchers have reported on the growing trend of drug resistant gonorrhoea and chlamydia [10, 11]. As such, there is a dire need for a paradigm shift from syndromic management to pathogen specific treatment of STIs to mitigate the limitation of syndromic management.

In light of these challenges, self-sampling for STI diagnosis has emerged as a promising alternative to syndromic management [12, 13]. Self-sampling allows people to collect their own biological specimens at a convenient location of their choice [13] and then the specimens are used for laboratory diagnosis of STIs. Self-sampling not only addresses the issues of stigma and lack of privacy [12, 14, 15] which are presented by syndromic management, but it also has the potential to improve access to STI healthcare even for individuals in resource-limited areas [16]. Furthermore, it is an effective alternative to screen for STIs, including asymptomatic infections where patients may not necessarily seek medical assistance [17, 18]. Despite its popular uptake in high-income countries (HICs), self-sampling remains an investigative intervention in LIMCs. The

affordability of self-sampling kits and practicability of delivering results are some of the factors that require careful consideration to effectively adopt self-sampling interventions in LMICs. However, these factors were not explored in this study.

We utilised a nominal group technique (NGT) to engage healthcare workers from primary healthcare clinics (PHCs) in underserved communities in eThekweni District Municipality in KwaZulu-Natal. The high prevalence of STIs in this province [19] made it a suitable study area because study findings would benefit many people at risk of STIs in this province. Through the NGT approach healthcare workers from diverse PHCs and backgrounds came together to identify barriers to young women accessing STI healthcare services. Subsequently, the healthcare workers collaborated to develop strategies for self-sampling to address the identified barriers. Considering that syndromic management is the current approach to treating and managing STIs in South Africa, the barriers to STIs being referred to in this study were in relation to symptomatic infections. This paper presents the findings of this NGT which includes identified barriers and strategies developed. By understanding the barriers and identifying strategies to mitigate barriers, we aim to contribute towards the development of a user-friendly self-sampling intervention easily accessible to young women in underserved communities.

The significance of involving healthcare workers

Healthcare professionals including nurses, medical doctors, and other staff involved in STI healthcare service provision are uniquely positioned to provide insight into the challenges of providing this service. They often serve as intermediaries between healthcare facilities and the communities which they serve promoting a patient-centred approach to healthcare service provision. As such, their involvement in this NGT is significant because they hold the necessary knowledge and expertise to identify barriers and develop strategies for self-sampling to improve access to STI healthcare. By engaging them we tapped into their collective knowledge and expertise to bridge the gap between real-life experiences at PHCs and research related to STI healthcare services. Contributions from our group of healthcare professionals were expected to yield strategies contextually relevant to STI healthcare nuances. Ultimately, their contribution led to the development of strategies grounded in the experiences of both the healthcare professionals and their patients.

Methods

STI healthcare service providers from PHCs located in underserved urban communities in eThekweni District Municipality were invited to participate in a co-creation workshop. This co-creation workshop was aimed towards identifying barriers that prevent young women from accessing STI healthcare services. It also aimed to identify key strategies for a self-sampling intervention to improve access to STI healthcare services for young women in underserved communities.

Sampling

Study participants were recruited directly from selected PHCs in eThekweni District Municipality. STI healthcare service providers that included nurses and medical doctors were requested to participate in the study. Despite rigorous recruitment strategies and issues of availability of medical staff, a total of eight nurses participated on the NGT. The following eligibility criteria were utilised to select eligible study participants:

Inclusion criteria

- Healthcare workers working in PHCs located in underserved communities in eThekweni district municipality.
- Healthcare workers involved in STI healthcare service provision at PHCs in underserved communities in the selected district municipality.

Exclusion criteria

- All healthcare personnel who reported no direct involvement in STI healthcare service provision.
- Healthcare workers from PHCs outside of those in underserved communities in the selected district municipality.

Challenges with participant recruitment and scheduling of NGT during sampling

The recruitment of study participants and scheduling of the NGT workshop presented challenges that were unexpected. As a result, data collection was delayed. The following is an account of the challenges experienced and the action taken to address them:

Participant recruitment

Clinic management personnel at the PHCs were welcoming and open to accommodate the research team for data collection. Communication about the study was shared with the relevant healthcare personnel

through the clinic manager. However, regardless of the process followed, there were numerous instances when staff was unavailable to speak to the research team because the PHCs were busy with a large number of patients. In those instances, the research team would be told to wait until the relevant healthcare workers were available. Initially a total of 16 participants were recruited for the NGT and promised their participation. However, in the end only eight participants were available for the NGT for various reasons. The reasons included not being able to get time off from patient consultations due to staff shortages, and being on sick leave. Ultimately, only eight nurses involved in STI healthcare participated in the NGT.

Scheduling of NGT

The PHCs from which participants were recruited were far from each other and this presented a challenge with scheduling of the NGT at a time and day suitable for all. The situation was further exacerbated by protest action at one of the clinics on a day on which NGT was scheduled. Since the research team could not access PHCs nor research the staff, the NGT had to be rescheduled. Although the NGT date changed several times, the NGT was eventually conducted.

Study design

The NGT is a highly regarded qualitative exploratory research method that merges idea generation and problem-solving within the context of group dynamics [20, 21]. This method operates through organized small group discussions, typically involving a cohort of 6 to 12 participants [22], with NGTs being optimal when consisting of five to nine participants [23, 24]. The application of this methodology is well-documented both within the healthcare and other research domains [25, 26]. It serves as an instrument in identifying pivotal attributes for effectively implementing Discrete Choice Experiments (DCEs) [27]. One unique attribute of the NGT approach is its capacity to foster the generation of diverse ideas while concurrently cultivating consensus among participants [25, 28]. This capability, which is transformative, is a direct result of its capacity to promote active engagement from all participants, even individuals who may be apprehensive and withhold their perspectives [25]. By being so inclusive, NGT mitigates the potential for dominant individual voices to overshadow the process of knowledge creation. This ensures that a wide range of multiple responses are received in response to the question posed.

The NGT method consists of three pivotal stages, namely silent generation, round-robin, and ranking of all contributions made. Silent generation is the initial stage where participants take time to think about their responses to a question that has been posed. During this stage participants contemplate and commit their insights to writing. Subsequently, the round-robin sharing stage follows where individual contributions are systematically revealed, documented, and discussed for clarification where necessary. This stage facilitates a robust exchange of ideas. Finally, all contributions are systematically ranked based on their perceived priority to each participant. This process renders the NGT method, rigorous and versatile to improve the quality of any research it informs.

Procedure

We conducted an NGT workshop on the 6th of February 2023 by collaborating with consenting healthcare workers involved in STI healthcare service provision at the selected PHCs [29]. The eight participants were split into two groups of four members. The NGT was conducted in two consecutive phases to address 2 questions. The participants were asked the following questions:

Question 1 (for phase 1): What are the barriers that prevent or limit young women from accessing current STI healthcare management services?

Question 2 (for phase 2): What would be the key strategies to deliver self-sampling for STI diagnosis among young women to mitigate the barriers to access?

In phase 1 the main focus was to determine barriers that hinder young women from accessing current STI healthcare services. Phase 2 mainly focused on determining the key strategies that can be employed to efficiently deliver self-sampling interventions for STI diagnosis in young women. Each phase was conducted in the following stages:

Phase 1: the healthcare workers were requested to share their knowledge about barriers that prevent young women from utilising the existing STI healthcare services. The PI (ZNJ) and facilitator instructed the stakeholders to independently group their contributions according to themes and present them to the entire group of participants. Thereafter ZNJ, listed the themes in a voting form to enable the study participants to independently rank each theme according to a level of importance. The level of importance was determined using a ranking score

between 1 to 7 where “1” represents a low priority barrier and “7” represents a high priority barrier.

Phase 2: in this stage stakeholders were asked to identify key strategies for delivering STI self-sampling to mitigate the previously outlined barriers to access. Thereafter all the stakeholders independently grouped their contributions into themes and presented them to the entire group of participants. Once again, ZNJ listed the themes in a voting form to enable voting through ranking. The ranking score was between 1 to 7 where “1” represented a low priority strategy and “7” represents a high priority strategy.

Following the NGT workshop, ZNJ compiled a report of the NGT proceedings and shared it with the stakeholders for comments.

Data management and analysis

Quantitative data collected during the ranking step was calculated in phase 1 as a total importance score for each barrier by adding individual participant scores. However, in phase 2 a total importance score of each strategy was calculated to signify the perceived efficacy of the suggested strategies for self-sampling to diagnose STIs. Thematic content analysis was utilised to analyse qualitative data to identify themes that emerged from data that was presented during the NGT discussions. To limit researcher bias through numerous theoretical perspectives and predetermined ideas, coding categories were directly extracted from data text.

Results

A total of eight key stakeholders from two clinics namely, Cato Manor Clinic and Sydenham Clinic agreed to participate in our study. All the participants were female nurses and employed at PHCs. Three nurses were aged between 25 to 35. Four nurses were aged between 36–45, and only one was between the age of 46 – 55 years. The characteristics of all stakeholders are outlined in Table 1 below.

Table 1 Characteristics of stakeholders

Age group in years	Number of nurses	PHC of employment
25 – 35	1	Sydenham Heights Clinic
	2	Cato Manor Clinic
36—45	2	Sydenham Heights Clinic
	2	Cato Manor Clinic
46—55	1	Sydenham Heights Clinic

Stakeholder perspectives of the barriers preventing young women from accessing STI management and treatment services

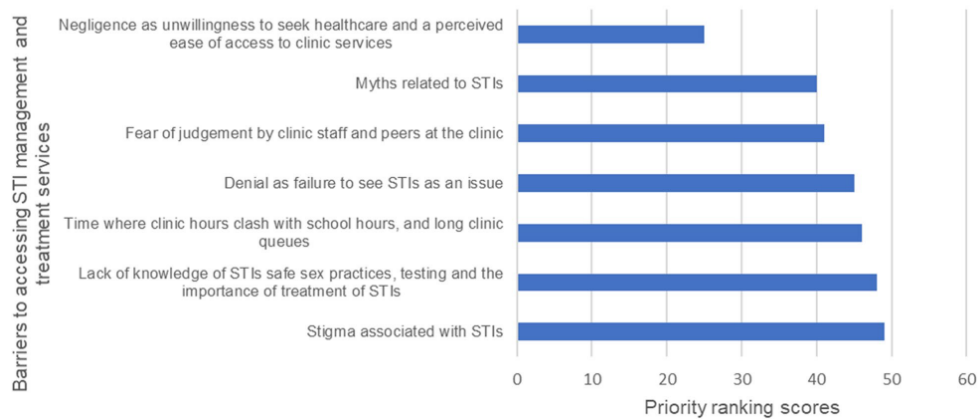


Fig. 1 Ranking of barriers that limit access to STIs healthcare services

Stakeholders outlined the following seven factors as barriers to young women accessing STI healthcare services (Fig. 1). The priority barrier that limits or prevents young women from accessing current STI healthcare management services was the stigma associated with STIs (49 scores). This was followed by a lack of knowledge of STIs and safe sex practices (48 scores), time related to clinic hours clashing with school hours (46 scores), denial as failure to see STIs as an issue (45 scores), fear of judgement by clinic staff and peers at the clinic (41 scores), and myths related to STIs (40 scores). Negligence seen as unwillingness to seek healthcare and perceived ease of access to clinic services received the lowest priority ranking score (25 scores).

Strategies for delivering self-sampling to diagnose STIs in young women

All eight participants were requested to suggest and rank delivery strategies to mitigate the barriers to accessing STI healthcare services, as previously outlined. Stakeholders reported the following seven strategies as idea strategies for the delivery of STI self-sampling among young women in eThekweni District Municipality (Table 2). Table 2 shows the suggested strategies in ascending order of ranking from low priority to high priority ranking. Stakeholders ranked handing out self-sampling kits at clinics, universities, schools, pharmacies or via outreach teams (98%) and educating people about the STI symptoms (98%) as the two highest priority

Table 2 Ranking scores for question 2

Delivery strategies for self-sampling for STI diagnosis	Summing by ranking votes Where 1 = low priority And 7 = high priority							Total number of voting scores (number of votes x ranking score)	Percentage of votes
	1	2	3	4	5	6	7		
Self-sampling kits can be handed out at popular restaurants	1	1	2	1	1	1	1	31	55
Individuals are to collect self-sampling kits in the security guard rooms		4	1					32	57
Results can be received via SMS, or email or can be collected at the clinic, where treatment is received				1	2			49	88
Improve youth friendly services at clinics				1	1			51	91
Educate the public on how to properly use the kits					1	1		53	95
Educate people about the STI symptoms						1	7	55	98
Handout out self-sampling kits at clinics, universities, schools, pharmacies or via outreach teams						1	7	55	98

Disease	Author, year published	Country of study	Study design	Study population (sex) and samples size	Mode of instruction for self-collection	Location of self-collection	Specimen and testing		
							Specimen (healthcare worker collected/self-collected)	Diagnostic platform Automated (run on instrument)/ manual (manual method used)	Assay type
CT	Arias et al. 2016 ³¹	Canada	Cross sectional	Female -189	Demonstration of collection method and self-collection had collection instructions	Study clinic	Vaginal swab/ vaginal swab	Automated	NAAT Aptima Combo 2
	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal/cervical classical sampling/vaginal swab	Automated	COBAS—Roche Diagnostics Kits
	De Marais et al. 2018 ²⁷	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima Combo2
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoombaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Ailplex STI Essential Assay
	Van Der Pol et al. 2019 ³⁰	USA	Cross sectional	Female = 3860	Not indicated	Not indicated	Vaginal swab/ vaginal swab, urine	Automated	NAAT—COBAS NG/CT test—the BD ProbeTec CT Qx and GC Qx amplified DNA assay; Aptima Combo 2 CT/NG; and the Abbott m2000 RealTime CT/NG assay
HPV	Boggan et al. 2015 ³²	Haiti	Cohort	Female = 1836	Orientation by a study nurse	Study clinic	Cervical swab/ vaginal swab	Automated	Hybrid Capture 2 High-Risk HPV DNA Test
	De Marais et al. 2018 ²⁷	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima HPV assay
	Kim et al. 2020 ³⁶	Korea	Cross sectional	Female = 151	Digital and written instructions provided	Study clinic	Cervical swab/ vaginal swab	Automated	multiplex real-time PCR Anyplex II HPV28 Detection assay
	McLarty et al. 2019 ²⁸	USA	Cross sectional	Female = 174	Individual instructions were provided	Home and study clinic	Cervical swab/ tampon, vaginal swab	Automated	Roche Cobas HPV method
	Obiri-Yeboah et al., 2017 ³⁸	Ghana	Cross sectional	Female = 333	Instructed on how to obtain a specimen	Study clinic	Cervical swab/ vaginal swab	Automated	CareHPV assay
MG	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal/cervical classical sampling/vaginal swab	Automated	TIB MOLBIOL LightMix—PCR Roche Diagnostics
	De Marais et al. 2018 ²⁷	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima analyte-specific reagent-based assay
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/ cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoombaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Ailplex STI Essential Assay

Continued

Disease	Author, year published	Country of study	Study design	Study population (sex) and samples size	Mode of instruction for self-collection	Location of self-collection	Specimen and testing		
							Specimen (healthcare worker collected/self-collected)	Diagnostic platform Automated (run on instrument)/ manual (manual method used)	Assay type
NG	Arias et al. 2016 ³¹	Canada	Cross sectional	Female = 189	Demonstration of collection method and self-collection had collection instructions	Study clinic	Vaginal swab/vaginal swab	Automated	NAAT Aptima Combo 2
	Barbee et al. 2021 ²⁶	USA	Cross-sectional	Female = 89	Not indicated	Study clinic	Endocervical swab/vaginal swab	Manual and automated	Culture and NAAT Aptima Combo 2
	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal/cervical classical sampling/vaginal swab	Automated	COBAS—Roche Diagnostics Kits
	De Marais et al. 2018 ²⁷	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/cervicovaginal swab	Automated	Aptima Combo2
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoombaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Allplex STI Essential Assay
	Van Der Pol et al. 2019 ³⁰	USA	Cross sectional	Female = 3860	Not indicated	Not indicated	Vaginal swab/vaginal swab, urine	Automated	NAAT—COBAS NG/CT test—the BD ProbeTec CT Qx and GC Qx amplified DNA assay; Aptima Combo 2 CT/NG; and the Abbott m2000 Real-Time CT/NG assay
TV	Camus et al. 2021 ³³	France	Cross sectional	Female = 1028	Instructions provided	Study clinic	Vaginal and cervical swabs/vaginal swab	Automated	TIB MOLBIOL LightMix—PCR Roche Diagnostics
	De Marais et al. 2018 ²⁷	USA	Clinical trial	Female = 193	Participants were instructed by a study nurse	Home and clinic	Cervical swab/cervicovaginal swab	Automated	Aptima TV assay
	Hawash et al. 2021 ³⁴	Saudi Arabia	Cross sectional	Female = 174	Instructions were provided and sample collection was done in the presence of medical personnel	Study clinic	Vaginal swab/vaginal swab	Manual, and automated	OSOM TV rapid test, wet prep, TV DNA PCR
	Khan et al. 2019 ³⁵	India	Cross-sectional	Female = 550	Participants were given instructions	Study clinic	Vaginal swab/vaginal swab	Manual	Trichomonas culture
	Lockhart et al. 2018 ³⁷	Kenya	Cross-sectional	Female = 350	Participants were instructed verbally	Study clinic	Cervical swab/cervicovaginal swab	Automated	Aptima combo assay
	Nodjikoombaye et al. 2019 ¹⁹	Chad	Cross-sectional	Female = 271	Training on specimen collection	Study clinic	Endocervical swab/veil sample	Automated	Multiplex real-time PCR—Allplex STI Essential Assay
	Schwebke et al., 2018 ²⁹	USA	Cross sectional	Female = 1867	Not indicated	Study clinic	Cervical swab/vaginal swab	Manual, and automated	In Pouch TV broth culture and Aptima NAAT for TV

Table 2. Characteristics of included studies. CT = *Chlamydia trachomatis*; NG = *Neisseria gonorrhoea*; TV = *Trichomonas vaginalis*; HPV = Human papillomavirus; DNA = Deoxyribonucleic acid; PCR = Polymerase Chain Reaction; Veil sample = self-collection device for cervicovaginal fluid collection.

study was excluded because only agreement data was reported and the other parameters were not reported³⁷. Similarly, the other study only reported sensitivity and specificity data²⁷. Figure 2 presents research findings for the subgroup analysis of four studies, where the summary estimate for sensitivity was 0.85 (95% Confidence

identified these same factors as deterrents for adolescent girls and young women seeking care for STI-related health issues [31]. The inability of young women to recognize STI symptoms emerged as another significant barrier, consistent with previous research that reported that young people lack knowledge about STIs and available healthcare services [32]. This lack of awareness about STIs often leads individuals to delay seeking immediate healthcare [33].

During the NGT, stakeholders suggested the following strategies for self-sampling as an intervention for STIs in women: distributing self-sampling kits at popular restaurants; making kits available in security guard rooms at PHCs; providing STI diagnostic results via SMS or email; enhancing youth-friendly services at clinics; educating the public on proper kit usage and STI symptoms; and distributing kits at clinics, universities, schools, pharmacies, or through outreach teams. The potential benefits of using these strategies in healthcare have been well documented. Notably, education is one of the key strategies to facilitate the link between available public services and the communities they are meant to serve [34]. Additionally, a study by Wang et al. [35] established that health education not only contributes to knowledge but also practices towards infectious diseases, which has the potential to improve healthcare seeking behaviour. However, it's crucial to emphasize while knowledge about STIs may confer precaution, it may not necessarily reduce risk-taking behaviour [36]. The sub-Saharan, has experienced rapid growth in the use of smartphones and the internet [37], thus offering a great potential for eHealth interventions to revolutionise healthcare interventions. The idea of patients receiving their STI diagnostic results via SMS or email thus aligns with the technological advancements. Several studies have proven that adopting eHealth opportunities can transform the user perceptions and accessibility of STI healthcare services, especially in LMICs [38–40].

Strengths and limitations

The utilisation of NGT fostered collaboration among healthcare service providers enabling the development of key strategies for self-sampling for STI diagnosis among women. True to NGTs, this collaborative approach resulted in a wide range of views which enhanced the comprehensiveness of the strategies to improve access to STI healthcare services. The use of NGTs to promote collaboration and generation of diverse perspectives in well known [25]. Using NGT limited the bias of having one dominant participant by utilising ranking to identify high priority strategies. This approach ensured that

the most critical strategies were identified based on consensus rather than individual influence. The use of NGT to eliminate bias and promote consensus has been well proven and established over time, dating back to Delbecq et al. in 1975 to date [28, 41].

Due to the nature of PHCs having limited medical personnel and being understaffed, most of the stakeholders who participated in the NGT were nurses involved in STI healthcare services. Due to the scarcity of medical doctors at PHCs, no medical doctor was available to participate in the NGT on the day that it was conducted. The limited representation of medical doctors due to staffing constraints at PHCs is a challenge recognised by the World Health Organization [42]. Although nurses and medical doctors work hand in hand to provide healthcare services to patients, there is a vast difference in the academic training received. The academic training of and duties of medical doctors is different from that of nurses. Medical doctors often have in-depth clinical expertise in diagnosing and treating STIs and so their participation could have enhanced the knowledge gathered and strategies developed. Additionally, the determination of the level of acceptability of the suggested delivery strategies by young women was not evaluated.

Conclusions

Our study identified key barriers and strategies for implementing self-sampling interventions for STIs in young women. These findings highlight the need to address stigma, fear of judgment, and provide comprehensive education to improve healthcare-seeking behaviour in young women. Furthermore, the study also indicates that embracing eHealth solutions could enhance the accessibility and efficiency of STI healthcare services in LMICs significantly. Our findings have the potential to influence policy changes regarding the provision of STI healthcare services for young women. Prior to the implementation of these strategies, a similar study to co-create strategies for self-sampling in young women in collaboration with young women is required. This proposed follow-up study is likely to foster the development of a more patient-tailored approach to the management of STIs within this population.

Abbreviations

DCE	Discrete Choice Experiment
HIC	High-income countries
LMIC	Low-and-middle income countries
NGT	Nominal Group Technique
PHC	Primary Healthcare Clinic
PI	Principal Investigator
TVET	Technical and Vocational Education and Training

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Authors' contributions

Z.N.J. wrote the main manuscript, B.M., W.M. and T.P.M-T. reviewed and edited the manuscript, and W.M. and T.P.M-T supervision. All authors reviewed the final manuscript.

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Availability of data and materials

All data generated or analysed during this study are available in the manuscript. However, additional datasets used are available from the corresponding author on reasonable request if required.

Declarations

Ethics approval and consent to participate

Permission to conduct the study was obtained from the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (reference number 136/2022) and the Provincial Department of Health of KwaZulu-Natal province in South Africa prior to conducting the NGT. All eligible study participants who volunteered to participate in the NGT received a verbal and written explanation of the study and the process that would be followed for data collection. All study participants gave written informed consent prior to study participation. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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5.2. Manuscript on NGT conducted with young women

Young women's perspectives on a user-friendly self-sampling intervention to improve the diagnosis of sexually transmitted infections in underserved communities in KwaZulu-Natal, South Africa

Short title: Self-sampling intervention to diagnose Sexually Transmitted Infections

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Abstract

Introduction

Young women are disproportionately affected by sexually transmitted infections (STIs), especially in the KwaZulu-Natal Province of South Africa. As such, they should have easy access to STI healthcare services. The main objective of this study was to collaborate with young women, using a nominal group technique (NGT), to identify barriers to existing STI healthcare services to ultimately identify strategies to inform attributes for a discrete choice experiment (DCE) towards developing a user-friendly self-sampling intervention for STI diagnosis in young women.

Methods

Eight young women, aged 18–24 years, were purposively selected from primary healthcare clinics in underserved communities. A NGT was conducted comprising the following steps: silent generation where individuals considered and recorded their responses to a question; round-robin sharing, recording and discussion of individual responses; followed by ranking of contributions.

Results

The following barriers to accessing STI healthcare services were identified: the clinics were too far from home; young women feared judgement by clinic staff; young women feared being told to inform their partners; clinic hours clashed with school hours and other personal commitments; and young women did not know enough about the signs and symptoms of STIs. The following strategies to improve access to STI healthcare services were suggested: campaigns to promote self-sampling; self-sampling kits should be available free of charge; online system to assess symptoms and register to receive self-sampling kits via delivery or collection to accommodate people with disabilities.

Conclusion

The strategies identified informed the attributes for the DCE, which was aimed towards the development of a user-friendly self-sampling interventions for STI diagnosis in young women in KwaZulu-Natal.

Keywords: access; diagnosis; self-sampling; sexually transmitted infections; young women

Background

Sexually transmitted infections (STIs) remain a public health concern globally (1, 2), with approximately 1 million infections acquired daily (3,4). Global statistics indicate that the highest burden of disease is concentrated in low-and-middle-income countries (3), and approximately 40% of the global STI burden is concentrated in sub-Saharan Africa (5, 6). STIs are prevalent among young people (7), particularly among adolescent girls and young women residing in sub-Saharan Africa (8, 9). In this region and globally, South Africa constitutes the highest number of STIs (10), and within South Africa, the KwaZulu-Natal province is more heavily burdened by STIs than the rest of the country (11). Young women in this province are disproportionately affected by STIs (12, 13). These findings are concerning when we consider the long-term health complications of STIs, which include infertility, increased risk of acquiring human immunodeficiency virus, and development of cervical cancer (14, 15). This affects young women's rights to pleasurable and safe sexual experiences, and ultimately their sexual wellbeing.

The high prevalence of STIs among young women can be attributed to various factors, including urbanisation and globalisation. These have played a critical role in the spread of infectious diseases across the globe (16, 17), including a spread from rural to urban areas (16, 18). An important example of the contribution of globalisation to the spread of infectious diseases is the COVID-19 pandemic, which saw a global spread (19, 20, 21). To further complicate matters, many pathogens, including STIs, are developing a resistance to multiple drugs (22).

While globalisation and urbanisation may contribute to the spread of infectious diseases, STI healthcare management and treatment approaches play a crucial role in the fight against such infections. Syndromic management is the method commonly employed to diagnose, manage, and treat STIs across the globe (23, 24), as well as in South Africa (25, 26). Using this approach, STIs are diagnosed based on verbal reports and physical examinations, and the most common causative agent is then treated (27, 28). Although the syndromic approach is useful when infected individuals seek medical care, it is limited when screening for asymptomatic infections (24, 28, 29).

Self-sampling interventions for STIs are widely accepted by users and have proved to be as reliable and accurate as healthcare worker collected specimens (30, 31). Self-sampling offers the opportunity for self-collected specimens to be tested in a laboratory to accurately identify the infectious agent, ensuring appropriate treatment and care targeted to the diagnosed infectious agent. Self-sampling can facilitate a paradigm shift from a syndromic approach

towards STI-specific treatment. To promote accurate STI diagnosis, self-sampling interventions should be widely used and be tailored to user needs and preferences. Previous studies have proven user acceptability and comfort with self-sampling interventions (32, 33, 34, 35). However, input on how service provision for such interventions should be conducted has seldom involved the input of users. Nominal group technique (NGT) has been used to identify attributes for interventions because of its structured approach and ranking method, which is used in a focus group setting (36, 37). Therefore, in this study, we used a nominal group technique (NGT) to identify barriers to accessing current STI healthcare services, and key attributes for a successful STI self-sampling intervention. This was done to inform the design of a preference weighed discrete choice experiment (DCE), which is a quantitative research method used to solicit the preferences of individuals for a service provided (38). The DCE would be towards developing a user-friendly self-sampling intervention for STI diagnosis among young women in underserved communities in KwaZulu-Natal, South Africa.

Methods

We invited young women aged 18–24 years from underserved urban communities to participate in a NGT, which aimed to develop a user-friendly, self-sampling intervention for STI diagnosis for women. We conducted one in-person NGT with eight young women from underserved urban communities in the eThekweni District Municipality, KwaZulu-Natal Province, South Africa.

Participant recruitment

Young women were purposively sampled from family planning- and youth clinics in primary healthcare facilities. The study was explained to prospective research participants, and young women who were interested were screened for eligibility before participation. The following eligibility criteria were used to select participants:

Inclusion criteria

- Young women aged 18–24 years old.
- Young women residing in underserved urban communities.
- Sexually active young women.

Exclusion criteria

- Women who did not fall in the stipulated age bracket.
- Women who were not sexually active.
- Women who did not reside in underserved urban communities.
- Women who were deemed unsuitable due to their mental capacity to comprehend the study.

All eligible young women were then invited to the NGT, which was held at a venue outside of the public health clinic on a day different from that of recruitment. Written informed consent was obtained before study participation. All identifiers were removed from the collected data before analysis.

Participant recruitment and NGT scheduling challenges:

Participant recruitment and the scheduling of the NGT workshop presented unexpected challenges, which led to the delay in data collection. Below is an account of the challenges experienced and the actions taken to address them:

Initial NGT workshop scheduling

For the initial NGT, 12 young women had been recruited and confirmed for attendance. However, on the day of the scheduled NGT, all the young women did not show up. Some reported unavailability on the morning of the scheduled NGT and some were unreachable on the day. As such, cancellation of the NGT workshop was inevitable for that day. Consequently, this meant participant recruitment had to be redone and the NGT workshop rescheduled.

Second NGT workshop scheduling

After re-recruiting, a total of 15 young women confirmed their attendance to the rescheduled NGT session. However, only 8 of them showed up on the day of the session. Nevertheless, since the minimum number of participants required for a productive NGT is 8, the session proceeded, and data collection was conducted accordingly.

Study design

The NGT is a qualitative, exploratory research method that combines the concept of idea generation with problem solving in a group setting (39, 40). This technique uses structured small group discussions comprising 6–12 participants (41). It has been used to identify priorities in healthcare and in research (42, 43), and to identify key attributes for DCEs (44). The NGT approach generates a wide range of ideas and obtains consensus by promoting participation from all individuals, including those who often withhold their ideas out of fear (39, 42). Compared to traditional focus groups, there is a smaller risk of confident participants dominating the knowledge creation process. Ultimately, multiple responses to the research question are generated. Finally, all participants then rank all contributions according to their perceived priority. The NGT consists of three main stages, including silent generation during which participants consider a question and pen their responses; round-robin sharing, recording and discussing individual responses; followed by ranking of contributions.

Procedure

The NGT was conducted on February 17, 2023. The NGT was performed in four consecutive phases. Phase 1 focused on identifying barriers to accessing current STI management and treatment services. Phase 2 focused on determining the key features of an efficient delivery method for self-sampling STI diagnostics. Phase 3 focused on presenting ideas to all participants. Phase 4 comprised of ranking the contributions of all study participants.

The research questions for the NGT were as follows:

Question 1: What are the barriers that prevent or limit young women from accessing current STI healthcare management services?

Question 2: What would be the key strategies to deliver self-sampling for STI diagnosis among young women to mitigate the barriers to access?

The participants were divided into two groups with four participants each. A question was posed to the participants' and time was allotted for silent generation, thereafter responses were written on a flip chart. A representative from each group presented their contributions to the rest of the participants through round-robin sharing. The NGT was facilitated by the principal investigator (PI) and a researcher who was responsible for taking notes. Participant responses were recorded and discussed where it was necessary. All responses were transcribed and checked against what was written on the flip charts for accuracy. After this, the participants ranked all contributions according to individual importance.

Data processing and analysis

Results were analysed separately for each question. A short break was taken while the PI and the researcher grouped the results according to themes. Thereafter, the participants ranked each response according to importance from their personal perspectives. The young women ranked each of the responses on a scale of 1–7 with “1” being low priority and “7” being high priority. Data was cross-checked to ensure that results were captured appropriately.

Results

Eight young women agreed to participate in the study. Four of the young women were from Umlazi township and the other four were from Cato Manor. The average participant age was 21 years. Seven participants were undergraduate students at local universities, and one participant was a postgraduate student. An overall score of the participants' ranking for each

barrier was used to identify the least important barrier from the most important, according to the participants. Based on this, then each barrier was ranked out of 56, which is the overall score based on the number participants and the highest-ranking score of 7.

Barriers to accessing STI healthcare services

Participants identified ten barriers to accessing current STI healthcare services. The barriers in order from least to most important, as ranked by the participants, were: clinics are far away from home, which received an overall ranking score of 31; afraid of clinic staff judging and shouting at the partner received overall ranking score of 41; afraid of being asked to inform a partner received overall ranking score of 42; clinic hours clashed with school hours and other personal commitments received an overall ranking score of 42; participants did not know the symptoms of STIs received overall ranking score of 48; participants were unwilling to seek medical care because of denial received overall ranking score of 50; participants were afraid of being judged by nurses or clinic staff for being sexually active received overall ranking score of 52; participants mentioned that STI healthcare services were an invasion of their privacy received overall ranking score of 54; fear of exposure of condition to parents, family and friends received overall ranking score of 54; and the most important barrier was the stigma associated with STIs which was ranked 55 overall (Fig 1).

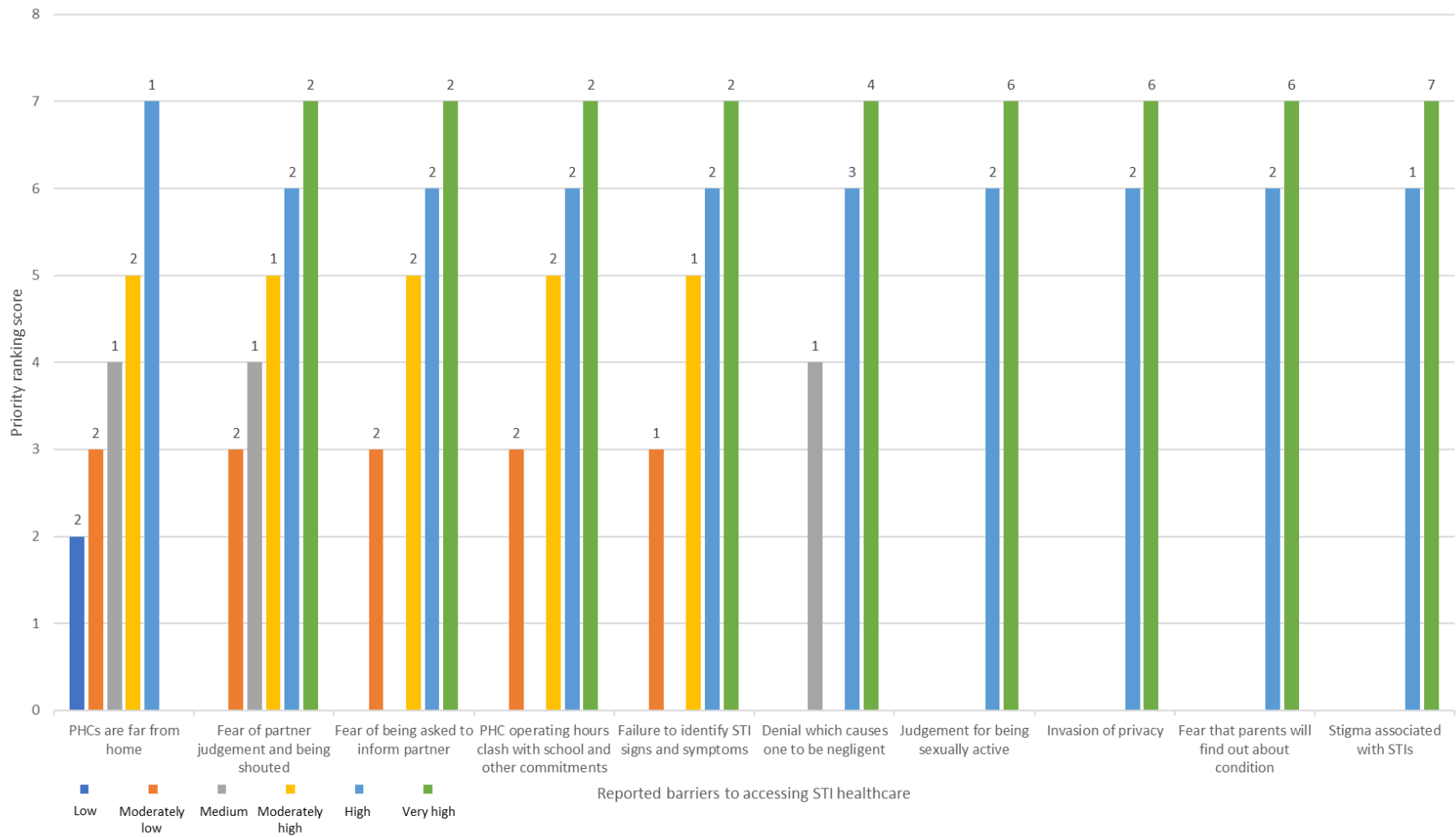


Figure 1. Ranking of barriers to accessing healthcare for sexually transmitted infections as identified by young women in underserved urban settings.

The overview of barriers, as presented by the participants, was as follows:

PHCs are far away from home.

Participants reported that their PHCs were far from their place of residence and so it prevented them from seeking medical attention for STI related issues.

Fear of being asked to inform a partner and fear of partner judgement and being shouted at.

In order to prevent the spread of infection, individuals who test positive for STIs are asked to inform their sexual partners and bring them to the clinic so they can also get treated. The young women expressed fear of informing their partners to get treatment. They also reported being afraid that if they test positive and inform their partners to get treatment, the clinic staff would shout at their partners.

“I fear the nurses will shout at my partner when he comes for treatment at the clinic.”

“I have fear of my partner’s judgement.”

PHC operating hours clash with school hours and other personal commitments.

A notable number of young women aged 18–24 years are still in school where they have to attend classes from Monday to Friday, which is during the time when their local PHCs are open. As such, they are often unable to get the medical attention they require because of this clash.

“Going to the clinic is a big challenge, because it during school hours and I cannot afford to miss classes.”

“I don’t have time, I have to be at school and at work.”

Failure to identify symptoms of STIs

The young women reported not being familiar with the signs and symptoms of having an STI and so they are unable to determine if they need medical attention or not.

“The truth is that I am ignorant about the symptoms of infection.”

“I fail to identify my symptoms.”

“Not enough awareness of the symptoms, because I don’t have enough exposure.”

Denial, which causes negligence and unwilling to seek medical care

They also reported that even if they were able to identify their symptoms and associate them with an STI, there is an unwillingness to accept being infected. By not accepting their infection status, they neglect seeking the medical care they require.

“Sometimes it’s just denial. I never think it’s something serious unless it’s severe.”

Judgement by clinic staff for being sexually active

Participants expressed anxiety about disclosing their sexual activity due to concerns about potential judgment from healthcare workers. Specifically, they feared being judged for engaging in sexual activity at a young age.

“As young adults we are expected to be celibate or abstain from any sexual activity so going there to be treated for an STI you would get judged.”

STI healthcare services were an invasion of their privacy

For some of the participants, seeking medical care for STIs is viewed as an invasion of privacy and so it deters them from doing so.

“I am relatively a person who does not like being touched. It makes me uncomfortable knowing that I have to be naked during the genital examination. I fear of being tested and checked by someone I do not know.”

“I see the genital examination as an invasion of my private parts.”

“It’s a very sensitive topic to speak about and introverts like myself have trouble talking about it.”

Fear their parents and others will find out their sexually active

There was a fear of parents and other family discovering about the engagement in sexual activity, because the clinic staff knew their parents and relatives. As such, this prevents them from seeking medical attention for STI related illness.

“Most nurses at my local clinic know my parents so they may disclose my condition.”

“Most healthcare workers at my local clinic are either family members or know my mom, so it’s very hard to seek that kind of help fearing they will disclose my status to her.”

Stigma associated with STIs

Stigma was ranked highest as a major barrier to accessing STI healthcare from local PHCs.

“There is a stigma that accompanies STIs and even nurses judge you.”

“Since they expect us to be celibate, they judge us when we have STIs because of the stigma.”

Strategies for self-sampling interventions for STI diagnosis in young women

Participants identified six strategies that might promote the delivery of self-sampling interventions to diagnose STIs in young women. The suggested strategies are presented in descending order in Table 1 from high to low priority. The following strategies were suggested:

run campaigns to promote self-sampling and handing out self-sampling kits at schools and universities; self-sampling kits should be available free of charge at local pharmacies, mobile clinics, schools, and universities; there should be an online system for assessing symptoms and registering for the delivery or collection of self-sampling kits; people with disabilities should be accommodated; there should be designated kit collection and drop-off locations at local clinics, so that young women do not have to interact with clinic staff; STI results should be communicated via email or SMS; and lastly regular campaigns should encourage and normalise testing of asymptomatic individuals.

Table 1. Suggested strategies for self-sampling in young women

Suggested strategies	Ranking (1 = low priority; 7 = high priority)							Score	Percentage of votes	Ranking
	1	2	3	4	5	6	7			
								56	100%	
Run campaigns to promote self-sampling.	-	-	-	-	-	-	8	56	100%	1
Self-sampling kits to be made available free of charge at local pharmacies, mobile clinics, schools, and universities.	-	-	-	-	-	1	7	55	98%	2
Online system for assessing symptoms and registering to receive or collect self-sampling kits to accommodate people with disabilities.	-	-	-	-	-	2	6	54	96%	3
Designated kit collection and drop-off locations at local clinics and collection of results once available – avoid contact with clinic staff.	-	-	-	-	2	2	4	50	89%	4
Results to be communicated via email and or SMS.	-	-	1	-	2	-	5	48	86%	5
Regular campaigns to encourage and normalise testing of asymptomatic individuals.	-	-	-	2	-	6	-	44	79%	6

Since participants were separated into two groups for the NGT, feedback and responses to all the questions are presented as feedback from the entire group and not as individuals.

Run campaigns to promote self-sampling and handout self-sampling kits

Participants ranked this strategy as the most important. They emphasised the usefulness of conducting campaigns in different places to promote awareness about STIs and using these opportunities to distribute self-sampling kits for diagnosing STIs.

“Campaigns of STIs at schools and communities can hand out self-sampling kits with condoms. Have self-sampling kits distributed like how they would distribute condoms at clinics and schools. Universities should set out public roll-out days to distribute self-collection kits to all students.”

Self-sampling kits should be available free of charge at local pharmacies, mobile clinics, schools, and universities

Participants suggested that self-sampling kits should be given to individuals for free and in places easily accessible to young women. This is to inhibit discrimination and enable people from different backgrounds to have easy access to STI healthcare services.

“Use mobile clinics to hand out kits. Mobile clinics help maintain anonymity because they have no signage so there is no judgement, so it would be more comfortable this way. Nobody can see and judge me. Free access to kits is provided from the nearest pharmacy. Make self-sample kits readily accessible like the first aid kits and condoms.”

Online system to assess symptoms and register to receive or collect self-sampling kits to accommodate people with disabilities

One of the main barriers identified in this study was that participants were afraid of being judged by the clinic staff for being sexually active. Participants were also afraid that family members will find out if they have an STI, because neighbours and relatives might work at the local clinics and might spread the news to parents. To mitigate this challenge, the participants suggested an online system for registering and requesting a self-sampling kit to be delivered to a location of their choosing. Additionally, the online system should screen patients for signs and symptoms of infection. An online system would help to maintain confidentiality and would allow young women with disabilities to access the service privately.

“Using electronic methods to communicate would maintain confidentiality. It would also allow sample collection to be done at home and then sent to the clinic for testing.”

“Online system to assess symptoms and register to receive or collect self-sampling kits to preserve confidentiality and anonymity and also to accommodate special groups such as people with disabilities.”

Designated kit collection and drop-off location at local clinics and collection of results once available

Participants were afraid of being judged by the clinic staff for being sexually active and afraid of being spotted by their peers while accessing STI healthcare services. As such, participants suggested having a designated collection and drop-off location for self-sampling kits.

“Being able to access the self-sampling kit without having to speak to anyone or disclose how you contracted the STI.”

Results communicated via email or SMS

Participants reported that clinic operating hours clashed with school hours which was a challenge for young women in school. Participants suggested that electronic communication of results would help to maintain confidentiality.

“Receive results via SMS or email. Electronic communication of results would maintain confidentiality.”

Regular campaigns to encourage and normalise testing of asymptomatic individuals

Due to the stigma associated with STIs, many young people are uncomfortable seeking medical attention for sexual reproductive health-related challenges. The participants attributed this stigma to ignorance in the community about STIs. Participants suggested that regular campaigns should be run in communities to bring awareness and educate communities about STIs.

“STI awareness and self-sampling for STI diagnosis to be normalised in the community. For it to be something that is done every month and not just because you experience symptoms.”

Discussion

We conducted an NGT with young women to identify barriers that hinder access to existing STI healthcare services in underserved communities and identify key strategies for self-sampling interventions for STI diagnosis. Our study findings provide valuable insights into priorities and preferences of young women in the selected communities to access STI healthcare services. Furthermore, the identified strategies serve as the attributes of STI self-

sampling interventions to inform the design of a DCE towards developing a user-friendly self-sampling intervention for the selected participant demographic.

All eight young women collectively identified and ranked ten distinct barriers to accessing STI healthcare services. The overall ranking score assigned to each barrier revealed a nuanced understanding of the challenges faced by young women when accessing these services. The most important barrier was the stigma associated with STIs, indicating its profound influence on healthcare-seeking behaviours. This finding is in line with existing literature, which highlights the significant impact of stigma on individuals' decisions to access STI healthcare services (45). The stigma associated with STIs hinders their willingness to seek medical care and, thus, compromises their overall reproductive health (46, 47).

In terms of the other barriers, participants also reported being afraid of being asked to inform their partners, were afraid of judgmental clinic staff, and were not willing to seek medical attention because of denial of infection. Participants also had little knowledge of the signs and symptoms of STIs, and clinic hours clashed with school hours. The lack of knowledge to identify the signs and symptoms of infection reflects the importance of education and awareness campaigns tailored to this patient demographic. These barriers are consistent with the barriers reported in previous studies. Avuvika et al. (48) reported that women did not seek medical care for STIs because they were asymptomatic, they were afraid of being judged, and they were afraid of testing positive. Similarly, another study reported that young women could not identify symptoms of STIs and were afraid of being judged (49). In the same study, not having integrated STI healthcare services and lack of confidentiality were also highlighted as inhibitors to young women from accessing STI healthcare services (49).

The NGT results highlighted various strategies that would promote the uptake of self-sampling interventions to diagnose STIs among young women, and thus eliminate the outlined barriers. Strategy prioritisation was determined through the ranking scores of individual participants based on their preferences. The idea of running campaigns to promote self-sampling and distribute self-sampling kits was ranked as most important. This highlights the potential of integrated STI healthcare into routine healthcare education efforts, which is in keeping with recommendations in previous research. Jayapalan (50) recommended STI health education as a strategy to improve healthcare-seeking behaviour. In another study, health education was associated with improved healthcare-seeking behaviour (51). The provision of self-sampling kits free of charge at local pharmacies, mobile clinics, schools, and universities was ranked as equally significant. This is an important strategy, considering that the cost of accessing healthcare is a significant barrier to healthcare access (52, 53). Although the cost of access

has been highlighted as a barrier, research has shown that it does not necessarily result in increased utilisation of healthcare services (52). In contrast, a study by Lim et al. (54, 55) reported an improvement in healthcare seeking behaviour when access to healthcare was available for free. Overall, as a strategy, STI health education has the potential to improve healthcare-seeking behaviour, whilst simultaneously addressing cultural issues and practices that prevent adults from talking to young people about sexual intercourse and providing suitable guidance.

Other strategies included participants emphasising the importance of maintaining confidentiality by incorporating online systems that eliminate interaction with healthcare workers. Such a strategy is not surprising, considering the previously highlighted barrier to accessing healthcare due to judgement by healthcare workers. In addition to maintaining confidentiality, our participants highlighted that the use of such systems would also accommodate individuals with disabilities. The use of various electronic (eHealth) platforms including SMS (text messages), email, and online systems to access healthcare services is well documented and has proven useful in places where access to basic services is limited (56). Several studies have further demonstrated the usefulness of eHealth solutions in improving access even for people living with disabilities (57). Additionally, Nourimand et al. (58) reported eHealth services as having the potential to improve STI healthcare and prevent infection, especially in young people. As such, suggesting an e-Health approach to effectively deliver a user-friendly self-sampling intervention has the potential to improve access to- and provision of STI healthcare services for young women.

The study addressed a significant public health concern of STIs among young women in underserved urban communities. By exploring barriers to accessing STI healthcare services and identifying strategies for self-sampling interventions, the study aimed to contribute towards developing attributes towards the development of a user-friendly self-sampling intervention to diagnose STI in young women using a DCE.

Utilising the NGT approach promotes active participation from all participants and ensures that multiple perspectives and ideas are considered. This enabled a comprehensive exploration of barriers and strategies, providing rich and in-depth findings. The strategies suggested by the participants, such as making self-sampling kits readily available, using online systems for registration and symptom screening, and running campaigns have the potential to inform the development and implementation of effective interventions tailored to the needs and preferences of young women in underserved urban communities.

Due to participant recruitment and NGT scheduling challenges, we ended up with a group of young women at a similar stage in their lives, in that they were all undertaking higher education studies. Some of the young women were employed and, thus, possibly more mature than their peers who are still doing undergraduate studies and some of whom may still be in high school. Therefore, our results may not truly reflect the sentiments of young women of school-going age. The participants were purposively sampled from family planning and youth clinics, and we did not consider women who may not be able to visit the clinics for various reasons. This may have introduced selection bias, because women who do not visit these clinics or who face additional barriers to accessing healthcare services may have different perspectives and experiences in relation to the questions posed during the NGT. In addition, study findings are based on self-reported responses from young women who participated in the NGT session. As such, it is possible that participants provided responses they perceived as expected, rather than their true opinions.

We recommend replicating the study in different settings and populations to validate the findings and assess generalisability of the results. Investigating the feasibility, acceptability, and effectiveness of using technology-based interventions in increasing testing rates and reaching young women in underserved populations may prove useful. We also recommend evaluating the costs and benefits of the suggested strategies to inform resource-allocation decisions and guide policymaking.

Conclusion

In this study, we collaborated with young women to identify barriers that prevent them from accessing STI healthcare services. We also collaborated to identify strategies to deliver self-sampling interventions for STI diagnosis that may lead to the development of user-friendly STI healthcare services for young women in underserved communities. Designing a self-sampling intervention tailored to user preferences, and aimed at improving access to STI healthcare services, based on the identified strategies would be useful. By co-creating strategies, we, thus, identified key attributes towards developing a user-friendly self-sampling intervention to diagnose STIs in young women. A similar NGT was conducted among healthcare workers to answer the same questions in this NGT and develop attributes of a user-friendly self-sampling intervention for STI diagnosis in young women (submitted to a reputable journal). Therefore, as a next step we suggest synthesising the findings from both NGTs to conduct a DCE to determine a user-friendly self-sampling intervention for STI diagnosis in young women in underserved urban communities in eThekweni District Municipality.

List of abbreviations

DCE: Discrete choice experiment

NGT: Nominal group technique

PI: Principal Investigator

STI: Sexually transmitted infection

Ethics approval and consent to participate

Ethical approval obtained from the Faculty of Health Sciences Research Ethics Committee of the University of Pretoria, reference number 136/2022.

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are available in the manuscript. However, additional datasets used (including NGT conducted among healthcare workers) are available from the corresponding author upon reasonable request, if required.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

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CHAPTER 6: MANUSCRIPT ADDRESSING OBJECTIVE 3

Following identifying barriers to accessing STI healthcare and developing attributes of an acceptable self-sampling intervention for STIs, it was essential to further investigate young women's preferences for this intervention. As such, Objective 3 was a discrete choice experiment (DCE) conducted among young women residing in underserved communities within the selected study area. The main aim was to better understand their preferences for a user-friendly self-sampling intervention based on the attributes developed using the nominal group techniques (NGTs). This chapter (Chapter 6) presents the protocol used to guide the DCE, and also presents the results obtained from the DCE. Both these are presented in manuscript format according to the requirements of the journals to which they were submitted.

6.1. Presents the manuscript for the DCE protocol, which was submitted to British Medical Journal (BMJ) Open journal under the title: *“Understanding the Preferences of Young Women in Self-Sampling Interventions for STI Diagnosis: A Discrete Choice Experiment Protocol”*

6.2. Presents the manuscript on the DCE conducted on young women which was submitted to PLOS ONE journal. The manuscript is titled: *“Young Women's Preferences for a Self-Sampling Intervention to Diagnose Sexually Transmitted Infections: A Discrete Choice Experiment”*

6.1. Manuscript presenting the DCE protocol

Understanding the Preferences of Young Women in Self-Sampling Interventions for STI Diagnosis: A Discrete Choice Experiment Protocol

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Abstract

Introduction

Sexually transmitted infections (STIs) are a significant public health concern globally, particularly affecting young women. Early diagnosis and treatment are essential to reducing or stopping the continuous spread of infections and the development of the associated complications. Syndromic management, which is commonly used for STIs, presents several barriers, particularly for young women. This protocol is for a study that aims to understand young women's preferences for a self-sampling intervention for STI diagnosis by using a Discrete Choice Experiment (DCE).

Methods and analysis

The following attributes of a self-sampling intervention were identified through a nominal group technique (NGT): accessibility, education, confidentiality, self-sampling method, youth-friendliness, and cost. A pilot study involving 20 participants was conducted to refine the DCE questionnaire. A total of 196 young women from underserved communities will be recruited. The participants will be sampled from communities, stratified by settlement type and socioeconomic status. Data will be analysed using the multinomial logit model and mixed logit model to assess preferences and heterogeneity.

Ethics and dissemination

The study findings have the potential to inform policies for STI treatment and management to align healthcare services with user preferences. This can improve STI healthcare access for young women in underserved communities. Ethical approval has been obtained, and results will be disseminated through peer-reviewed journals and health conferences.

Keywords: Sexually transmitted infections, underserved communities, self-sampling intervention, discrete choice experiment, user preferences.

Introduction

Sexually transmitted infections (STIs) are a major public health problem in South Africa, particularly among young women, who constitute a large portion of the overall infections (1, 2, 3). Early diagnosis and treatment of STIs is crucial to prevent the spread of these infections and long-term complications which include sexual and reproductive health complications (4, 5, 6, 7). Although STI healthcare services are available at local healthcare facilities, individuals in resource-limited settings and underserved communities have limited access to quality basic services including healthcare (8, 9). Additionally, young women may be reluctant to access STI healthcare services in these communities due to various factors potentially related to the syndromic management of STIs.

Although widely used, particularly in low-and-middle-income countries (LMICs), syndromic management presents several challenges that impact STI healthcare seeking behaviour, particularly in young women (10). These factors include the inability to detect asymptomatic infection, failure to identify symptoms of STI, fear of being judged for being sexually active, fear of stigmatisation, and discomfort with invasive associated genital examinations (10, 11). Self-sampling interventions have been proposed as a potential solution to eliminate challenges presented by syndromic management and increase access to STI screening services for young women in underserved communities (12, 13). The effectiveness and acceptability of self-sampling interventions are well understood. However, the preferred delivery method of self-sampling interventions based on user preferences has not been developed particularly in the South African context.

Discrete choice experiments (DCEs) are a method that is used to uncover people's preferences for products, services or certain scenarios (14). It is an attributes-centred approach with a significant outcome of being able to quantify individuals' trade-offs between attributes. Ultimately, DCEs uncover how much an individual is willing to forgo to gain more of another attribute (15, 16, 17). DCEs have been used in public health to understand and inform various significant healthcare-related decisions. For example, in the United Kingdom, a DCE was used to assess patient preferences for attributes of primary care services which included appointment waiting time and provider continuity (18). This DCE helped to inform service design and resource allocation. In another study, a DCE was used to investigate the healthcare professional preferences for the allocation of resources in healthcare settings (19). The findings of this study guided the optimisation of resource allocation for decision-makers.

When considering the proven usefulness of self-sampling interventions as a tool to address challenges with access and screening of asymptomatic STIs, it is imperative to investigate user preferences for the delivery method. As such, the objective of this study is to develop a user-friendly self-sampling intervention for diagnosing STIs in young South African women from underserved communities using a DCE. A DCE involving young women aged 18–25 years from underserved communities in eThekweni District Municipality in KwaZulu-Natal, South Africa, will be utilised. It is anticipated that the findings of this study will contribute to the development of a user-friendly self-sampling intervention for STI screening that is tailored to the needs and preferences of young women from underserved communities in eThekweni District Municipality, KwaZulu-Natal, South Africa. This study is important because it addresses a critical gap in the literature on STI screening interventions in South Africa. Furthermore, it has the potential to contribute to the development of an effective and acceptable solution to increase access to STI screening services for young women in underserved communities.

Aim

The main aim of this study is to utilise a DCE to determine young women's most preferred self-sampling intervention for STI diagnosis. We particularly explore trade-offs between ease of accessibility and convenience, cost, education and normalisation, confidentiality and communication, self-sampling collection method, and youth-friendliness. To our knowledge, this is the first study to utilise a DCE to determine young women's self-sampling preferences for STI diagnosis.

Methods and analysis

Identifying and defining attributes

Determining key attributes and levels for the DCE is an important step. Employing qualitative methods such as the nominal group technique (NGT) to select and frame attributes improves the significance and pertinence of the study findings (23). The number of key attributes must be kept at a reasonable number to avoid confusing participating individuals (24, 25). For simplicity, the number of attributes is maintained between four to eight (16).

Nominal group technique

The key attributes for the self-sampling intervention were developed using two NGT co-creation workshops which were conducted on separate occasions. The NGT is a qualitative exploratory method combining the generation of ideas with the concept of enquiry within a small group (20, 21) often comprising six to twelve participants (22). Participants in one NGT

comprised eight healthcare personnel involved in STI healthcare service provision at a primary healthcare clinic (PHC) located in underserved urban communities in eThekweni District Municipality. Another NGT comprised eight sexually active young women aged 18–25 years residing in underserved urban communities in eThekweni District Municipality. In both NGTs, the participants were asked to identify barriers that hindered young women from accessing STI healthcare services. The identified barriers were then ranked from high priority to low priority according to the choice of each person. Once this was complete, NGT participants developed attributes for a self-sampling intervention that would address some of the barriers which were highlighted.

One on one interviews

Following the NGT co-creation workshops, ten young women were interviewed to confirm the validity of the attributes identified during the NGT. The young women interviewed were aged 18–25 years residing in underserved communities. The interviews did not yield any new information that contradicted what was already identified during the NGTs.

Determining the list of attributes and preference levels

Ultimately, a total of eight attributes emerged from the NGTs namely accessibility, education, communication, convenience, youth-friendliness, self-sampling method, and cost of self-sampling kit. An expert research panel was asked to review these attributes and they suggested a merging of a few which resulted in six attributes. The final list of attributes includes accessibility and convenience, education and normalisation, confidentiality and communication, self-sampling method, youth-friendliness, and cost of self-sampling kits. See Table 1 for a detailed list of attributes and their preference levels.

Table 1: Attributes and levels

Attribute (regression label)	Description	Levels (preference parameters)
Accessibility and Convenience	Refers to the ease with which young women can obtain self-sampling kits for STI screening and the level of convenience in the process.	<ul style="list-style-type: none"> ● Self-sampling kits are available at clinics only. ● Self-sampling kits are available at clinics, universities/schools, and pharmacies. ● Self-sampling kits are available through outreach teams, clinics, universities/schools, and pharmacies, with online symptom assessment and designated kit collection locations.
Education and normalisation	Refers to the level of information and awareness provided to young women about STIs and self-sampling, as well as education efforts to reduce stigma and promote testing.	<ul style="list-style-type: none"> ● No educational material or campaigns provided. ● Educational material provided with the self-sampling kit. ● Educational material provided with the self-sampling kit, along with regular campaigns to encourage and normalise testing.
Confidentiality and communication	Focuses on how screening and testing results are handled, focusing on the level of privacy and mode of result communication.	<ul style="list-style-type: none"> ● Results are communicated in person at the clinic. ● Results are communicated via phone call, text message, email, or secure online portal.
Self-sampling collection method	Refers to the sampling kit or tool used to collect the specimen.	<ul style="list-style-type: none"> ● A kit that includes a swab for vaginal specimen collection. ● A kit that requires a urine sample for specimen collection. ● A kit that offers a choice of collection methods (e.g., vaginal swab or urine) to accommodate individual preferences.
Youth-friendliness	Improving youth-friendly services at clinics could help to make the experience more comfortable and welcoming for young women.	<ul style="list-style-type: none"> ● No improvements made to youth-friendly services at PHCs. ● Improvements made to youth-friendly services at PHCs (e.g., separate waiting area for young women, more comfortable exam rooms, youth-friendly staff training). ● Significant improvements made to youth-friendly services at PHCs (e.g., clinic hours extended to accommodate school schedules, dedicated youth-friendly clinic space).
Cost of self-sampling kits	Making the self-sampling kits available free of charge at local pharmacies, mobile clinics, schools,	<ul style="list-style-type: none"> ● Payment required to obtain self-sampling kits anywhere. ● Self-sampling kits are provided free of charge at clinics only.

	and universities could remove financial barriers to accessing STI screening services.	<ul style="list-style-type: none">● Self-sampling kits are provided free of charge at clinics, universities/schools, pharmacies, and mobile clinics.
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Accessibility and convenience

Various studies report accessibility of healthcare services as a common challenge for young women (26, 27). By affording individuals the opportunity to self-collect specimens in a place that is convenient for them, self-sampling intervention improves accessibility (28, 29). Furthermore, in the age of technology, the use of online eHealth systems to improve access and convenience is well documented. As such, it was fitting for our NGT co-creation workshop participants to identify accessibility and convenience as an attribute for self-sampling interventions. We present the following choice or preference levels for self-sampling interventions to diagnose STIs in young women: making self-sampling kits available at clinics only; making self-sampling kits available at clinics, universities/schools, and pharmacies; or self-sampling kits available through outreach teams, clinics, universities/schools, and pharmacies, with online symptom assessment and designated kit collection locations.

Education and normalisation

In the past health education campaigns have proved effective in destigmatising and normalising certain diseases as an intervention to encourage individuals to seek healthcare (30). Considering the stigma associated with STIs and barriers experienced by young people, health education campaigns have the potential to de-stigmatise and normalise these infections (31), and potentially improve healthcare seeking behaviour among this population. As an attribute of a self-sampling intervention, the main aim will be to educate the community about STIs and self-sampling as an intervention. We present the following choices or preference levels for this attribute: no educational material or campaigns provided; providing educational material together with the self-sampling kit; or providing educational material provided with the self-sampling kit, along with regular campaigns to encourage and normalise testing.

Confidentiality and communication

The lack of confidentiality and invasion of privacy have previously been highlighted as barriers to young people accessing STI healthcare services (32, 33). To this effect self-sampling as an intervention provides privacy and autonomy and mitigates this barrier, and potentially improves STI healthcare-seeking behaviour among young people (34). This attribute refers to being able to maintain confidentiality during the STI healthcare process from diagnosis, to communicating results and providing treatment and minimise interaction with healthcare personnel until the point of treatment where required. The following choice or preference levels are presented for this attribute: results are communicated in person at the clinic; or results are communicated via phone call, text message, email, or secure online portal.

Self-sampling collection method

Since STIs are caused by various types of microorganisms including bacteria and viruses, an ideal specimen for diagnosis is one in which all these pathogens can be detected. Self-collected specimens that have been used for STI diagnosis include urine and vaginal swabs (35, 36). To accommodate the differing preferences, the following choice or preference parameters are recommended in the DCE: a kit that includes a swab for vaginal specimen collection; a kit that requires a urine sample for specimen collection; or a kit that offers a choice of collection methods (e.g., vaginal swab or urine) to accommodate individual preferences.

Youth-friendliness

Previous studies have highlighted challenges related to the interaction of young people with healthcare workers at healthcare facilities, particularly with issues related to sexual and reproductive healthcare (37, 38). This has an impact on their healthcare seeking behaviour and as such negatively impacts healthcare outcomes. Improving youth-friendly services at clinics could help to make the experience more comfortable and welcoming for young women. As an attribute of self-sampling interventions, the following choice or preference levels are presented: no improvements made to youth-friendly services at clinics; improve youth-friendly services at clinics (e.g., separate waiting area for young women, more comfortable exam rooms, youth friendly staff training); or significantly improve youth-friendly services (e.g., clinic hours extended to accommodate school schedules, have dedicated youth-friendly clinic space).

Cost of self-sampling kits

Individuals in underserved communities are often faced with the plight of having limited access to basic resources. Therefore, there is a concern about the cost of self-sampling kits for the intervention, especially among underserved communities. Previous studies have reported on the feasibility of self-sampling interventions as an alternative to syndromic management (39), which may sometimes lead to overdiagnosis and overtreatment of patients. The current attribute is mindful of this and speaks of making the self-sampling kits available free of charge at locations that are easily accessible to young people. The following choice or preference levels are presented for this attribute: self-sampling kits are provided free of charge at clinics only; or self-sampling kits are provided free of charge at clinics, universities/schools, pharmacies, and mobile clinics.

Pilot study

Experimental design and development of choice tasks A pilot study was conducted to pre-test the list of attributes and levels as identified by stakeholders. Although there is no clear

consensus about the required number of choice sets for a DCE, the usual number is said to be between 8 and 16 (40, 41). Through a group consensus, the development of the choice tasks using the six attributes and choice set levels was done. The pilot survey consisted of 16 choice tasks based on the six attributes identified by our stakeholders during the NGT co-creation workshops. Since there were no known findings about young women’s preferences, null priors were assumed. Each choice task comprised a scenario for the participants to respond to with a choice set of their preference. See Box 1 below for an example of a choice task with the scenario and Table 2 is an example of a choice task:

Box 1: Scenario for choice task

Choice task scenario to contextualise the DCE
<p>Imagine you are a young woman living in an underserved community, and you are considering getting tested for sexually transmitted infections. Self-sampling is a potential option for STI healthcare provision that allows you to collect your own specimen for laboratory diagnosis. It is an alternative current STI healthcare service that is fully facilitated by healthcare personnel in primary healthcare clinics. You are presented with options for a self-sampling intervention which include accessibility and convenience, education and normalisation, confidentiality and communication, self-sampling method, youth-friendliness, and cost of the self-sampling kit. Please consider the following choice task and select the option that is most suitable for you.</p>

Table 2: Example of a choice task

Attributes	Option A	Option B
Accessibility and convenience (refers to efforts to make STI healthcare services more accessible for young people)	Self-sampling kits are available through outreach teams, clinics, universities/schools, and pharmacies, with online symptom assessment and designated kit collection locations.	Self-sampling kits are available at clinics, universities/schools, and pharmacies.
Education and normalisation (this refers to attempts to destigmatise STIs)	Educational material provided with the self-sampling kit, along with regular campaigns to encourage and normalise testing.	No educational material or campaigns provided.

<p>Confidentiality and communication (this refers to maintain confidentiality different options may be used to communicate diagnostic results)</p>	<p>Results are communicated via phone call or text message.</p>	<p>Results are communicated via email or a secure online portal.</p>
<p>Self-sampling collection method (this refers to the tool or kit used to collect your own biological specimen for diagnosis)</p>	<p>A kit that offers a choice of collection methods, either a swab for vaginal specimen collection or a urine sample for specimen collection.</p>	<p>A kit that includes a swab for vaginal specimen collection.</p>
<p>Youth-friendliness (referring to healthcare services that provide youth-friendly services and environment)</p>	<p>Significant improvements made to youth-friendly services at clinics, e.g., clinic hours extended to accommodate school schedules, and dedicated youth-friendly clinic space.</p>	<p>No improvements made to youth-friendly services at clinics.</p>
<p>Cost of self-sampling kit (referring to the cost associated with using self-sampling kits for diagnosis)</p>	<p>Self-sampling kits are provided free of charge at clinics, universities/schools, pharmacies, and mobile clinics.</p>	<p>Self-sampling kits are not provided free of charge.</p>
<p>Which option would you choose? (mark with “X”)</p>		

Pilot testing

Since there is no clear guidance on the sample size for DCE pilot studies, we utilised guidance by Bekker-Grob et al (39), which suggests that twenty to forty participants are sufficient for a pilot study. To satisfy our study, the pilot survey was distributed to thirty-five randomly selected young women aged 18–24 years, residing in underserved communities in eThekweni District

Municipality. Twenty young women completed the survey. Since this number is within the recommended total of twenty to forty participants, the pilot study data was accepted and analysed. The pilot tool was also used to determine the ease with which participants could complete the survey in terms of comprehension and time taken to complete it. All participants reported ease and no comprehension challenges. However, 80% of participants reported that the tool was too long with a lot of choice tasks. They suggested reducing the number of choice tasks from sixteen to ten. All participants agreed that the attributes were all relevant and so did not need to change. The tool was amended accordingly, based on participant comments.

Sampling and recruitment

Young women from underserved urban communities will be recruited for this study. Participant recruitment will be based on stratified random sampling where the underserved communities will be stratified into three subpopulations namely, core informal settlement, fringe informal settlement, and core township (40). The three strata will be defined according to the Council for Scientific and Industrial Research (CSIR) settlement typology of 2002 (40) as follows: core informal settlement refers to previously or currently illegal and unplanned settlements within inner cities or towns close to the traditional CBD (central business district) or areas of employment, mostly with shacks as the predominant housing type; fringe informal settlement is defined as freestanding, previously or currently illegal and unplanned settlements (mostly with shacks) located far away from the traditional CBD and often far from places of employment as well, resulting in extensive commuting patterns; and core township is defined as formal mass-built settlements (old or new) within inner cities or towns close to the traditional CBD or areas of employment. Furthermore, participant recruitment will also be based on socio-economic classification of households within the strata, and young women from poor households will be randomly selected.

The rule-of-thumb calculation as proposed by Johnson and Orme (41, 42) will be used to calculate the sample size for the experiment. The formula for the minimum sample size N calculation is as follows:

$$n > 500 c/(t \times a)$$

In the above equation, c is the largest number of levels for any one attribute; t represents the number of choice tasks; and a represents the number of alternatives in each choice task (42). Therefore, for our DCE using six attributes, with a maximum of three levels, and ten choice sets with two alternatives for each task, our required sample size is 75. Considering the wide range of data quality issues that have been reported for DCEs (43), we anticipate the exclusion of 30% of the respondents (44). As such, we will increase our sample size by 30% to accommodate any data quality issues, which increases our sample size to 98. We will

investigate the heterogeneity of preferences and so we will double our sample size to 196 participants.

Data analysis

Trade-offs between the attributes will be determined using the multinomial logit (MNL) model. By analysing participant preferences, it will help us to identify which factors influence participant preferences. The overall optimisation model will be optimised with the use of the MNL model as a framework (45). Although it is useful, the MNL model ignores heterogeneity and cannot manage random differences in individual preferences. However, the mixed logit model compensates for this shortfall because it does allow explanatory variables that are random (46).

The mixed logit model will be used to investigate preferences between participants in the different strata. Presentation of results will include tables displaying coefficients for attribute levels and covariates, accompanied by pertinent statistical indicators, such as pseudo R-squared, log likelihood test, and Akaike information criterion to assess model fit. Furthermore, the calculation of marginal rates of substitution, derived from the negative ratio between estimated coefficients, will provide insight into the relative importance of different attributes. This analysis will enable policymakers and clinicians to comprehend respondents' willingness to trade-off certain attributes for the acquisition of others.

Ethics and dissemination

Ethical approval was obtained from the University of Pretoria Research Ethics Committee (reference number 136:2022) and the KwaZulu-Natal Department of Health (reference number KZ_202208_005) before data collection. Written informed consent was obtained from all research participants who participated in the NGT. All participants who completed the pilot survey provided written consent prior to their participation. Written informed consent will be obtained from all participants prior to data collection for the main study. Research findings will be submitted to a peer-reviewed journal for publication. The research findings will also be presented at a relevant health conference.

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6.2. Manuscript presenting the DCE conducted among young women

Young Women's Preferences for a Self-Sampling Intervention to Diagnose Sexually Transmitted Infections: A Discrete Choice Experiment

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Abstract

The high rates of sexually transmitted infections (STIs) in young women in South Africa warrants the use of innovative interventions, like self-sampling, to diagnose both symptomatic and asymptomatic infections. Although proven as an effective measure in the fight against STIs, there is limited evidence on the preferred attributes of this intervention. We conducted a discrete choice experiment (DCE) to understand young women's preferred attributes for self-sampling, which included accessibility and convenience of self-sampling kits, education, and normalisation of STIs testing and appropriate self-collection, confidentiality and communication of results, self-sampling collection method, cost of the self-sampling kits, and youth-friendliness at healthcare facilities, as developed using a nominal group technique. A total of 206 young women, aged between 18–24 years, residing in underserved communities in eThekweni Metropolitan Municipality in KwaZulu-Natal, participated in the study. Study findings highlighted young women's preference for enhanced accessibility, comprehensive education on STIs and self-sampling, confidential result communication, autonomy in self-collection method selection, and youth-friendly healthcare environments. The design of effective self-sampling interventions that promote STI testing, thereby reducing transmission of infection, should address these preferences. Policymakers and healthcare providers should engage youth in the design of such initiatives and promote patient-centred healthcare to meet their preferences and improve STI-related health outcomes in this population.

Keywords: Sexually transmitted infections, healthcare, young women, self-sampling intervention, discrete choice experiment, user preferences.

Introduction

South Africa faces a major public health challenge with the high prevalence of sexually transmitted infections (STIs) (1, 2, 3). With a large portion of the overall infections being among young women, early diagnosis and treatment is paramount to prevent the spread and development of the associated long-term sexual and reproductive health complications (4, 5, 6, 7). Syndromic management is a long-standing intervention used to provide STI healthcare services, particularly in low-and-middle-income countries (LMICs), like South Africa, where quality healthcare is not easily accessible to all (8, 9). Although widely used, this intervention is unable to detect asymptomatic infections, which are common with STIs. By requiring patients to visit a healthcare facility for medical assistance, it deters patients for various reasons (10). Some common deterrents include the discomfort with associated invasive genital examinations and fear of judgement for being sexually active and the stigma associated with STIs (10, 11). Furthermore, since syndromic management does not rely on laboratory confirmation to administer treatment, it often leads to over-diagnosis and over-treatment of STIs, which may promote drug resistance. Antimicrobial resistance is a growing global concern (12, 13), and STIs are not exempt. Several researchers have reported on the growing trend of drug-resistant gonorrhoea and chlamydia (14, 15, 16), which are both curable bacterial STIs. Considering this, there is an urgent need for innovative, accessible interventions to promote and improve healthcare-seeking behaviour and minimise the development and spread of antimicrobial resistance, especially among young women.

Self-sampling for STI diagnosis, as an intervention that eliminates the main challenges presented by syndromic management, has gained recognition. Self-sampling interventions have been proposed as a potential solution to eliminate challenges presented by syndromic management and increase access to STI screening services for young women in underserved communities (17, 18). Although not used in practice in South Africa and most LMICs, its ability to eliminate the main challenges posed by syndromic management is well understood. Furthermore, it does not only increase healthcare access in resource-limited settings, but also enables screening and testing of asymptomatic infections (19, 20). When considering the reported STI crisis among young women and the challenges that negatively impact their healthcare-seeking behaviour, an intervention that is acceptable and accessible would prove useful. Self-sampling, as an intervention, appears to be a good alternative to enable easy access and promote STI testing within this population. Based on this, a model for providing this intervention according to user preferences, particularly in the South African context, would prove beneficial.

Choice experiments have been utilised to understand decision-making processes and people's preferences in various contexts. A common example of such experiments is the attribute-centred discrete choice experiment (DCE), in which individuals' trade-offs between attributes are quantified to determine user preferences (21). The ultimate purpose of these experiments is to reveal the extent to which an individual is willing to give up to benefit more from another attribute (22, 23, 24). Considering the need for an STI healthcare model that is acceptable for young women, a DCE is the ideal approach to ascertain young women's preferences for a self-sampling intervention for STI diagnosis. Therefore, a DCE was conducted among young women aged 18–24 years to establish their preferences for a self-sampling intervention to diagnose STIs. We investigated trade-offs between attributes, which included accessibility and convenience of self-sampling kits, education and normalisation, confidentiality and communication of results, self-sampling collection method, cost, and youth-friendliness, as developed using a nominal group technique.

The young women were selected from underserved communities in eThekweni Metropolitan Municipality, an area with the highest population density in KwaZulu-Natal. In South Africa, the province of KwaZulu-Natal constitutes the largest portion of people with STIs (25). Based on this, it was an ideal site for the study to be conducted. Understanding young women's preferences can inform policy and guide the development of more effective user-friendly interventions to address the existing STI burden. This could reduce stigma, increase STI testing uptake, improve healthcare outcomes, and ultimately align with Sustainable Development Goal (SDG) 3 to ensure universal access to sexual and reproductive healthcare services (26).

Methods and analysis

Study design

A DCE is a quantitative data collection method employed to determine user or participant preferences for a service or goods provided. The DCE is founded on three theories, including the random utility theory (RUT), Lancaster's characteristics theory of demand, and the standard microeconomic theory of consumer (27). The random utility theory suggests that there is a "true" utility that individuals derive from consuming products, but this utility cannot be fully observed by researchers (28). Instead, it is summarised by two components: a systematic (explainable) component and a random (unexplainable) component (28). The Lancaster's characteristics theory, on the other hand, suggests that product utility doesn't lie in the actual product, instead it lies in the characteristics of the product (29). According to the standard microeconomic theory, the individual sensibly seeks to maximise utility using

available information and constraints (30). The DCE process determines preference based on a series of attributes with a series of associated options or choice tasks for users to select (23, 31, 32). In this way, researchers can ascertain the level of importance that participants place on each attribute which illuminates the trade-offs they are willing to make on one attribute versus another (22, 23).

Selection of attributes and levels

A DCE survey was conducted with young women residing in underserved communities in eThekweni Metropolitan Municipality between February and March 2024. In the DCE, participants completed a survey comprising a series of *choice tasks* presented with hypothetical scenarios for attributes of a self-sampling intervention for diagnosing STIs. The attributes consisted of different levels. Participants were presented with two different alternatives of attribute configurations to choose from for each scenario. Prior to conducting the survey, attributes were co-created with healthcare workers from primary healthcare clinics (PHCs) and young women in underserved communities using a nominal group technique (NGT) (33, 34). After the NGTs, a total of eight attributes emerged, namely accessibility, education, communication, convenience, youth-friendliness, and cost of the self-sampling kit. We opted to utilise the vaginal swab and urine collection as the self-sample collection methods. This decision was informed by literature that highlights these collection methods as non-invasive (35) and the most commonly used for STI diagnosis in women (36, 37). After an expert research panel review of all the attributes, a few of these were merged resulting in six attributes for use in the survey. The final attributes included accessibility and convenience, education and normalisation, confidentiality and communication, self-sampling method, youth-friendliness, and cost of self-sampling kits. See Table 1 for attribute description and their levels.

Table 1: Attribute description and levels

Attribute (regression label)	Description	Levels (preference parameters)
Accessibility and Convenience (access)	Refers to the ease with which young women can obtain self-sampling kits for STI screening and the level of convenience in the process.	<ul style="list-style-type: none"> ● Kits are only available at clinics. ● Kits are available at clinics, schools, and pharmacies. ● Kits available through outreach, clinics, schools, pharmacies, and with online support.
Education and normalisation (education)	Refers to the level of information and awareness provided to young women about STIs and self-sampling, as well	<ul style="list-style-type: none"> ● No educational material on STIs is provided with the kit. ● Basic information on STIs is provided with the kit. ● Comprehensive information provided with kits and campaigns in the community to encourage testing.

	as education efforts to reduce stigma and promote testing.	
Confidentiality and communication (confid)	Focuses on how screening and testing results are handled, focusing on the level of privacy and mode of result communication.	<ul style="list-style-type: none"> ● Results given at the clinic. ● Remote sharing of results via phone, text, email, or online portal.
Self-sampling collection method (self)	Refers to the sampling kit or tool used to collect the specimen.	<ul style="list-style-type: none"> ● Vaginal swab kit issued. ● Urine sample kit issued. ● Kit offers a choice of methods (swab or urine).
Youth-friendliness (youth)	Improving youth-friendly services at clinics could help to make the experience more comfortable and welcoming for young women.	<ul style="list-style-type: none"> ● No improvements made to create a youth friendly environment for young people during clinic visit. ● Clinics make minor improvements to create a youth friendly environment (e.g. separate area, comfortable rooms, trained staff). ● Clinics make major improvements efforts to create a youth friendly environment (e.g. extended hours, dedicated youth-friendly space).
Cost of self-sampling kits (cost)	Making the self-sampling kits available free of charge at local pharmacies, mobile clinics, schools, and universities could remove financial barriers to accessing STI screening services.	<ul style="list-style-type: none"> ● Kits need to be purchased. ● Kits are free at clinics only. ● Kits are free at clinics, schools, pharmacies, and mobile clinics.

Questionnaire design

Pilot study

A total of 20 participants were involved in the pilot study to pre-test the survey tool and determine the robustness and feasibility of the DCE. The pilot study was used to determine whether the attributes and levels were relevant and understandable to participants, and the overall clarity of the questionnaire. It also sought to determine the amount of time it took to complete the tool in order to determine the level of burden that participation would place on those who agreed to participate. The overall aim was to make it as simple and convenient for the participants. Participants reported ease and no comprehension challenges. A majority of the participants (80%) reported the length of the tool as a challenge and suggested a reduction in the number of choice tasks. Participants agreed on the relevance of suggested attributes and made no suggestions for additional ones. The tool was amended accordingly, based on participant comments. Thereafter, it was reviewed once again by five volunteers, who met the participant eligibility criteria, and deemed it suitable for data collection.

Experimental design

The DCE had six attributes (5x3 levels, 1x2 levels), meaning that there were 486 (3x3x3x3x3x2) different potential combinations of attributes, *choice tasks*, and levels in a full factorial design. However, this number of choice tasks is too high and would prove burdensome for the participants. Based on this, we utilised an efficient design, which includes both random parameters and an error component in the utility functions using Ngene software. This design choice was particularly suited to our sample size of 196 and aimed to reduce participant burden, while maintaining statistical rigor. Random parameters capture individual-level variability in preferences, while error components account for unobserved sources of variability and stochasticity in choices. The experimental design yielded 12 choice tasks which offered participants two options to choose from. Since there is no prior evidence of such an investigation, having two options in the survey was suitable to gain a nuanced understanding of young women's preferences and perceptions of a self-sampling intervention to diagnose STIs. It further enabled the collection of foundational insights into the subject of investigation. Additionally, the simplicity of this approach reduces the cognitive load on the participants, leading to effortless decision-making, with potentially more reliable responses. In addition to the 12 experimental choice tasks, two additional choice tasks were added. One of these choice tasks was for the participants to practice before completing the actual survey and the other was a repeat of the third choice task to assess consistency (38). Therefore, participants completed 14 choice tasks.

Questionnaire design

The questionnaire comprised three sections. Section 1 was mainly to collect demographic information about the participants, including age, knowledge about STIs, and socioeconomic information. Section 2 provided introductory guidance and examples on how to complete the survey, including a practice choice task. They were asked to imagine the following scenario as a way to stimulate their thoughts about the choice they would make to become familiar with the process for completing the survey:

You are a young woman who recently had unprotected sex with a man you do not trust. Concerned about the potential risk of STIs, you find yourself contemplating getting tested. The decision weighs heavily on your mind as you consider various factors that might influence your choice.

Each of the participants then proceeded to complete all 14 choice tasks. Following the completion of the choice tasks, Section 3 presented statements describing and enquiring about the participants' experience with understanding the DCE survey in terms of relevance, significance, clarity and complexity.

Participants

Participant selection and eligibility were based on participants being aged between 18–24 years, residing in an underserved community in the selected study areas, and having knowledge about STIs. All interested participants provided written informed consent before the completion of the survey. Those who were not willing to provide consent were excluded from participating in the study. All consenting participants answered screening questions to determine eligibility before completing the survey. Thereafter, a walkthrough of the survey questions was provided to facilitate understanding and ease of completion. Due to safety concerns, a paper-based survey was completed, and the information gathered was later transferred onto an Excel spreadsheet. However, where possible, the survey was administered electronically using a Google form.

Data analysis

The demographic and socioeconomic characteristics of the respondents are described. Categorical data is presented by absolute and relative frequencies (n and %). Bivariate logistic regression was conducted to model participant preferences for self-sampling attributes. Binary outcome variables indicating preference or non-preference for each attribute level were used with predictor variables. The regression coefficients, odds ratios, and statistical significance of predictor variables were analysed to determine the preferences of participants for different self-sampling attributes. Additionally, the kappa coefficient was calculated to measure agreement regarding ease of understanding of the survey tool. Model fit was assessed using both a log-likelihood ratio (LLR) test, Akaike's Information Criterion (AIC), and Bayesian Information Criterion (BIC) (39). Model selection criteria, such as the Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) were reported.

A DCE protocol was developed for this study and is accessible on <https://www.medrxiv.org/content/10.1101/2024.01.05.23299719v1>

Results

Participant characteristics

The target sample size for the DCE was 196, however, a total of 206 young women aged between 18–24 years participated in the survey. This means study participation was 105%. In this research, the demographic characteristics, socioeconomic status, and healthcare knowledge of participants were studied. Most participants were aged 18–21 years (53%) and 22–24 years (47%). Household income varied, with notable percentages in the R1–R4800/month (40%) and R4801–R9600/month (38%) brackets. Urban formal settlements were more common (69%) than urban informal ones (31%), and a majority of participants

owned their dwellings (70%). High levels of STI awareness (98%) and knowledge about local healthcare services (99%) were observed. However, a significant portion of participants (32%) expressed discomfort with available healthcare services, suggesting areas for improvement in service delivery or patient experience. Table 2 below presents a summary of participant characteristics.

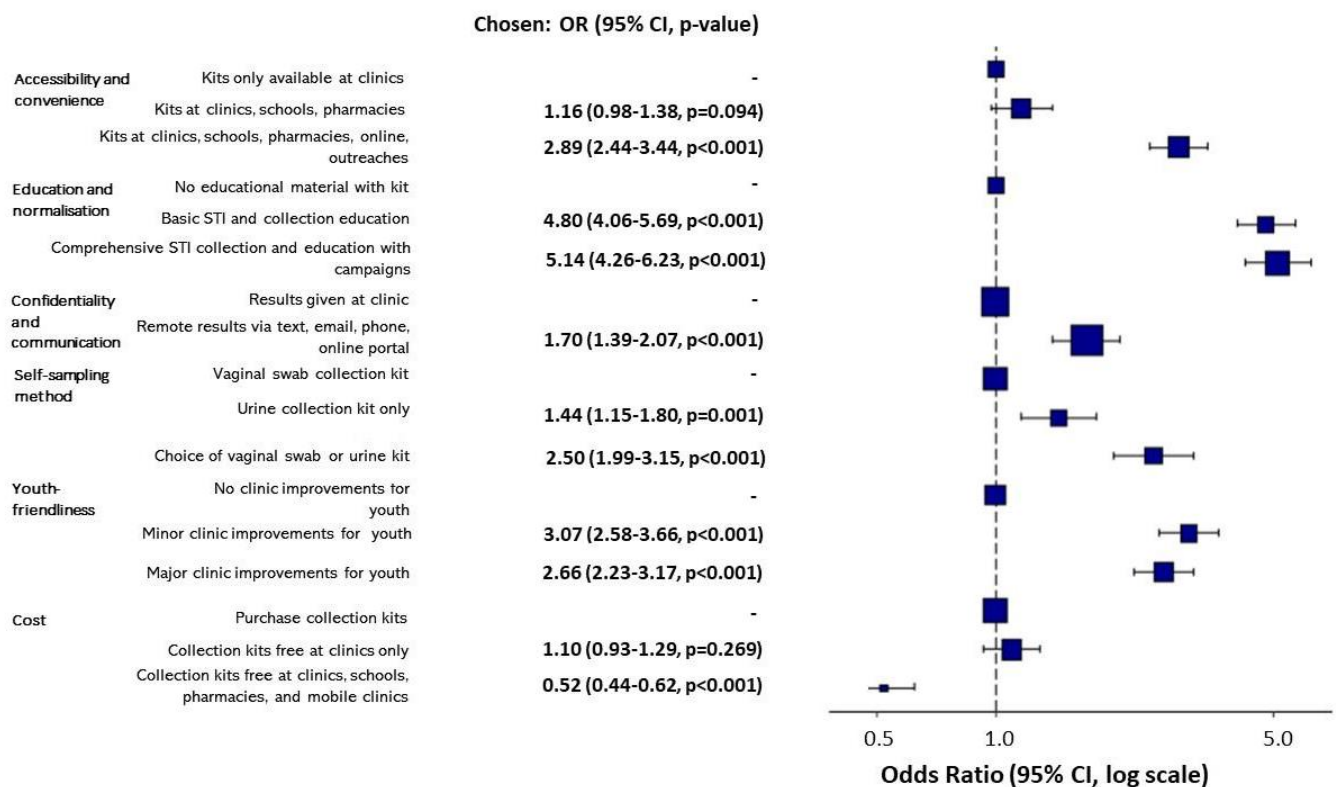
Table 2: Summary of demographic, socioeconomic status, and healthcare knowledge

Variable name	Categories	Frequency	Percentiles
Age	18–21 years	109	53
	22–24 years	97	47
Household Income	No Income	32	16
	R1–R4800/Month	81	40
	R4801–R9600/Month	78	38
	R9601–R19200/Month	12	5
	>R19200/Month	3	1
Dwelling Type	Urban Formal Settlements	142	69
	Urban Informal Settlements	64	31
Dwelling Status	Owned	145	70
	Rented	61	30
STI Awareness	Yes	201	98
	No	5	2
Knowledge about local STI healthcare services	Yes	204	99
	No	2	1
Feelings about the available healthcare service	Comfortable	140	68
	Uncomfortable	66	32

Young women’s preferences for a self-sampling intervention

Figure 1 reports the model fitness and participants’ preferences for the self-sampling attributes. Model fit was assessed using both a log-likelihood ratio (LLR) test, Aikake’s Information Criterion (AIC), and Bayesian Information Criterion (BIC). The logistic regression model exhibited robust fit, as indicated by the log-likelihood (-3712.87) and information criteria (AIC: 6377.74, BIC: 6456.77). For accessibility and convenience, participants were more likely (OR 2.892 $p < 0.001$) to opt for kits to be available through outreach, clinics, schools, pharmacies, and online support compared to clinics only. For education and normalisation, participants were more likely to opt for comprehensive information on STIs and self-sampling to be provided with the kits and community campaigns compared to not having any information

at all. Concerning confidentiality and communication, the participants were 1.696 ($p < 0.01$) more likely to opt for the sharing of results via text, phone, email, or using an online platform compared to collecting results from the clinic. For self-sampling collection method our participants were 1.441 ($p < 0.01$) more likely to opt for urine self-collection method compared to the vaginal swab. Additionally, for the same attribute, another portion of participants were more likely (2.659 $p < 0.001$) to prefer the option to choose between urine or vaginal swab self-collection compared to only self-collecting a vaginal swab. Concerning the cost of self-sampling kits, 48% (OR 0.523 $P < 0.001$) of the participants were less likely to opt for free kits at clinics, schools, pharmacies, and mobile clinics compared to kits being purchased.



Note: Significance: *** P-value < 0.001, ** P-value < .01, * P-value < .05; OR: Odds ratio

Figure 1: Summary of preferences and model fitness

Clarity and robustness of survey

Additional variables were evaluated to ascertain participant experiences with the survey tool to determine clarity and robustness of the survey (see Figure 2 below for summary). Regarding the understanding of the survey, 202 participants (98%) agreed that they found the survey easy to understand, while three participants (1.5%) were uncertain, and only one participant (0.5%) disagreed.

In terms of information needs to inform decision-making between choice set options, 102 participants (49%) agreed that they needed more information, 51 participants (25%) were uncertain, and 54 participants (26%) disagreed with the need for additional information.

When considering confusion between competing options, 97 participants (47%) did not find it confusing, 64 participants (31%) were uncertain, and 45 participants (22%) agreed that they were confused when deciding between options. Regarding the perceived ease of answering more choice sets, 181 participants (88%) agreed that answering more questions improved their ability to make a choice, while 24 participants (11.5%) were uncertain, and one participant (0.5%) disagreed with this notion. Only 180 (87%) participants believed their study participation would impact the provision of STI healthcare services, 18 (9%) were uncertain, and only eight (4%) did not believe so.

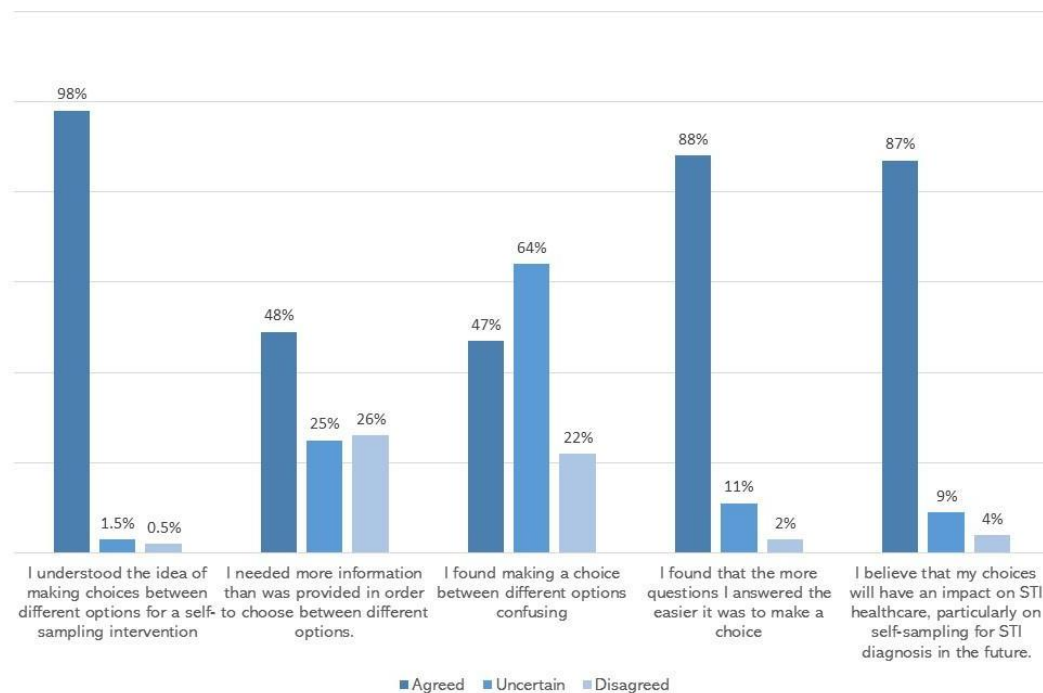


Figure 2: Summary of survey tool clarity and robustness

Using this data, the kappa coefficient was calculated to assess the level of agreement beyond chance among participants across these variables. The kappa coefficient was approximately 0.456, indicating moderate agreement beyond what would be expected only by chance.

Discussion

The main objective of this study was to conduct a DCE among young women in underserved communities to understand their preferences for a self-sampling intervention to diagnose STIs. Most of the young women who participated in our study were aged under 21 years. This indicates that there is a large portion of youth with specific healthcare needs and preferences in relation to STIs. Considering that STI prevalence is reportedly high among young people across the globe (40, 41), the proportion of young women who participated is of great significance. It is important to note that some of the participants had no income or were from lower middle-income households, having little to no household income. This is not surprising, considering the World Bank report, which reports on a high concentration of poverty in Sub-Saharan Africa (42). When reviewed in conjunction with the notable portion of participants from rented urban informal settlements, the influence of these socioeconomic nuances on STI prevalence and accessibility of healthcare is clear. Living in poverty may lead to reckless sexual behaviour stemming from desperate circumstances for survival (43, 44), where reckless sexual behaviour increases the risk of STI acquisition.

Our study highlights a preference for self-collection kits to be widely available through various channels, including outreach programmes, clinics, schools, pharmacies, and online platforms, to enhance access and convenience of self-sampling interventions. This finding underscores the significance of having a multi-faceted approach to accessibility to such STI screening interventions to promote uptake and utilisation among young women. This aligns well with previous studies that demonstrate increased self-care, which increases uptake when healthcare services are easily accessible (45). The more convenience and ease of access to a service, the higher the chances of use or engagement with it. There was a strong preference for comprehensive educational materials to accompany the self-collection kits, highlighting the role of education in normalising STI-related screening and healthcare seeking behaviour. This aligns with existing literature that supports educating the public on sensitive issues, such as those related to sexual health, to reduce STIs and empower individuals to make better informed decisions (46, 47). As such, the provision of detailed information about STIs and self-sampling procedures not only empowers individuals to make informed decisions, but also contributes to reducing stigma and further increases awareness about sexual health in this population age group.

The importance of maintaining confidentiality and privacy of STI diagnosis for the chosen population was demonstrated by their preference to receive diagnostic test results through modern communication channels such as text messages, emails, phone calls, or online

portals. This mode of result communication not only maintains confidentiality, but also ensures timely access to results, which leads to timely access to treatment. Furthermore, this reduces interaction with healthcare providers, thereby addressing previously-reported fear of judgement and stigma by healthcare providers as a barrier to seeking medical care for STIs. Concerning the self-collection method, our findings suggest participants have a strong desire for autonomy and choice in the self-sampling method. Having the option to choose between different collection methods, instead of being restricted to a single method, empowers individuals to make choices that suit their preferences. This resonates with the principle of patient-centred care that encourages healthcare provision in partnership with patients, recognising their preferences and values (48).

The preference for designated youth-friendly areas at healthcare facilities highlights the importance of creating an inclusive environment suitable for youth. For instance, having a space dedicated to youth, staff trained to deal with young people, comfortable rooms, and extended clinic hours can potentially reduce reluctance and increase utilisation of STI-related medical services. This aligns with studies that highlight the need for designated youth-friendly services to improve the delivery of STI -related services to young people (49). Interestingly, our study highlighted that the option to purchase or receive kits for free had no significant influence on participant preferences when compared to the other attributes. This suggests that, while cost may be an important factor to consider, the other attributes may play a more significant role in shaping individual preferences and behaviours related to STI screening and diagnosis for self-sampling.

Policy, practice, and research implications

The study findings have important implications for policy, practice and further investigation in the area of self-sampling interventions for STI diagnosis in young women. Concerning policy, there is a clear need to increase focus on initiatives that enhance the accessibility of self-sampling kits using various approaches, including clinics, schools, community outreach programmes, and online platforms. Policies should also advocate for the development and implementation of comprehensive education initiatives to provide clear and accurate information about STIs and self-sampling procedures. This would help to promote testing for STIs, even among asymptomatic individuals and reduce associated stigma. Policy frameworks should also emphasise the importance of maintaining confidentiality and privacy regarding the communication of diagnostics results by using secure channels including text, phone calls, and online platforms, where possible. Additionally, policy should advocate for the creation of youth-friendly environments in healthcare facilities to enhance engagement with STI-related healthcare services by young people.

In relation to practice, a patient-centred approach should be adopted by offering options and autonomy in self-sampling collection methods. Individuals engaging in self-sampling interventions should be provided with comprehensive education and counselling to address concerns that arise and also cultivate a culture of regular testing to improve healthcare-seeking behaviour. Additionally, to ensure that services are utilised, it is essential to engage young people in the design and implementation of self-sampling for screening and diagnosis of STIs.

We recommend a longitudinal study to assess the long-term impact of preferred self-sampling intervention attributes on the uptake of such an intervention for STI diagnosis and health outcomes among young women. A comparative effectiveness study to evaluate different models of the intervention is also recommended. Future research should consider health equity and technology integration in effectively delivering self-sampling interventions to diverse communities. Ultimately, there is a great need for policy and practice interventions that address young women's preferences and needs concerning self-sampling to improve STI-related healthcare-seeking behaviour and reduce rates of STI transmission.

Limitations

Our study findings may be limited in their application to the broader community of young women, because we did not investigate certain demographic information, including employment status, source of income, marital status, and parental status. Data was only collected among young women residing in underserved urban communities, who may have unique circumstances that do not necessarily apply to those residing in other types of communities. As such, our findings may only apply to young women residing in other areas similar to those of the study. Our investigation only focused on a set of attributes and there is a potential that other factors and preferences that could influence participant behaviour and decision-making for STI diagnosis were overlooked.

Conclusion

In conclusion, the study demonstrates a clear preference for enhanced accessibility, comprehensive education on STIs and self-sampling, confidentiality in results communication, individual autonomy in self-collection method selection, and youth-friendly environments in healthcare facilities. These preferences underscore the need to address key attributes to design self-sampling interventions that effectively promote STI screening and diagnosis behaviour, which ultimately reduces rates of transmission. As a result, there is a need for

policymakers and healthcare providers to engage young people in designing and delivering STI-related services, prioritise initiatives to improve accessibility, support education on STIs and self-sampling education, ensure confidentiality and privacy in result communication, create youth-friendly environments, and promote patient-centred care.

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CHAPTER 7: SYNTHESIS OF FINDINGS

7.1. Introduction

The province of KwaZulu-Natal (KZN) in South Africa faces a notably high prevalence of sexually transmitted infections (STIs), particularly among young women (1, 2). As in other low- and middle-income countries (LMICs), South Africa primarily uses syndromic management for STIs, due to limited access to healthcare resources (3, 4). Despite its widespread use, STI prevalence remains high, likely due to the limitations of syndromic management, which can negatively impact health outcomes if infections are not diagnosed and treated promptly. As such, is a need for an innovative, convenient, and accessible intervention, such as self-sampling for STI diagnosis, to address STI-related disparities in resource-limited areas. Self-sampling can enable screening of asymptomatic STIs and maintain confidentiality through specimen self-collection, thus overcoming some common challenges presented by clinic-based syndromic management. While self-sampling is fast becoming a popular intervention for diagnosing STIs in high-income countries (HICs), its adoption in LMICs has been slow with continued reliance on syndromic management. This low adoption may be attributed to various factors that include socio-cultural issues related to negative perceptions towards sexual reproductive health (5). Scepticism of healthcare providers about the competence of individuals collecting their own specimens and individual preference of clinician collected specimens may also hinder adoption (6). Furthermore, slow adoption may also be influenced by the lack of clarity on the cost implications of adopting and integrating such an intervention into existing health system (7, 8).

To maximise the potential of such an intervention to improve STI health outcomes, it is essential to engage the population most affected by STIs, which, in this case, are young women. According to Lobb and Colditz (9), stakeholder involvement is crucial to ensuring the relevance of research and, ultimately, influencing the uptake of interventions. Consequently, this study aimed to develop a user-friendly self-sampling intervention to diagnose STIs in young women, specifically focusing on young South African women residing in underserved communities in KZN.

7.2. Summary of findings

This study was conducted using a sequential exploratory method with a mixed-method approach. This section presents all research activities in the sequence they were conducted.

A preliminary scoping review was conducted to map evidence on the use of self-sampling interventions for STI diagnosis in young women. The findings revealed that self-sampling interventions were more commonly used in high-income countries (HICs) compared to LMICs. Evidence highlighted the feasibility and ease-of-use of self-sampling interventions among women of various ages and healthcare access levels. However, there was a need to provide evidence of the accuracy of self-collected specimens compared to those collected by healthcare workers, and to engage stakeholders to identify key attributes of an acceptable and user-friendly self-sampling intervention for STI diagnosis. Based on these findings, we determined to conduct the following:

- A systematic review and meta-analysis on the accuracy of self-collected specimens compared to healthcare worker-collected specimens.
- Nominal group techniques (NGTs) to collaborate with key stakeholders, including young women and healthcare workers, to identify barriers to accessing available clinic-based STI healthcare services and key attributes for a self-sampling intervention.
- A discrete choice experiment (DCE) to understand young women's preferences for user-friendly self-sampling interventions to diagnose STIs.

We then proceeded with the systematic review and meta-analysis to determine the diagnostic accuracy of self-collected specimens compared to healthcare worker-collected specimens. This systematic review included studies that used both self-collected and healthcare worker-collected specimens to diagnose STIs such as chlamydia, human papilloma virus (HPV), *Mycoplasma genitalium*, gonorrhoea, and trichomoniasis in females. The findings indicated that self-collected specimens exhibited diagnostic accuracy similar to that of healthcare worker-collected specimens. Given the benefits of self-sampling interventions, which include the detection of asymptomatic STIs and maintaining patient confidentiality, these interventions have the potential to improve access to STI healthcare delivery in various settings.

Following the systematic review and meta-analysis, two NGTs were conducted. The NGTs aimed to identify barriers that prevent young women from utilising existing clinic-based syndromic management for STIs, and to co-create key attributes for a self-sampling intervention. One NGT was conducted with young women aged between 18 -25 years, and another with healthcare workers involved in STI healthcare service provision. Selection of healthcare workers was not based on any ranking or gender, rather on the being involved in STI healthcare provision at the PHC. Both groups answered the same questions, but the NGTs were conducted separately.

The following barriers were highlighted:

- Clinics being too far from home.
- Fear of judgment for being sexually active and contracting an STI, and associated stigma.
- Concerns about informing partners of infection status.
- Clinic operating hours coinciding with school hours and other commitments.
- Inability to identify symptoms of STIs due to limited knowledge.

Participants were then asked to identify key attributes for a self-sampling intervention that would enhance access to STI healthcare services for young women. The following attributes were identified:

- Promoting self-sampling as an STI intervention through outreach community campaigns and education to destigmatise and encourage testing.
- Making self-sampling kits easily accessible through various distribution methods, including healthcare facilities, restaurants, schools, universities, clinics, pharmacies, and community outreaches.
- Providing STI educational material with the self-collection kits and clear collection instructions.
- Using an online system for symptom assessment and kit delivery or collection.
- Remote access to diagnostic results via text, email, or an online system.
- Enhancing youth-friendly services at clinics, such as having a separate area for youth consultations.

Once the key attributes were identified, we conducted a DCE survey. The DCE survey comprised questions on demographic information and 13 choice sets related to the self-sampling attributes identified during the NGTs. It was administered to young women aged 18–24 years, residing in underserved urban communities in the eThekweni Metropolitan Municipality. A total of 206 participants completed the survey. For each choice set, participants selected options based on their personal preferences.

Our findings demonstrate a clear preference for enhanced accessibility to self-sampling kits, including access not only from clinics, but also from pharmacies, schools, and online platforms. There was a preference for comprehensive educational information on STIs and self-sampling methods, and maintaining confidentiality in results communication through texts, email, phone calls, or an online system. Young women also preferred having autonomy concerning the method used for self-collection, and favoured clinics making provisions to accommodate them in a more youth-friendly environment. The preferred attributes typically

address the barriers to accessing STI healthcare highlighted during the NGTs. See the summary of findings in Figure 7.1 below.

RESEARCH SUMMARY FINDINGS

<p>PRELIMINARY OBJECTIVE: TO MAP EVIDENCE OF SELF-SAMPLING INTERVENTIONS FOR STIs IN WOMEN (CHAPTER 2)</p> <p>JOURNAL ARTICLE Mapping Evidence of Self-Sampling to Diagnose Sexually Transmitted Infections in Women: A Scoping Review</p> <p>CFIR component: Intervention characteristics</p> <p>APPROACH A scoping review</p> <p>KEY FINDINGS Feasibility, acceptance and ease of use of self-sampling interventions, common types of self-sampled specimens, laboratory diagnostic assays for STIs using self-sampled specimens. There is a lack of evidence of self-sampling interventions designed according to user preferences.</p> <p>RECOMMENDATIONS We recommend studies to collaborate with women to co-develop user-friendly self-sampling interventions to diagnose STIs in women.</p>	<p>OBJECTIVE 1: TO CONDUCT A SYSTEMATIC REVIEW AND META-ANALYSIS TO FOR DIAGNOSTIC ACCURACY (CHAPTER 4)</p> <p>JOURNAL ARTICLE Accuracy of self-collected versus healthcare worker collected specimens for diagnosing sexually transmitted infections in females: an updated systematic review and meta-analysis</p> <p>CFIR component: Intervention characteristics</p> <p>APPROACH A systematic review and meta-analysis</p> <p>KEY FINDINGS The analysis revealed that the diagnostic accuracy of self-collected specimens was comparable to that of healthcare worker-collected specimens across most STIs.</p> <p>RECOMMENDATIONS Future research should investigate the diagnostic accuracy of self-collected specimens in larger and more diverse populations.</p>	<p>OBJECTIVE 2: TO CONDUCT NOMINAL GROUP TECHNIQUES FOR CO-CREATION PART 1 (CHAPTER 5)</p> <p>JOURNAL ARTICLE Nurses' perspectives on user-friendly self-sampling interventions for diagnosis of sexually transmitted infections among young women in eThekweni district municipality: a nominal group technique</p> <p>CFIR component: Outer and inner settings, and characteristics of individuals.</p> <p>APPROACH A nominal group technique</p> <p>KEY FINDINGS Barriers: negligence; myths about STIs, fear of judgement, operating hours, and stigma associated with STIs. Strategies: make self-sampling kits accessible, provide relevant education through outreaches, remote sharing of results, develop youth-friendly services.</p> <p>RECOMMENDATIONS Address stigma and fear of judgment and provide comprehensive education to improve healthcare-seeking behaviour in young women.</p>	<p>OBJECTIVE 2: TO CONDUCT NOMINAL GROUP TECHNIQUES FOR CO-CREATION PART 2 (CHAPTER 5)</p> <p>MANUSCRIPT UNDER REVIEW Young women's perspectives on a user-friendly self-sampling intervention to improve the diagnosis of sexually transmitted infections in underserved communities in KwaZulu-Natal, South Africa</p> <p>CFIR component: Outer and inner settings, and characteristics of individuals.</p> <p>APPROACH A nominal group technique</p> <p>KEY FINDINGS Barriers: clinics are too far, fear or judgement, operating hours, don't know signs of infection. Strategies: campaigns to promote self-sampling; self-sampling kits should be available free of charge; online system to assess symptoms and delivery or collection of kits.</p> <p>RECOMMENDATIONS Address stigma and fear of judgment and provide comprehensive education to improve healthcare-seeking behaviour in young women.</p>	<p>OBJECTIVE 3: CONDUCT A DISCRETE CHOICE EXPERIMENT TO UNDERSTAND PREFERENCES</p> <p>MANUSCRIPT UNDER REVIEW Young Women's Preferences for a Self-Sampling Intervention to Diagnose Sexually Transmitted Infections: A Discrete Choice Experiment</p> <p>CFIR component: Characteristics of the individuals</p> <p>APPROACH A discrete choice experiment</p> <p>KEY FINDINGS Young women's preference for enhanced accessibility, comprehensive education on STIs and self-sampling, confidential result communication, autonomy in self-collection method selection, and youth-friendly healthcare environments.</p> <p>RECOMMENDATIONS Policymakers and healthcare providers should engage youth and promote patient-centred healthcare to meet preferences and improve STI-related health outcomes in this population.</p>
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Note: the scoping review was guided by Arksey and O'Malley 2005 framework (6), and by Levac et al. 2010 guidelines (7).

Figure 7.1: Summary of study findings

7.3. Discussion

For LMICs and resource-limited settings, syndromic management remains the primary approach for managing STIs, including in South Africa. Despite this, STI rates remain high, particularly among young women in KwaZulu Natal (KZN), where the prevalence is the highest in the country (2). This underscores the need for innovative interventions, such as self-sampling, to conveniently screen and diagnose both symptomatic and asymptomatic STIs. To address this need, we conducted a study to understand young women's preferences for an acceptable and user-friendly self-sampling intervention for STI diagnosis, focusing on underserved communities in the eThekweni Metropolitan Municipality, KZN, South Africa. Using a multi-methods research design, our investigation provided significant insights.

The scoping review demonstrated the widespread use and efficiency of self-sampling interventions for STI diagnosis in women, aligning with previous research findings (10). Our review supports the World Health Organization (WHO) guidelines on self-care interventions for health and well-being (2022 revision), which highlight self-sampling as an effective self-care intervention (11). It also revealed the common use of such interventions in HICs compared to LMICs. This suggests a need for a paradigm shift in LMICs from clinic-based syndromic management to self-sampling to reduce STIs among women. Addressing these inequalities is key to achieving universal health coverage, in line with Sustainable Development Goal (SDG) 3 on health and well-being (12). Affirming the diagnostic accuracy of self-collected specimens for diagnosing various STIs through our systematic review supports the alignment of such interventions with point-of-care approaches and diagnostics. Point-of-care aims to provide reliable, accurate, easily accessible, and simple-to-use services, ensuring quality healthcare in resource-limited settings, as is the case with self-sampling (13). Ensuring quality healthcare provision aligns with South Africa's National Development Plan 2030 (14) and ultimately supports SDG 3 on combating infectious diseases (12). Thus, self-sampling interventions present an alternative approach worth exploring to combat the STI public health burden in underserved communities in LMICs.

The barriers identified during the NGTs corroborated existing literature on what prevents young women from accessing clinic-based STI healthcare or syndromic management (15, 16, 17, 18). According to Okes (19), identifying the root cause of a problem is essential for designing effective solutions. Identifying access barriers provided a solid foundation for designing intervention attributes to improve STI healthcare access among young women. Following barrier identification, attributes for a suitable intervention were co-created with key stakeholders to address these barriers. The attributes developed were suited to address the

barriers that were identified. This approach not only provides a foundation for solutions, but the developed attributes also align with SDG 3 and SDG 5 on promoting gender equity and addressing social determinants of health (12). The efficiency of self-sampling for STIs is well proven, making the co-creation of key attributes with key stakeholders a suitable approach for designing a suitable and acceptable intervention. This is supported by Hewitt and McLeod (20), who emphasised the importance of stakeholder involvement in intervention development. Similarly, French et al. (21) highlight that user involvement in intervention development is key to enhancing the utility of the intervention.

In the final phase of the study, following the NGTs, a DCE was conducted to understand young women's preferences for a user-friendly and acceptable self-sampling intervention. The findings reflect a multifaceted set of young women's preferences aimed at eliminating the barriers identified during the NGTs. These preferences align with WHO self-care principles of making healthcare services more accessible to users to increase uptake (11) and support a patient-centred approach to promote uptake (22). Our findings offer actionable insights for policymakers and healthcare providers to improve accessibility and increase the uptake of STI healthcare services in this population. This contributes to the SDG 3 objective of reducing the burden of STIs and promoting sexual and reproductive health (10). Beyond SDG 3, our study also contributes to advancing SDGs 5, 10, and 17.

- SDG 5 focuses on achieving gender equality and empowering all women and girls (12). By specifically targeting young women and addressing their unique needs and barriers to STI healthcare, our study supports gender equality in healthcare access.
- SDG 10 aims to reduce inequality within and among countries (12). By addressing disparities in STI healthcare access between LMICs and HICs, our findings promote health equity.
- SDG 17 emphasises partnerships for the goals (12). Our study's collaborative approach, involving community-based participatory research and stakeholder engagement, exemplifies the partnerships needed to enhance the effective uptake of STI healthcare services.

Our study approach provides a promising foundation for integrating self-sampling interventions into existing STI healthcare services.

Our study adopted TDF and CFIR frameworks to systematically investigate factors including social, and behavioural factors that influence the uptake of self-sampling interventions for STI diagnosis in our study population. The scoping review findings highlight inadequacies in

organisational and health systems in LMICs versus HICs. The systematic review and meta-analysis findings support advocacy towards self-sampling for STI diagnosis. These findings highlight the relevance of CFIR in understanding factors that influence implementation in different contexts. Furthermore, the DCE findings align with TDF's emphasis on empowering individuals to participate in the decision-making process. TDF enabled us to understand drivers of certain behaviour while CFIR helped to uncover organisational influences, throughout all the phases of the research project. Ultimately, these frameworks provided a multidimensional perspective to not only understand individual factors but systemic factors which are also crucial to implement effective STI interventions.

Although our study findings substantially contribute to literature related to STI healthcare, various external factors, including political, economic, social, technological, legal, and environmental (PESTEL) factors, also play a crucial role in the successful implementation of such interventions. For a holistic outlook on our findings, we contextualise young women's preferences within these broader external factors through a PESTEL analysis.

- **Political factors:** Government policies can facilitate the distribution of self-sampling kits and their integration into existing healthcare systems, promoting relevant public health initiatives.
- **Economic factors:** Affordability significantly influences choice. Cost-effective solutions are essential to ensure access, especially in resource-limited settings. Subsidising the cost of kits can make them more affordable.
- **Social factors:** STI-associated stigma and the preference for remote sharing of results to maintain confidentiality significantly influence healthcare service uptake. Open discussions about STI stigma and sexual healthcare are crucial to promote STI testing and improve health outcomes.
- **Technological factors:** The use of technology to streamline the availability of test results underscores its crucial role. Remote sharing of results through various platforms is essential.
- **Environmental factors:** Distance from healthcare facilities impacts access. Ensuring equitable access across diverse settings is necessary to address health disparities.
- **Legal factors:** Maintaining patient confidentiality and ensuring compliance with self-sampling regulations are paramount to ensuring ethical and legal practices within self-sampling frameworks.

Considering these PESTEL factors in the design and implementation of the intervention based on user preferences is essential for its success.

7.4. Study strengths

The use of a mixed-method approach, which included systematic reviews, NGTs, and a DCE, enabled a comprehensive investigation. Triangulating data from various investigations and perspectives provided a nuanced and holistic understanding of the phenomenon under investigation, thereby validating the research findings (17, 18). Conducting a scoping review to map evidence of self-sampling interventions provided a clear, evidence-based foundation for the study through synthesising findings from various sources, including grey literature (23). This was further enhanced by the rigorous and transparent process of the scoping review, guided by the Arksey and O'Malley framework (24).

Using a qualitative approach, the NGT enabled direct engagement with young women and healthcare workers to identify and address barriers that have historically hindered young women from accessing STI healthcare services. This approach not only promotes health equity, but also empowers individuals to take charge of their sexual health and seek timely and appropriate care. Involving both the end-users (the young women) of STI healthcare services and the healthcare providers in the investigation provided more nuanced and varied perspectives. This ensured alignment with key implementation science concepts that emphasise the significance of involving all stakeholders in understanding the environment in which the service will be provided (19), further validating the research findings.

Likewise, involving end-users in the co-creation of attributes ensures not only the effectiveness of the intervention, but also its acceptability and user-friendliness, increasing the likelihood of adoption and uptake of self-sampling. By focusing on young women, who bear a significant portion of the STI burden, the study highlights their challenges and provides a platform for them to express their preferences, leading to a more tailored approach. Overall, the investigation presents a groundbreaking approach to STI healthcare that incorporates end-user inputs in the development of STI healthcare services, aligning with recommendations for a patient-centred approach to improve uptake (16). This research addresses a critical gap in healthcare services and sets a precedent for future studies and initiatives aimed at improving STI health outcomes and promoting equity in healthcare access.

7.5. Study limitations

Despite the groundbreaking nature of this investigation and its contributions towards understanding young women's preferences for STI self-sampling intervention, we acknowledge several limitations. We did not collect demographic data that included the highest level of education, employment status, source of household income, and parental and marital status from our participants. This missing information could have provided a more nuanced understanding of some of the socio-economic factors that contribute to healthcare barriers and expressed preferences for self-sampling. The study was exclusively conducted in underserved urban communities in eThekweni Metropolitan Municipality, KZN, among young women aged 18–24 years. The focus on young women in underserved urban communities may not be representative of young women in rural areas, where healthcare access may be a greater challenge and STI prevalence is lower. While it is essential to focus on the specific needs of the target population, there is a missed opportunity to investigate the needs of adolescent girls, among whom STI prevalence is also high. Furthermore, the focus on young women limits the generalisability of our findings to older women and people of other genders. It is also important to note that the research data was collected at a single point in time, but barriers and preferences for STI healthcare can evolve due to societal attitudes, technological advancements, and policy changes.

7.6. Conclusion and implications for practice

The expressed need for increased access to self-sampling kits indicates the necessity of broadening STI service provision beyond traditional clinic-based interventions, making them available in pharmacies, schools, community outreach programs, and online platforms. Increasing access would likely lead to higher rates of STI testing and screening, resulting in early detection. The preference for comprehensive education on STIs and the self-sampling process underscores the significance of integrating educational components into STI healthcare services. Printed materials, community outreach programmes, and online platforms could be used to achieve this. Maintaining confidentiality when communicating diagnostic results is crucial for protecting patient privacy and inspiring confidence to continually engage with STI healthcare services. Providing different types of self-sampling kits allows individuals to choose the most comfortable option, giving them autonomy. Healthcare facilities are encouraged to design specific areas for youth services and designate staff to create a non-judgmental atmosphere, reducing fear of judgment and STI-associated stigmatisation.

The study also underscores the importance of involving end-users in designing and implementing healthcare interventions to meet their specific needs and preferences. Community-based participatory research and stakeholder engagement should be integral components of future health intervention programmes to enhance the effective uptake of STI healthcare services. Healthcare providers should embrace technological advancements, such as online platforms for result communication and telehealth services, to significantly enhance the accessibility and convenience of STI testing, particularly for populations in underserved areas. Policymakers should leverage these findings to inform the development of public health policies and programmes that prioritise the needs and preferences of young women. This can ultimately improve STI detection and treatment in young women, thereby enhancing sexual and reproductive health outcomes.

7.7. Recommendations

7.7.1. Recommendations for practice

The following framework presents recommendations for future practice based on the findings of the research conducted. Recommendations presented are for implementers and policymakers of STI healthcare services, using self-sampling interventions to diagnose STIs young women in settings such as those investigated in this study (see Figure 7.2 below).

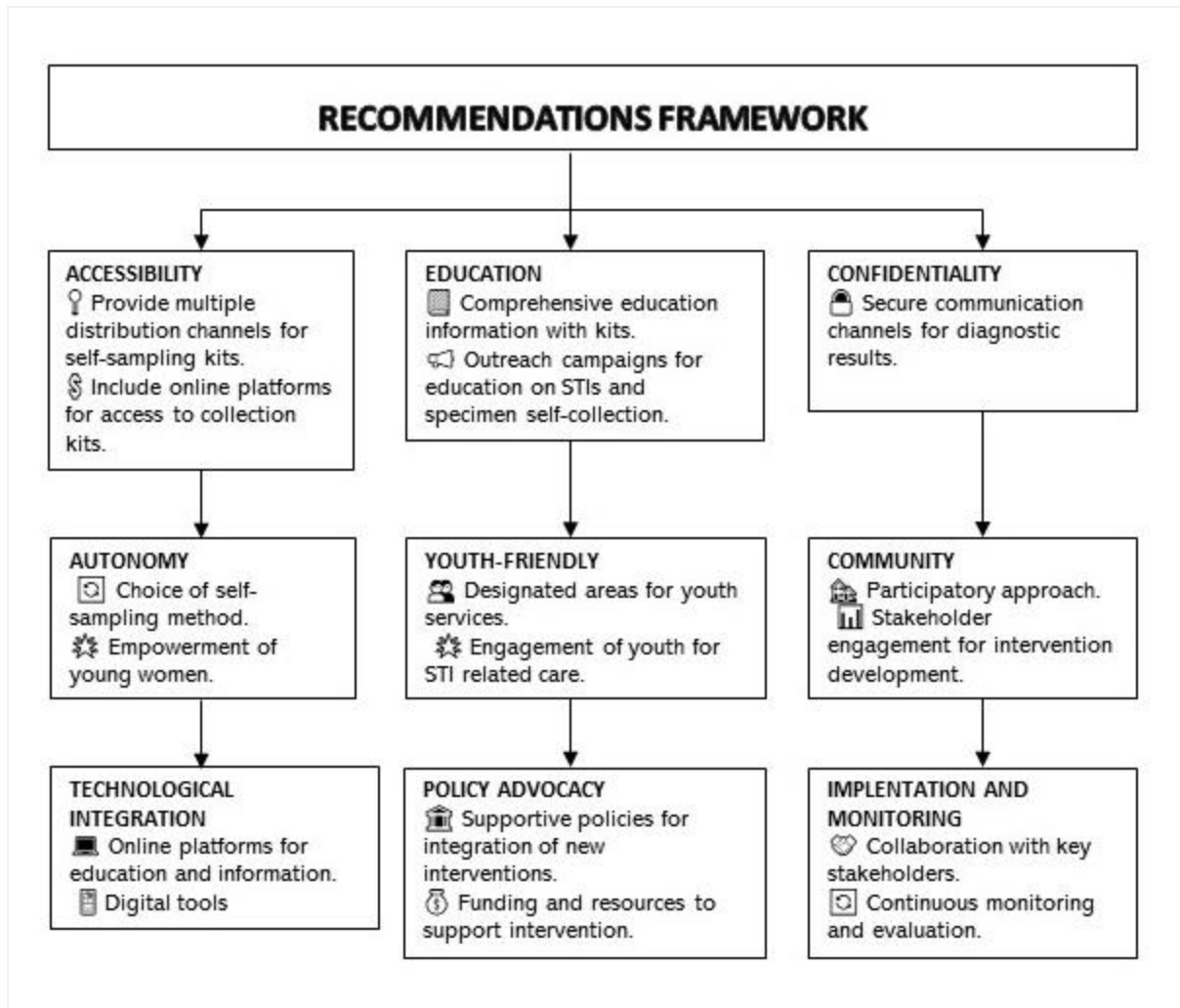


Figure 7.2: Recommendations framework

7.7.2. Recommendations for research

Although the research contributes to the existing body of literature, we make several recommendations for future studies to expand knowledge in this area:

- Future research should aim to include a more diverse demographic, including employment status, level of education, marital and parental status.
- Given the high prevalence of STIs among adolescent girls, future studies should include this age group to address their unique needs and challenges to enable the development of tailored interventions.
- Longitudinal studies could help to understand the long-term effectiveness and sustainability of self-sampling interventions in relation to healthcare-seeking behaviour, STI rates, and health outcomes.
- Investigate the role of emerging technologies in enhancing self-sampling interventions including the use of mobile apps, telehealth consultations, and artificial intelligence to

improve user engagement, provide real-time support, and streamline the process of receiving and interpreting test results.

- Research should investigate the most effective distribution channels of self-sampling kits, partnerships with community organisations, and methods for integrating self-sampling into existing healthcare systems.
- Research should develop and test different educational interventions aimed at increasing knowledge and awareness about STIs and self-sampling including evaluating the effectiveness of various educational formats (e.g., online modules, community workshops, peer education) in improving understanding and reducing stigma.
- Studies should also investigate the economic benefits of self-sampling interventions compared to traditional methods, considering factors such as reduced healthcare costs and increased productivity due to better health.

By addressing the above areas, future research can build on the current study's findings to develop more effective, equitable, and user-friendly STI healthcare services for adolescent girls and young women, and ultimately contribute to better health outcomes and advancing public health goals.

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8. Appendices

Appendix A: University of Pretoria ethics approval letter



Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0278 Approved for use through August 31, 2023.

Faculty of Health Sciences **Research Ethics Committee**

4 July 2022

**Approval Certificate
New Application**

Dear Mrs ZN Jaya

Ethics Reference No.: 136/2022

Title: Towards the development of an acceptable and user-friendly self-sampling intervention for diagnosing sexually transmitted infections among young women in eThekweni District Municipality, South Africa

The **New Application** as supported by documents received between 2022-03-30 and 2022-06-29 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2022-06-29 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year and needs to be renewed annually by 2023-07-04.
- Please remember to use your protocol number (136/2022) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely



On behalf of the FHS REC, Dr R Sommers

MBCChB, MMed (Int), MPharmMed, PhD

Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

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Fakulteit Gesondheidswetenskappe
Lefapha la Disaense lea Maphelo

Appendix B: University of Pretoria ethics approval letter annual renewal



Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567. Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0278 Approved for use through August 31, 2023.

Faculty of Health Sciences **Research Ethics Committee**

15 June 2023

Approval Certificate Annual Renewal

Dear Mrs ZN Jaya,

Ethics Reference No.: 136/2022 – Line 1

Title: Towards the development of an acceptable and user-friendly self-sampling intervention for diagnosing sexually transmitted infections among young women in eThekweni District Municipality, South Africa

The **Annual Renewal** as supported by documents received between 2023-05-30 and 2023-06-14 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2023-06-14 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2024-06-15.
- Please remember to use your protocol number (136/2022) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely



On behalf of the FHS REC, Professor C Kotzé

MBChB, DMH, MMed(Psych), FCPsych, PhD

Acting Chairperson: Faculty of Health Sciences Research Ethics Committee

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

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Lefapha la Disaense le Maphelo

Appendix C: eThekwini Health District approval letter



KWAZULU-NATAL PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

DIRECTORATE: DISTRICT DIRECTOR

Physical address: 83 King Cetshwayo Highway; Highway House; Mayville 4091
Postal Address: private Bag X 54318, Durban 4000 eThekwini District Office
Tel: 031 240 5309 Fax: 031 240 5555 Email: Thabisile.sakyl@kznhealth.gov.za
www.kznhealth.gov.za

Enquiries: Zandile Matyo
Date: 27/07/2022

Dear Mrs ZN Jaya
University of Pretoria
Faculty of Health Sciences

RE: SUPPORT FOR RESEARCH STUDY TOWARDS THE DEVELOPMENT OF AN ACCEPTABLE AND USER-FRIENDLY SELF-SAMPLING INTERVENTION FOR DIAGNOSING SEXUALLY TRANSMITTED INFECTIONS AMONG YOUNG WOMEN IN ETHEKWINI DISTRICT MUNICIPALITY, SOUTH AFRICA

I have the pleasure in informing you that the District is granting you support to conduct the research study titled, 'Towards the development of an acceptable and user-friendly self-sampling intervention for diagnosing sexually transmitted infections among young women in eThekwini District Municipality, South Africa.'

Please note the following:

1. Please ensure you adhere to all the policies, procedures, protocols, and guidelines of the department of health with regards to this research.
2. This research will only commence once this office has received confirmation from the provincial health research committee in the KZN department of health.
3. Please ensure this office is informed before you commence your research.
4. The District office/facility will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to the district office/facility

Thanking you.
Sincerely,

(District Director) EThekwini Health District

Date: 2022/07/27

GROWING KWAZULU-NATAL TOGETHER

Appendix D: KwaZulu-Natal Department of Health approval letter



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address: 330 Langalibalele Street, Pietermaritzburg
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www.kznhealth.gov.za

DIRECTORATE:

Health Research & Knowledge
Management

NHRD Ref: KZ_202208_005

Dear Mrs ZN Jaya
(University of Pretoria)

Approval of research

1. The research proposal titled '**Towards the development of an acceptable and user-friendly self-sampling intervention for diagnosing sexually transmitted infections among young women in eThekweni District Municipality, South Africa**' was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

The proposal is hereby **approved** for research to be undertaken at Cato Manor CHC; Addington Gateway, Athole Park Hall, Chesterville, Clare Estate, Clermont, Glen Earle, Newlands West, Osizweni (Umlazi Q) Prince Zulu CDC, Reservoir Hills, Sea Cow Lake, Shallcross, Sydenham Heights, Tshelimnyama, Umlazi D and Umlazi G clinic.

2. You are requested to take note of the following:
 - a. *All research conducted in KwaZulu-Natal must comply with government regulations relating to Covid-19. These include but are not limited to: regulations concerning social distancing, the wearing of personal protective equipment, and limitations on meetings and social gatherings.*
 - b. *Kindly liaise with the facility manager BEFORE your research begins in order to ensure that conditions in the facility are conducive to the conduct of your research. These include, but are not limited to, an assurance that the numbers of patients attending the facility are sufficient to support your sample size requirements, and that the space and physical infrastructure of the facility can accommodate the research team and any additional equipment required for the research.*
 - c. *Please ensure that you provide your letter of ethics re-certification to this unit, when the current approval expires.*
 - d. *Provide an interim progress report and final report (electronic and hard copies) when your research is complete to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za*
 - e. *Please note that the Department of Health shall not be held liable for any injury that occurs as a result of this study.*

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge

Chairperson, Provincial Health Research Committee

Date: 14/08/2022

Fighting Disease, Fighting Poverty, Giving Hope

Appendix E: Participant Screening Form for the Nominal Group Technique

Participant Screening Tool

Name of principal investigator: Ziningi Jaya
Institution: University of Pretoria
Designation: PhD candidate
Student number: 21848522
Address: 136 Bidston road, Westridge 4091
Email: u21848522@tuks.co.za
Contact number: 067 227 0287

Greetings

Thank you for your interest in participating in our research study. The main purpose of this screening tool is to provide you with a brief overview of the proposed research and to evaluate your eligibility to participate in it. Before we proceed to the screening questions, here is a brief overview of the research topic.

1. Research overview

1.1 Research title

Towards the development of an acceptable user-friendly self-sampling interventions for diagnosing sexually transmitted infections in young South African women.

1.2 Purpose for which research is conducted

Doctor of Philosophy Degree aimed at developing a user-friendly self-sampling intervention for the diagnosis of STIs among young women

1.3 Research background and overview

Sexually transmitted infections (STIs) are a major burden and challenge in the whole world. Unfortunately, the level of STI infections is highest in young people, especially adolescent girls and young women. Depending on the type of STI, some infected individuals experience signs and symptoms of infections and in other instances there are no signs and symptoms experienced. In order to get treatment for STIs, individuals must present themselves to healthcare facilities. Here individuals are then diagnosed and treated based on reported signs and symptoms and observations by medical staff. This type of diagnosis and treatment is known as syndromic management. However, most of the common STIs do not cause any signs and symptoms which means that these infections are missed when syndromic management is used to diagnose and treat STIs. This means that

infected individuals who do not experience signs and symptoms of infection are left undiagnosed and untreated and spread infection without knowing it.

Self-sampling interventions are methods in which individuals can collect their own specimens either in a medical facility, or at home, or anywhere they are comfortable. The self-sampled specimens are then taken to a healthcare facility for testing and diagnosis of STIs. Self-sampling interventions are commonly used to screen and diagnose STIs that cause signs and symptoms and those that do not. The aim of this research is to gather information that will contribute towards developing a user-friendly self-sampling intervention used to diagnose STIs in young women aged 18 -24 years. This research will be conducted among young women that live in poor communities in city of eThekweni, in eThekweni District Municipality in KwaZulu-Natal, South Africa.

1.4 Participation

Study participation will be voluntary, and participants will have the freedom to withdraw consent at any point of the study. The entire consent process will be documented. All consenting participants will be required to confirm their participation by signing participant consent forms. A copy of the signed participant consent form will be given to participating individuals for their own records.

1.5 Confidentiality

We will not record your name anywhere and no one will be able to connect you to the answers you give. Your answers will be linked to a fictitious code number or a pseudonym (another name). Your privacy and dignity will be respected at all times.

The records provided in this document may be reviewed by people responsible for making sure that research is done properly, including members of the Research Ethics Committee. They are all required to keep your identity confidential. Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records. All hard copy information will be kept in a locked facility, for a minimum of 10 years and only the research team will have access to this information.

2. EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS

If you agree to participate, you will be asked to provide information about your personal details. We do not think that completing the screening too will cause any physical or emotional discomfort or risk.

You may find that some questions are sensitive, for instance, questions about your sexual activity.

If questions feel too personal or make you uncomfortable, you do not have to answer them.

2.1 Screening questions

NB: Please write an X next to the relevant response (where applicable)

Question/enquiry	Response
1. What is your gender?	
2. How old are you?	
3. What is your date of birth?	
4. Do you have a contact number where you can be reached? 5.	Yes___ No___
6. Are you sexually active?	Yes___ No___
7. Do you know about sexually transmitted infections?	Yes___ No___
8. How do healthcare workers determine if someone has an STI?	

Thank you for your time. Please do not hesitate to ask questions. For emergency or further questions contact the study PI. Use contact details on first page of this informed consent.

Please kindly note that signing of this document does not mean confirmation of study participation, it merely confirms that you have been through the screening process.

3. Confirmation of participation in the screening process

Participant full name: _____

Date : _____

Signature : _____

Study PI name : _____

Date : _____

Signature : _____

Appendix F: Information Letter and Informed Consent for the NGT

**PARTICIPANT'S INFORMATION AND INFORMED CONSENT DOCUMENT FOR A
CO-CREATION WORKSHOP RESEARCH STUDY**

Study title: ... Towards the development of an acceptable and user-friendly self-sampling intervention for diagnosing sexually transmitted infections among young women in eThekweni District Municipality, South Africa

Principal Investigator: Ziningi Nobuhle Jaya

Supervisor: Professor TP Mashamba-Thompson

Co-supervisor: Dr W. Mapanga

Institution: University of Pretoria

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):

Daytime number/s: 067 227 0287

Afterhours number: 067 227 0287

Date and time of informed consent discussion:

			:
date	month	year	Time

Dear Prospective Participant

Dear Miss/ Ms / Mrs.

1) INTRODUCTION

You are invited to volunteer for a research study. I am doing this research for Doctoral degree purposes at the University of Pretoria. This document gives you information in this document is provided to help you decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about what we will be discussing during the focus group discussion.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to explore and develop research is to develop a user-friendly self-sampling intervention to diagnose sexually transmitted infections (STIs) in young women residing in poor urban communities in eThekweni District Municipality in KwaZulu-Natal, South Africa. Self-sampling refers to specimens collected by the patient either in the healthcare facility or at home and not by a healthcare worker. The specimen is then sent to the laboratory for diagnosis of STIs.

Part of the study will be a co-creation workshop in which the nominal group technique will be used to conduct a group discussion. A co-creation workshop involves discussion and brainstorming of ideas in a group in order to bring out ideas from all members and develop a better approach to address a specific topic. A nominal group technique group discussion is where a few people – usually about 8 or 12 – get together with the researcher to discuss a specific topic with the aim of identifying issues, generating a solution and making a decision based on contributions made by each group member through collaboration. The discussion will be arranged at a time that is convenient to you and will take place at Al Falaah College, in Durban.

3) EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS

If you agree to participate, you will be asked to participate you will be asked to participate in co-creation workshop which will take about 6 and a half hour (390 minutes). You and the other

participants will be asked some questions about your opinion about the use of a user-friendly self-sampling interventions to diagnose STIs in young women in order to co-design a preferred intervention.

We will not ask any questions about your personal experience. With your permission, the discussions will be recorded on a recording device to ensure that no information is missed.

4) RISKS AND DISCOMFORTS INVOLVED

We do not think that taking part in the study will cause any physical or emotional discomfort or risk.

You do not have to share any knowledge you are not comfortable with.

During the focus group discussion, you may find that some questions are sensitive; for instance, questions about barriers that prevent young women from seeking healthcare for STIs, and questions about your preferred type of self-collected specimen.

If questions feel too personal or make you uncomfortable, you do not have to answer them.

If you need psychological support or counselling during or after the focus group discussion, I will be able to refer you to your local primary healthcare clinic or community healthcare clinic.

5) POSSIBLE BENEFITS OF THIS STUDY

You will not benefit directly by being part of this study. But your participation is important for us to better understand STI healthcare management interventions that are preferable to young women. The information you give may help the researcher to co-create self-sampling interventions that are acceptable for the diagnosis of symptomatic and asymptomatic STIs among young women.

6) COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study. Transportation to the venue and refreshments will be provided during the workshop.

7) VOLUNTARY PARTICIPATION

The decision to take part in the study is yours and yours alone. You do not have to take part if you do not want to. You can also stop at any time during the interview without giving a reason. If you

refuse to take part in the study, this will not affect you in any way. You will still receive standard care and treatment if you require it.

8) ETHICAL APPROVAL

This study was submitted to the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria, Medical Campus, Tswelopele Building, Level 4-59, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been given by that committee. The study will follow the Declaration of Helsinki (last update: October 2013), which guides doctors on how to do research in people. The researcher can give you a copy of the Declaration if you wish to read it.

9) INFORMATION ON WHO TO CONTACT

If you have any questions concerning this study, you should contact:

The principal investigator Ziningi N Jaya on 067 227 0287

10) CONFIDENTIALITY

We will not record your name anywhere and no one will be able to connect you to the answers you give. Your answers will be linked to a fictitious code number or a pseudonym (another name) and we will refer to you in this way in the data, any publication, report or other research output. Please kindly note that you will not be required to disclose your STI status in order to participate in the study. Displaying knowledge about STIs will be sufficient to determine your eligibility to participate in the study.

All records from this study will be regarded as confidential. Your privacy and personal information will be protected using carefully controlled procedures for collecting, storing and accessing data that comply with privacy, and human rights. Your dignity and confidentiality will be respected at all times. Results will be published in medical journals or presented at conferences in such a way that it will not be possible for people to know that you were part of the study.

The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the Research Ethics Committee. All of these people

are required to keep your identity confidential. Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

All hard copy information will be kept in a locked facility, for a minimum of 10 years and only the research team will have access to this information.

Although all participants of the workshop will be requested to keep the discussion confidential, the researcher cannot guarantee that they will do so. I therefore request that you do not disclose any information of a very personal or sensitive nature to anyone.

10) CONSENT TO PARTICIPATE IN THIS STUDY

- I confirm that the person requesting my consent to take part in this study has told me about the nature and process, any risks or discomforts, and the benefits of the study.
- I have also received, read and understood the above written information about the study.
- I have had adequate time to ask questions and I have no objections to participate in this study.
- I am aware that the information obtained in the study, including personal details, will be anonymously processed and presented in the reporting of results.
- I understand that I will not be penalised in any way should I wish to discontinue with the study and my withdrawal will not affect my treatment and care.
- I am participating willingly.
- I have received a signed copy of this informed consent agreement.

Participant's name (Please print)

Date

Participant's signature

Date

Researcher's name (Please print)

Date

Researcher's signature

Date

I understand that the co-creation workshop group discussion will be audiotaped. I give consent that it may be audio recorded.

YES

NO

AFFIRMATION OF INFORMED CONSENT BY AN ILLITERATE PARTICIPANT (if applicable)

I, the undersigned,, have read and have explained fully to the person, named, the participant informed consent document, which describes the nature and purpose of the study in which I have asked the person to participate. The explanation I have given has mentioned both the possible risks and benefits of the study and the alternative treatments available for his/her illness. The person indicated that they understand that they will be free to withdraw from the study at any time for any reason and without jeopardizing their standard care.

I hereby certify that the person has agreed to participate in this study.

Participant's name (Please print)

Date

Participant's signature or thumbprint

Date

Investigator's name (Please print)

Date

Investigator's signature

Date

Name of the person who witnessed the informed consent (Please print)

Date

Signature of the witness

Date

Appendix G: Ward Councillor permission letter

Ziningi Nobuhle Jaya
136 Bidston road, West ridge 5091
Student number u21848522
University of Pretoria

KwaZulu-Natal
eThekweni Metropolitan Municipality 4001
Ward Councillor

RE: Request for Permission to Collect Research Data in Ward ::

Dear(Ward councillor name)

I trust this letter finds you well. My name is Ziningi Nobuhle Jaya, and I am a PhD candidate at the University of Pretoria, conducting research on a project entitled **Towards the development of an acceptable and user-friendly self-sampling intervention for diagnosing sexually transmitted infections among young women in eThekweni District Municipality, South Africa.** To ensure transparency and adherence to ethical standards, I have obtained ethical approval for my research from the University's Ethics Review Board.

I am writing to request your permission to collect research data within your Ward for my study. My study focuses on determining young women's preferences for a self-sampling intervention to diagnose sexually transmitted infections in underserved communities. This study is of particular importance as it addresses critical public health concerns in underserved communities, and the findings aim to contribute to the development of effective interventions to improve sexual health outcomes.

The data collection process will involve a survey with young women aged 18-24 years, and I am committed to ensuring that the research is conducted with the utmost respect for the community and its residents. I recognize the importance of community engagement and involvement in research endeavours, and I am eager to collaborate with you and the community to make this research as beneficial and as meaningful as possible. Your support in granting me permission for data collection within your ward will greatly contribute to the success and impact of this study.

Thank you for considering my request, and I look forward to the possibility of working together to advance knowledge and contribute to the well-being of the community.

Sincerely,

Ziningi Nobuhle Jaya

Signature:

Ward councillor consent

I, _____, serving as the Ward Councillor for Ward _____, hereby confirm that I am aware of the research being conducted by Ziningi Nobuhle Jaya. She will be conducting a survey on young women aged 18-24 in the community. This letter serves as official confirmation that Ms Jaya and her research team have my permission to conduct her research within the community. I am supportive of this study, recognizing its potential contribution to our community.

If you have any questions or require further information regarding this matter, please feel free to contact my office on _____.

Other contact community leader _____ contact number _____.

Thank you for your kind corporation.

Sincerely,

(Ward Councillor name)

Signature

Appendix G: Survey Tool with Information and Informed Consent for Discrete Choice Experiment

Title of study

Towards the development of an acceptable and user-friendly self-sampling intervention for diagnosing sexually transmitted infections among young women in eThekweni District Municipality, South Africa

Principal Investigator: Ziningi Nobuhle Jaya

Supervisor: Professor TP Mashamba-Thompson

Co-supervisor: Dr W. Mapanga

Institution: University of Pretoria

Introduction to the study

Thank you for agreeing to participate in our study. We appreciate your participation in this important research which aims to better understand your preferences regarding self-sampling for sexually transmitted infection (STI) diagnosis. Unlike current STI healthcare services that require you to present to the healthcare facility and undergo a genital examination, self-sampling allows you to use a specimen collection kit to collect your own biological specimen in the comfort of your home so that it can be used to diagnose STIs. In this experiment, participants will be given a series of hypothetical choices between combinations of different self-sampling strategies/ attributes for STI diagnosis. These options may vary in terms of the method of self-sampling, privacy, convenience, or other relevant factors. By analysing the choices participants make, we will gain insights into the features or aspects of self-sampling interventions that are most important to young women. You are required to answer a few questions based on your own preferences. The survey consists of 14 questions. You will not be required to disclose your STI status in order to participate in the study. Displaying knowledge about STIs will be sufficient to determine your eligibility to participate in the study.

EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS

If you agree to participate, you will be asked to answer a series of hypothetical questions and select the most suitable choice for you. This will take about 20 minutes of your time. We will not ask any questions about your personal experience with STIs.

RISKS AND DISCOMFORTS INVOLVED

We do not think that taking part in the study will cause any physical or emotional discomfort or risk. You do not have to share any knowledge you are not comfortable with. During the process, you may find that some questions are sensitive, for instance, questions about your preferred type of self-collected specimen. If questions feel too personal or make you uncomfortable, you do not have to answer them. If you need psychological support or counselling during or after you complete the survey, you may visit to your local primary healthcare clinic or community healthcare clinic.

POSSIBLE BENEFITS OF THIS STUDY

You will not benefit directly by being part of this study. But your participation is important for us to better understand STI healthcare management interventions that are preferable to young women. The information you give may help the researcher to identify the factors that influence young women's preferences, providing valuable information for designing effective and user-friendly interventions in STI diagnosis for this specific demographic.

COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study. Transportation to the venue and refreshments will be provided where applicable.

VOLUNTARY PARTICIPATION

The decision to take part in the study is yours and yours alone. You do not have to take part if you do not want to. You can also stop at any time during the interview without giving a reason. If you refuse to take part in the study, this will not affect you in any way.

ETHICAL APPROVAL

This study was submitted to the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria, Medical Campus, Tswelopele Building, Level 4-59, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been given by that committee (reference number 136/2022). The study will follow the Declaration of Helsinki (last update: October 2013), which guides doctors on how to do research in people. The researcher can give you a copy of the Declaration if you wish to read it.

CONFIDENTIALITY

All records from this study will be regarded as confidential. Your privacy and personal information will be protected using carefully controlled procedures for collecting, storing and accessing data that comply with privacy, and human rights. Your dignity and confidentiality will be respected at all times. Results will be published in medical journals and presented at conferences in such a way that it will not be possible for people to know that you were part of the study, your details will not be disclosed.

CONSENT TO PARTICIPATE IN THIS STUDY

- I confirm that the person requesting my consent to take part in this study has told me about the nature and process, any risks or discomforts, and the benefits of the study.
- I have also received, read and understood the above written information about the study.
- I have had adequate time to ask questions and I have no objections to participate in this study.
- I am aware that the information obtained in the study, including personal details, will be anonymously processed and presented in the reporting of results.
- I understand that I will not be penalised in any way should I wish to discontinue with the study and my withdrawal will not affect my treatment and care.
- I am participating willingly.
- I have received a signed copy of this informed consent agreement.

Participant's initials and surname (Please print)

Signature and date

Researcher's initials and surname (Please print)

Signature and date

SECTION 1

Screening and demographic information (mark relevant response with “x”)

1. What is your age? 18 – 21 years 22 – 24 years
2. Do you know about sexually transmitted infections? Yes No
3. Are you aware of STI healthcare services in your local clinic? Yes No
4. How do you feel about STI healthcare services in your local clinic?
- Comfortable Uncomfortable
6. Briefly state the reason for your discomfort.
-

5. How would you describe your home?

- 4.1 Formal settlement Informal settlement
- 4.2 Bought Owned Rented

6. How would you describe your monthly household income?

- No income R1 – R4 800 R4 801 – R 9 600 R9 601 – R19 200 > R19 200

SECTION 2

In this section we want to understand how people choose between different types of treatment. There are 14 questions for you to complete, after the example. Please answer them all.

Each choice will describe two alternatives of the self-sampling intervention that you can receive. We would like you to read the options carefully and select the option that is best suited for you.

- In each choice, please imagine that you can only have one of the 2 options.
- At first glance the choices may appear the same, but they are different so read carefully before you make your selection.
- We understand that some of the choices will be difficult to make, but there are no right or wrong answers. We require your personal preference.

THE FOLLOWING PAGE CONSISTS OF AN EXAMPLE OF A CHOICE QUESTION FOLLOWED BY 13 QUESTIONS FOR YOU TO ANSWER.

PLEASE READ THE EXAMPLE CAREFULLY, BEFORE YOU PROCEED WITH THE REST OF THE SURVEY.

EXAMPLE CHOICE QUESTION: Imagine the following scenario and select the option that is most suitable for you:

Example 1

You are a young woman who recently had unprotected sex with a man you do not trust. Concerned about the potential risk of STIs, you find yourself contemplating getting tested. Your health and well-being are important to you, and you want to make the best choice for your needs. The decision weighs heavily on your mind as you consider various factors that might influence your choice.

	Option A	Option B
Accessibility and convenience	Self-sampling kits are available at clinics, universities/schools, and pharmacies.	Kits available through outreach, clinics, schools, and pharmacies, with online support.
Education and normalisation	No educational material or campaigns provided).	Educational material provided with the self-sampling kit, along with regular campaigns to encourage and normalize testing.
Confidentiality and communication	Results are communicated via email or a secure online portal.	Results are communicated via phone call or text message.
Self-sampling collection device	A kit that includes a swab for vaginal specimen collection.	A kit that offers a choice of collection methods, either a swab for vaginal specimen collection or a urine sample for specimen collection.
Youth -friendly	No improvements made to youth-friendly services at clinics.	Significant improvements made to youth-friendly services at clinics, e.g., clinic hours extended to accommodate school schedules, dedicated youth-friendly clinic space.
Cost	Self-sampling kits are not provided free of charge.	Self-sampling kits are provided free of charge at clinics, universities/schools, pharmacies, and mobile clinics.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input checked="" type="radio"/>

By choosing option B, this person indicates that this option is better than option A.

Use the same scenario above to answer example 2 (for you to practice)

	Option A	Option B
Accessibility and convenience	Self-sampling kits are available at clinics only.	Kits available through outreach, clinics, schools, and pharmacies, with online support.
Education and normalisation	No educational material or campaigns provided).	No educational material or campaigns provided).
Confidentiality and communication	Results are communicated via email or a secure online portal.	Results given at the clinic.
Self-sampling collection device	A kit that includes a swab for vaginal specimen collection.	A kit that offers a urine sample for specimen collection.
Youth -friendly	Minor improvements (separate area, comfortable rooms, trained staff).	Significant improvements made to youth-friendly services at clinics, e.g., clinic hours extended to accommodate school schedules, dedicated youth-friendly clinic space.
Cost	Self-sampling kits are not provided free of charge.	Self-sampling kits are provided free of charge at clinics, universities/schools, pharmacies, and mobile clinics.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

To answer all following questions (choice set/ task), PLEASE IMAGINE THE SCENARIO BELOW:

You recently had unprotected sex with a man you do not trust. Concerned about the potential risk of STIs, you find yourself contemplating getting tested. Your health and well-being are important to you, and you want to make the best choice for your needs. The decision weighs heavily on your mind as you consider various factors that might influence your choice. Please review the following choice set and select options that align with your preferences for each choice set:

Choice set 1

	Option A	Option B
<i>Accessibility and convenience</i>	Kits available through outreach, clinics, schools, pharmacies, and with online support.	Kits are only available at clinics.
<i>Education and normalisation</i>	Comprehensive information provided with kits and campaigns in the community to encourage testing.	Comprehensive information provided with kits and campaigns in the community to encourage testing.
<i>Confidentiality and communication</i>	Results given at the clinic.	Results given at the clinic.
<i>Self-sampling collection device</i>	Kit offers a choice of methods (swab or urine).	Kit offers a choice of methods (swab or urine).
<i>Youth -friendly</i>	No improvements made to create a youth friendly environment for young people during clinic visit.	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).
<i>Cost</i>	Kits are free at clinics, schools, pharmacies, and mobile clinics.	Kits are free at clinics, schools, pharmacies, and mobile clinics.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 2

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are only available at clinics.	Kits are available at clinics, schools, and pharmacies.
<i>Education and normalisation</i>	Basic information on STIs is provided with the kit.	Comprehensive information provided with kits and campaigns in the community to encourage testing.
<i>Confidentiality and communication</i>	Remote sharing of results via phone, text, email, or online portal.	Results given at the clinic.
<i>Self-sampling collection device</i>	Vaginal swab kit issued.	Urine sample kit issued.
<i>Youth -friendly</i>	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).	No improvements made to create a youth friendly environment for young people during clinic visit.
<i>Cost</i>	Kits are free at clinics only.	Kits are free at clinics only.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 3

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are available at clinics, schools, and pharmacies.	Kits are available at clinics, schools, and pharmacies.
<i>Education and normalisation</i>	Comprehensive information provided with kits and campaigns in the community to encourage testing.	Comprehensive information provided with kits and campaigns in the community to encourage testing.
<i>Confidentiality and communication</i>	Remote sharing of results via phone, text, email, or online portal.	Remote sharing of results via phone, text, email, or online portal.
<i>Self-sampling collection device</i>	Vaginal swab kit issued.	Vaginal swab kit issued.
<i>Youth -friendly</i>	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).	No improvements made to create a youth friendly environment for young people during clinic visit.
<i>Cost</i>	Kits need to be purchased.	Kits need to be purchased.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 4

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are only available at clinics.	Kits are only available at clinics.
<i>Education and normalisation</i>	No educational material on STIs is provided with the kit.	Basic information on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Results given at the clinic.	Remote sharing of results via phone, text, email, or online portal.
<i>Self-sampling collection device</i>	Urine sample kit issued.	Kit offers a choice of methods (swab or urine).
<i>Youth -friendly</i>	No improvements made to create a youth friendly environment for young people during clinic visit.	No improvements made to create a youth friendly environment for young people during clinic visit.
<i>Cost</i>	Kits need to be purchased.	Kits need to be purchased.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 5

	Option A	Option B
<i>Accessibility and convenience</i>	Kits available through outreach, clinics, schools, pharmacies, and with online support.	Kits are available at clinics, schools, and pharmacies.
<i>Education and normalisation</i>	No educational material on STIs is provided with the kit.	Comprehensive information provided with kits and campaigns in the community to encourage testing.
<i>Confidentiality and communication</i>	Results given at the clinic.	Results given at the clinic.
<i>Self-sampling collection device</i>	Kit offers a choice of methods (swab or urine).	Vaginal swab kit issued.
<i>Youth -friendly</i>	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).
<i>Cost</i>	Kits need to be purchased.	Kits are free at clinics, schools, pharmacies, and mobile clinics.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 6

	Option A	Option B
<i>Accessibility and convenience</i>	Kits available through outreach, clinics, schools, pharmacies, and with online support.	Kits are available at clinics, schools, and pharmacies.
<i>Education and normalisation</i>	Basic information on STIs is provided with the kit.	No educational material on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Remote sharing of results via phone, text, email, or online portal.	Remote sharing of results via phone, text, email, or online portal.
<i>Self-sampling collection device</i>	Urine sample kit issued.	Urine sample kit issued.
<i>Youth -friendly</i>	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).	No improvements made to create a youth friendly environment for young people during clinic visit.
<i>Cost</i>	Kits are free at clinics only.	Kits are free at clinics only.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 7

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are available at clinics, schools, and pharmacies.	Kits are only available at clinics.
<i>Education and normalisation</i>	Basic information on STIs is provided with the kit.	No educational material on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Results given at the clinic.	Remote sharing of results via phone, text, email, or online portal.
<i>Self-sampling collection device</i>	Kit offers a choice of methods (swab or urine).	Urine sample kit issued.
<i>Youth -friendly</i>	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).
<i>Cost</i>	Kits are free at clinics, schools, pharmacies, and mobile clinics.	Kits are free at clinics only.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 8

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are available at clinics, schools, and pharmacies.	Kits available through outreach, clinics, schools, pharmacies, and with online support.
<i>Education and normalisation</i>	Basic information on STIs is provided with the kit.	Basic information on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Results given at the clinic.	Remote sharing of results via phone, text, email, or online portal.
<i>Self-sampling collection device</i>	Urine sample kit issued.	Vaginal swab kit issued.
<i>Youth -friendly</i>	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).
<i>Cost</i>	Kits are free at clinics, schools, pharmacies, and mobile clinics.	Kits are free at clinics, schools, pharmacies, and mobile clinics.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 9

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are only available at clinics.	Kits available through outreach, clinics, schools, pharmacies, and with online support.
<i>Education and normalisation</i>	No educational material on STIs is provided with the kit.	Basic information on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Remote sharing of results via phone, text, email, or online portal.	Remote sharing of results via phone, text, email, or online portal.
<i>Self-sampling collection device</i>	Kit offers a choice of methods (swab or urine).	Vaginal swab kit issued.
<i>Youth -friendly</i>	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).
<i>Cost</i>	Kits are free at clinics, schools, pharmacies, and mobile clinics.	Kits are free at clinics only.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 10

	Option A	Option B
<i>Accessibility and convenience</i>	Kits available through outreach, clinics, schools, pharmacies, and with online support.	Kits are only available at clinics.
<i>Education and normalisation</i>	Comprehensive information provided with kits and campaigns in the community to encourage testing.	No educational material on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Results given at the clinic.	Results given at the clinic.
<i>Self-sampling collection device</i>	Urine sample kit issued.	Kit offers a choice of methods (swab or urine).
<i>Youth -friendly</i>	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).
<i>Cost</i>	Kits are free at clinics only.	Kits need to be purchased.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 11

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are only available at clinics.	Kits available through outreach, clinics, schools, pharmacies, and with online support.
<i>Education and normalisation</i>	Comprehensive information provided with kits and campaigns in the community to encourage testing.	No educational material on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Remote sharing of results via phone, text, email, or online portal.	Results given at the clinic.
<i>Self-sampling collection device</i>	Vaginal swab kit issued.	Kit offers a choice of methods (swab or urine).
<i>Youth -friendly</i>	No improvements made to create a youth friendly environment for young people during clinic visit.	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).
<i>Cost</i>	Kits need to be purchased.	Kits are free at clinics, schools, pharmacies, and mobile clinics.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 12

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are available at clinics, schools, and pharmacies.	Kits available through outreach, clinics, schools, pharmacies, and with online support.
<i>Education and normalisation</i>	No educational material on STIs is provided with the kit.	Basic information on STIs is provided with the kit.
<i>Confidentiality and communication</i>	Remote sharing of results via phone, text, email, or online portal.	Results given at the clinic.
<i>Self-sampling collection device</i>	Vaginal swab kit issued.	Urine sample kit issued.
<i>Youth -friendly</i>	No improvements made to create a youth friendly environment for young people during clinic visit.	Clinics make major improvements efforts to create a youth friendly environment (eg. extended hours, dedicated youth-friendly space).
<i>Cost</i>	Kits are free at clinics only.	Kits need to be purchased.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

Choice set 13

	Option A	Option B
<i>Accessibility and convenience</i>	Kits are available at clinics, schools, and pharmacies.	Kits are available at clinics, schools, and pharmacies.
<i>Education and normalisation</i>	Comprehensive information provided with kits and campaigns in the community to encourage testing.	Comprehensive information provided with kits and campaigns in the community to encourage testing.
<i>Confidentiality and communication</i>	Remote sharing of results via phone, text, email, or online portal.	Remote sharing of results via phone, text, email, or online portal.
<i>Self-sampling collection device</i>	Vaginal swab kit issued.	Vaginal swab kit issued.
<i>Youth -friendly</i>	Clinics make minor improvements to create a youth friendly environment (eg. separate area, comfortable rooms, trained staff).	No improvements made to create a youth friendly environment for young people during clinic visit.
<i>Cost</i>	Kits need to be purchased.	Kits need to be purchased.
Which option would you choose? (mark with an "X")	Option A <input type="radio"/>	Option B <input type="radio"/>

SECTION 3

Survey participation experience: Considering the information and questions in this questionnaire, please indicate how strongly you agree or disagree with each of the following statements.

PLEASE INDICATE YOUR CHOICE WITH AN 'X' IN THE ONE BOX ONLY WHICH IS CLOSEST TO YOUR OPINION FOR EACH ROW:

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I understood the idea of making choices between different options for a self-sampling intervention.					
I needed more information than was provided in order to choose between different options.					
I found making a choice between different options confusing					
I found that the more questions I answered the easier it was to make a choice					
I believe that my choices will have an impact on STI healthcare, particularly on self-sampling for STI diagnosis in the future.					

Thank you for your time. Please do not hesitate to ask questions. For emergency or further questions contact the study PI. Use contact details on first page of this informed consent.

Thank you for your time and for participating in our survey. Your input is invaluable for our research. If you have any questions or concerns, please contact the researcher on the following: Email: u21848522@tuks.co.za Cell phone: 0671075667

Appendix H: Proof of Submission to Journals for Publication

BMJ Open submission

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Understanding the Preferences of Young Women in Self-Sampling Interventions for STI Diagnosis: A Discrete Choice Experiment Protocol

Journal: BMJ Open

Manuscript ID: bmjopen-2023-082981

Status: Awaiting decision

Submission date: 08 December 2023

Authors: Jaya, Mrs. Ziningi Nobuhle; Mapanga, Dr. Witness; Mashamba-Thompson, Prof. Tivani Phosa

If you would like more information about the status of your paper please contact info.bmjopen@bmi.com

Manuscript submission progress



Editorial recommendation received! Awaiting final decision by the handling Editor

24 January 2024, 03:10

We have submitted the peer review reports and additional editorial recommendation, if applicable, for your paper to the Editor to make a final decision on your paper. The Editor may find that additional peer review reports are needed and ask for additional reviewers to be invited to review your paper.

ⓘ Decision pending

If your paper remains at this stage for a prolonged period, it's likely because the editor requires additional peer review reports and has requested additional reviewers.

BMC Women's Health submission

An email has been sent to buhledwayisa@yahoo.com with more details.

Submit amendment

Need help?
If you have any questions about this submission, you can [email the Editorial Office](#).
For general enquiries, please look at our [support information](#).

How was your experience today?

Awful Bad OK Good Great

Send feedback

Your submission

Title
Young women's perspectives on a user-friendly self-sampling intervention to improve the diagnosis of sexually transmitted infections in underserved communities in KwaZulu-Natal South Africa

Type
Research

Journal
BMC Women's Health

Submission ID
d13ab793-7104-45e5-ba5d-d8abe940bbff

Submission history

Event	Date
Peer review	
Revision received	23 May 2024
Submission under peer review	24 Sep 2023
Technical check	
Submission passed technical check	24 Sep 2023
Submission is under technical check	11 Sep 2023
Submission received	
Submission received	11 Sep 2023

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Action	Manuscript Number	Title	Initial Date Submitted	Current Status
Action Links	PONE-D-24-20939	Young Women's Preferences for a Self-Sampling Intervention to Diagnose Sexually Transmitted Infections: A Discrete Choice Experiment	May 23 2024 6:15PM	Manuscript Submitted to Journal

Page: 1 of 1 (1 total submissions)

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