Self-Sampling Interventions for Sexually Transmitted Infections in Women: A Scoping Review Protocol

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Protocol

Keywords: Self-sampling, self-collected, self-obtained, self-administered, diagnostic specimens, sexually transmitted infections, women

Posted Date: August 26th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-64831/v1

Abstract

Background: Research shows a high prevalence of sexual transmitted infections (STIs) among sexually active women throughout the world. Patient self-testing and self-sampling strategies are pivotal to facilitate rapid diagnosis of disease among key populations. The main objective of this study is to map evidence on self-sampling methods utilised to facilitate STIs diagnosis among women.

Methods: We propose to conduct a scoping review, which will be guided by Arksey and O'Malley framework, Levac et al, 2010 and the Joanna Briggs Institution 2015 recommendations. We will conduct a database search for relevant peer-reviewed articles to answer our research question. We will search the following databases: PubMed, Google Scholar, Journal Storage, Science Direct, Web of Science, and MEDLINE (via EBSCOHost). We will also search for grey literature from World Health Organisation (WHO) and Department of Health websites. We will present the results of the review following the Preferred Resulting Items for Systematic reviews and Meta-Analyses extension for scoping reviews (PRISMA-ScR). We will employ Nvivo version 12 for thematic content analysis of the included studies. We will conduct quality appraisal of the included studies using the Mixed Method Appraisal Tool (MMAT)-version 2018.

Discussion: It is anticipated that findings of this scoping review will highlight gaps for further investigation to address the global burden of STIs. This could assist policy makers and developers of diagnostic equipment to develop evidence-based interventions to enable self-sampling and early diagnosis of STIs among women.

Systematic Review Registration

Submitted to Open Science Framework on 25 July 2020.

Background

Despite various innovative interventions by various healthcare organisations, sexually transmitted infections (STIs) remain a major health challenge throughout the world (1). A review by Makhudu et al (2019) revealed a large amount of research evidence on self-sampling for Human Immunodeficiency Virus (HIV) when compared to other infectious diseases (2). As such, the current research aims to map evidence on STIs, excluding HIV, that have been previously neglected due to a high research focus on HIV. Approximately 1 million people are infected with STIs in the world every day, some of which are incurable (1, 3). Women in low-and-middle-income countries (LMIC) are disproportionately affected by this pandemic (4). A large portion of STIs are asymptomatic (5, 6), and as such may be spread unknowingly, making it more difficult to curb the pandemic. According to Shrestha et al (2015) initial exposure to STIs often occurs during early days of sexual debut due to risky behaviour (7). Unfortunately, if untreated and undiagnosed at this stage, the risk of long term disease complications which include infertility; chronic pelvic pain; cervical cancer; and ectopic pregnancy; increases (9, 10). Furthermore, some STIs increase the risk of HIV transmission and acquisition (11).

In LMICs, syndromic management is the common approach to symptomatic infections (12). The challenge with syndromic management is that asymptomatically infected individuals are often missed and excluded. Other challenges include procrastination and reluctance of individuals to seek medical assistance due to social stigma; attitudes and perceptions associated with STIs; and discomfort of pelvic examinations (6, 8, 13). Furthermore, in resource-limited settings where access to healthcare facilities is limited, this approach places these populations at a disadvantage (6). According to various research, routine screening of STIs is imperative for proper management and control (6, 14). High income countries use various interventions to screen both symptomatic and asymptomatic infections, thus improve the management of STIs (6). One such intervention is self-sampling for the diagnosis of STIs. In self-sampling, specimen collection kits are issued to individuals to collect their own specimens either at home or at a healthcare facility (10). The convenience and confidentiality offered by self-sampling interventions, make it ideal to facilitate screening and broaden STI services to populations with limited access to healthcare resources (14). Self-sampling also allows for the screening of asymptomatically infected individuals, that would otherwise go undiagnosed and untreated, and thus risk complication of disease (6).

This research aims to map evidence on the types of self-collected specimens and laboratory assays used for STI diagnosis in women. The research also aims to map evidence on the effectiveness of self-sampling interventions for STIs in women. It is anticipated that research findings will yield data that will inform future research and. guide healthcare policy makers to develop with a effective approaches to manage and control the STI pandemic.

Methodology

We propose a scoping review of evidence on self-sampling interventions for STIs among women. The scoping review will be guided by Arksey and O'Malley (15), Levac et al 2010 and the 2015 Joanna Briggs Institution recommendations (16, 17). Primary research published in peer-reviewed journals, review articles, the World Health Organization (WHO) and the Department of Health (DoH) websites, and other grey literature will be reviewed and included according to their suitability and relevance. All types of research study designs will be included. NVivo version 12, will be used to extract and collate relevant thematic data from the selected publications. The Mixed Method Appraisal Tool (MMAT)-version 2018 will be used to appraise studies that will be included in the review (18). The Preferred Resulting Items for Systematic reviews and Meta-Analyses extension for scoping reviews (PRISMA-ScR) will be used to present the research findings (19).

Eligibility of the research question for a scoping review study

The research question is: What is the evidence on the use of self-sampling interventions for the diagnosis of STIs among women?

The Population, Concept, and Context (PCC) mnemonic was used to determine the eligibility of our research for a scoping review study. This is illustrated in Table 1 below:

Table 1
PCC determining eligibility of the research question

DETERMINANT	DESCRIPTION
Population	**Women**
Concept	**Patient self-sampling interventions for sexually transmitted infections (STIs).**
Context	**Global**

Identification of relevant studies

The Principal Investigator (PI) will conduct a search on different electronic databases and select relevant studies through title screening. The following databases will be searched for peer reviewed publications: PubMed, Google Scholar, Journal Storage, Science Direct, Web of Science, MEDLINE (EBSCOhost), and Open Grey for grey literature. The search will be conducted using the following keywords: Self-sampling; self-collected; self-administered; self-obtained; sexually transmitted infections; women; diagnostic specimens. Boolean terms AND, and OR will be used to separate the keywords during the database search. Match terms or synonyms will also be used to conduct the literature search where applicable. We will also search WHO and DoH websites for relevant grey literature including policy documents, reports, and relevant dissertations from repositories of different institutions. A pilot search was conducted on PubMed in order to demonstrate the feasibility of conducting the proposed study (Table 2).

Table 2
Pilot search on PubMed

Keyword search	Date of Search	Name of database searched	Number of publications received
((((((sexually transmitted infection) AND women) AND self-sampling) OR self-collected) OR self-administered) OR self-obtained) AND diagnostic specimens Best match information: MeSH Terms: women; sexually transmitted diseases; diagnosis	29 April 2020	PubMed	583

Selection criteria

We have developed eligibility criteria for this study to ensure retrieval of relevant publications to answer our research question.

Inclusion criteria

Publications fulfilling the following criteria will be included:

- Peer reviewed journal articles.
- Studies presenting evidence on self-sampling interventions for STIs of interest for this research.
- Studies presenting evidence on self-sampling in women for STI diagnosis.
- Studies of all types of designs with relevant information.
- Studies that focus on types of self-collected specimens, acceptability and feasibility, and effectiveness of self-sampling.

Exclusion criteria

Publications that present evidence on the following will not be included:

- Studies that consist of self-sampling interventions for HIV only.
- Studies that present evidence of specimens for STI diagnosis collected by healthcare workers only.

In order to ensure that relevant articles are included in the review, data screening will occur in three stages. In the first stage, the PI will screen titles of the relevant studies in the chosen databases. An Endnote reference library will be created using EndNote X9 and references of eligible articles will be exported to the library. All duplicate references will be deleted from Endnote library prior to abstract screening.

In the second stage, a second reviewer and the PI will screen the abstracts of the studies selected by the PI during the title screening. The PI and the second reviewer will conduct the abstract screening and extract relevant data independently. The reviewers will resolve any screening discrepancies that may arise during this stage of the screening process, among each other. Discrepancies in reviewers' responses will be discussed among the review team until a resolution is reached.

In the final stage of the screening process, the PI will select and search for all full articles that qualify for the full article screening stage. Assistance from University of KwaZulu-Natal library services will be sought in the search for full articles. Two reviewers including the PI, will conduct full article screening by using the eligibility criteria as a guide. A third reviewer will be invited to resolve any discrepancies following full article screening. The PRISMA-ScR flow chart will be used to present screening results (19).

Data Charting

A data charting tool was developed using google forms in order to characterize studies that fulfil inclusion criteria (Table 3). The review team will pilot the form using randomly selected included studies. The data charting tool will be updated accordingly on a continuous basis in order to ensure that relevant information is extracted from selected studies.

Table 3
Data Charting Tool

Author and date
Study Title
Aim
Study Design
Study Setting
Study Population
Type of Specimens
Type of Diagnostic Test
FDA approved
Key Findings
Significant Findings
Conclusion

Collating, summarizing and reporting findings

A content thematic analysis of the included studies using NVivo version 12 will be conducted and a narrative account of the findings from the included studies will be presented.

Quality appraisal

The MMAT-version 2018 will be used to appraise the studies that will be included in the review (15). The different types of studies will be grouped according to their respective study designs i.e. qualitative or quantitative, and appraised using relevant sections of the tool. The MMAT guidelines will be used to calculate the reliability, validity and relevance of each of the studies reviewed based on the percentage of criteria fulfilled. Studies that score 1–25% will be scored as low quality because they meet minimum criteria, studies that score 26–50% will be scored as average, studies that score 51–75% will be scored above average, and studies that meet all criteria will be scored 76–100%.

Discussion

Syndromic management of STIs, which is common practice in LMICs, addresses symptomatic infections. However, asymptomatic infections remain undiagnosed and untreated (10). Other barriers include stigmatization and judgement associated with issues of sexual ill-health (8, 20). Moreover, some women find invasive genital examinations embarrassing and uncomfortable and as such procrastinate seeking medical assistance, and as such risk disease complications (11, 14). Innovative interventions that alleviate such barriers are necessary to facilitate management of the STI pandemic. Self-sampling

interventions offer privacy and convenience, and thus have the ability to alleviate these barriers (14, 20). Self-sampling is ideal for screening of STIs (20). This scoping review aims to map evidence on the types of specimens and laboratory assays used in self-sampling interventions for STIs in women. Since research has shown that women, particularly those in LMICs, are disproportionately affected by this pandemic (21), this research will focus on STIs studies in women. Studies that include research on self-sampling interventions for STIs will be included. A study by Mashudu et al revealed that a large amount evidence of innovative interventions used to address HIV compared to other STIs in low-and-middle-income settings and other resource-limited settings (2). As such, in an effort to shift focus from HIV to other STIs, HIV will be excluded from this study and publications that include evidence on HIV infections and interventions will not be included in this review. This study will review evidence on self-sampling for STIs in women, and therefore publications that present evidence solely on specimens conventionally collected at healthcare facilities will be excluded.

It is anticipated that findings of this research will highlight gaps for research in addressing the global burden of STIs. This could assist policy makers and developers of diagnostic assays to develop innovative STI management interventions. Research findings will be published in a peer-review journal and presented at local and international conferences for STIs.

Abbreviations

STI – Sexually Transmitted Infections

HIV- Huma immunodeficiency Virus

LMIC – Low-and-Middle Income Countries

PI – Project Investigator

WHO –World health Organization

DoH – Department of Health

MMAT – Mixed Method Appraisal tool

PRISMA-ScR – Preferred Resulting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

PCC – Population Concept Context

Declarations

Ethics approval and consent to participate

This study does not involve human participants and therefore an application for exemption will be submitted to the ethics committee.

Consent for publication

Not applicable.

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Competing interests

The authors would like to declare that there are no competing interests.

Funding

We would like to thank the following institutions:

University of KwaZulu-Natal, and Mangosuthu University of Technology for their support and enabling access to resources used in preparing this protocol.

Authors' contributions

ZJ and TPMT conceived and designed the protocol. ZJ wrote the original draft manuscript. TPMT supervised, reviewed and edited the draft manuscript. RP reviewed and edited the draft manuscript. All authors approved the final manuscript.

Acknowledgements

Not applicable.

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Supplementary Files

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- PRISMAPchecklist.pdf