The Effect of Three Methods of Delivering Clinic-Based STI Training on STI Syndromic Management in South Africa

A Cluster Randomized, Controlled Trial

October 2015

PEPFAR

DEPARTMENT OF GLOBAL HEALTH
UNIVERSITY of WASHINGTON

I-TECH
International Training & Education Center for Health

health
Department: Health
REPUBLIC OF SOUTH AFRICA

Acknowledgments

I-TECH would like to express its gratitude to the following individuals:

South Africa National Department of Health
Ms. Eva Marumo, Ms. Lufuno Malala, Ms. Thuthukile Mabuella, and Ms. Thato Chidarikire at the South Africa National Department of Health STI sub-directorate

North West Department of Health
Provincial DOH, Bojanala District DOH- Dr. J.M. Tumbo, Moretele (Ms. Mangezi), Madibeng (Ms. Leseto) and Rustenburg (Mr. Tlhowe)DOH Sub-Districts and the Clinic Managers from Bosplaas, Maubane, Leseding, Lefathleng, Makapanstad, Lebotloane, Sediane, Tladistad, Kutlwanong, Ngobi, Mmakaunyane, Ga-Motla, Rekopantswe, Mphoyabatho, Mogogelo, Classic, Gateway, Boitekong, Sunrise, Karlienpark, Kana, Thekwane, Mfidikwe, Anna Legoale, Hartebeesfontein, Monakato, Luka, Chaneng, Phatsima, Mothutlung, Broederstroom, Rabokala, Madidi, Jericho, Fafung, Maboloka, Lethlabile, Segwaelane, Bapong and Wonderkop Clinics, and all of the nurses who willingly participated.

Howard University
Tamara Owens for developing the actor cases and providing training for the actors.

Morgeez Casting Agency
And their talented actors who served as standardized patients.

University of Washington
Marcia Weaver, Principal Investigator
King Holmes, Sean Galagan, Jennifer Gilvydis, Gabrielle O'Malley, Harnik Gulati, Linda Campbell, Elizabeth M. Frick, Anya Nartker, and Liz Scott.

I-TECH South Africa
Erushka Pillay, Suzanne Jed, Evasen Naidoo, Julia DeKadt, Gladys Makati Mema, Shumani Makatu, Fulufhelo Malamatsho, Sipho Mazibuko, Mary-Jane Ratlagang, Lebogang Isidoro, Jessica Grignon, and Albert Bakor.

Funding

The developers of REDCap were supported by grant UL1 RR025014 from National Center for Research Resources of the US Department of Health and Human Services, National Institutes of Health. This information/content and conclusions are those of the author(s) and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.

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Abstract

Introduction

The South African National Department of Health (NDOH) updated the national guidelines for syndromic management of sexually transmitted infections (STI) in 2009. However, training on appropriate STI syndromic management continues to be a need, and the NDOH requested assistance with training health care workers. I-TECH designed six STI modules for training at primary health care clinics (PHCs), and conducted a cluster randomized trial to test the effect of the training and compare three training delivery methods: 1) lecture-based classroom; 2) online/CD-ROM; and 3) paper-based distance learning.

Methods

Forty PHCs were randomly assigned to four arms, with 10 clinics per delivery method and a delayed intervention arm that served as a control. Clinicians participated in on-site training on two modules per week for three weeks. Three or four actors serving as unannounced Standardized Patients (SPs) visited each of the clinics pre- and post-training. Male actors reported symptoms of male urethritis syndrome and female actors reported symptoms of vaginal discharge syndrome. The quality of STI management was measured by the number of five key STI management items completed during an SP encounter. STI knowledge was measured using case-based tests on each module.

Results

An average of 31% of clinicians from each PHC attended the beginning of each module. Participation was lower in the online/CD-ROM arm (25%) compared to the paper-based distance learning (38%) and lecture-based classroom (31%) arms.

During pre-training SP encounters (n=128), clinicians prescribed correct medications to 30.3% of SPs, offered an HIV test to 52.2%, provided male and/or female condoms to 22.2%, gave partner notification slips to 29.3%, and offered genital exams to 39.4%. Post training (n=131) there was no change in the number of STI tasks completed in the control arm and a 11% increase in the training arms (Relative Risk (RR)=1.11, 95% CI=0.86, 1.44). Across delivery arms, there was a 26% increase (RRR=1.26, 95% CI=0.77, 2.06) associated with the lecture-based classroom arm, 17% increase (RRR=1.17, 95% CI=0.59, 2.28) with paper-based distance learning, and a 13% decrease (RRR=0.87, 95% CI=0.40, 1.90) with online/CD-ROM relative to the control. None of these changes were statistically significant.

Average STI knowledge test scores increased from 52.5% pre-test to 65.7% post-test ($p<0.001$) when all delivery methods were combined. Comparing delivery methods, the increase was greatest for the lecture-based classroom arm.

Discussion

The clinic-level design was based on 100% participation in training, with the expectation that any clinician who treated a SP post training would reflect the effects of the training program. However, given the low levels of training participation, the SP encounters were not necessarily with the clinicians who participated in the training. Multiple factors are hypothesized as leading to the low training attendance, including low staffing levels, high clinic patient volumes, and conflicting priorities. Additionally, the computer and paper-based training methods were conducted on site rather than maximizing their strengths as distance-based learning methodologies.

While STI knowledge test scores increased, systemic challenges such as low rates of condom and partner-notification slip provision, as well as medication stock outs may have led to difficulties in implementing this knowledge. Improvements were noted among the didactic training participants in areas where they could implement learning without systemic support, notably in offering HIV tests. Systemic issues affect delivery of services, regardless of training or clinician knowledge, highlighting the importance of a comprehensive approach to improving STI services, rather than providing training in isolation.

Conclusion

The results showed an improvement in STI management for two of the three training delivery methods, specifically in areas in which the nurses could effect change without systemic intervention. Lessons learned include challenges related to provision of on-site facility-based training, the necessity of systemic intervention to support implementation of knowledge gained during

I. Introduction

Syndromic management for the diagnosis and treatment of sexually transmitted infections (STI) in primary care settings is recommended and widely utilized in many African countries.[i, ii, iii, iv, vvi, vii, viii, ix] In practice, syndromic management of STIs is a presumptive diagnosis of STIs based on symptoms and easily recognized signs of infection and is typically directed by national treatment protocols.[x] National protocols are regularly updated based on microbiological studies, as the prevalence of etiologic agents and treatment resistance profiles for STIs change. For example, the South African National Department of Health (NDOH) updated the national STI guidelines in 2009 to reflect changing gonorrhea resistance profiles and to add acyclovir as part of first-line therapy for genital ulcer syndrome management.[xi]

The NDOH sought to train health professionals on STIs to meet one of the objectives of their HIV/AIDS and STI Strategic Plan for South Africa 2007-2011,[xii] as well as update clinicians on the revised national guidelines. The NDOH supported a decentralized approach to in-service training, implemented at the clinic level, such as the educational outreach of the Practical Approach to Lung Health in South Africa (PALSA)[xiii] and for the Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) intervention.[xiv] The approach builds capacity among doctors and nurses, and minimizes absenteeism due to training. The International Training & Education Center for Health (I-TECH) worked with the NDOH to develop three clinic-based training delivery methods to improve STI diagnosis and treatment. The three training delivery methods were: 1) lecture-based classroom; 2) online/CD-ROM; and 3) paper-based distance learning.

Several articles have reported on the effectiveness of off-site STI syndromic management training programs[ix, xv, xvi, xvii] but less is known about the effectiveness of clinic-based STI training programs. To compare the effectiveness of the three delivery methods, 40 primary health care clinics (PHCs) in the North West Province were randomly assigned to one of four arms, one for each delivery method and a delayed implementation arm that served as a control during the trial. The effectiveness of the delivery methods were compared using unannounced standardized patient (SP) encounters.

The results of the comparisons are reported below. The primary hypothesis was that the pre/post change in STI management as measured by SP encounters would be statistically significantly greater at clinics where STI training occurred relative to the control arm. The two secondary hypotheses were:

- The pre/post change in STI management as measured by SP encounters would be statistically significantly lower at the clinics in the online/CD-ROM and paper-based distance learning arms relative to lecture-based classroom arm;
- STI knowledge as measured by a pre/post test completed by training participants would be statistically significantly higher post training than pre training.

II. Methods

Trial Design

The primary hypothesis was tested with a cluster randomized trial to compare the pre/post change in the STI tasks completed between the intervention and control arms. The same design was used for the comparison between online/CD-ROM and paper-based distance-learning arms relative to the lecture-based classroom arm.

The secondary hypotheses about STI knowledge was tested with a pre/post comparison of the average test scores at each PHC. Clinicians at the clinics in the control arm did not take these tests.

Changes to Trial Design

The trial was designed with two sets of post-training SP encounters: one month and five months after training. The second set of post-training encounters was cancelled.

Sites

Forty stationary PHCs in the Bojanala Platinum district of the Northwest province were selected to participate in the trial. A PHC varies in size from two to 33 assigned clinicians and 40 to 230 patients per day. Two or three PHCs in each sub-district provide 24-hour services, while most operate fewer hours per day and days per week, generally Monday to Friday, 7:30 am to 4 pm. The DOH District Management Team selected three subdistricts for the trial: Madibeng, Moretele, and Rustenberg. They purposively selected the 40 clinics with perceived gaps in STI management for the trial. Clinics that were national STI clinical surveillance sites (CSS) were excluded.

Participants

The training program participants were the nurses assigned to the clinics.

Training

I-TECH developed a six-module STI diagnosis and treatment training program. The learning objectives for each module are presented in Table 1. Each module was designed to take about one hour to complete. The modules were based on the South African national guidelines, including the 2009 update, and were developed to comply with I-TECH clinical and training standards. The six modules were packaged in three different delivery methods as explained above. The online/CD-ROM modules are available at http://edgh.uw.edu/series/sexually-transmitted-infections.

The time allocated to training was the same for all three delivery methods, and all trainings were provided at the facility site after working with the clinic manager to schedule the trainings. For the lecture-based classroom arm, an I-TECH trainer traveled to each clinic once a week for three weeks to teach two modules per week. Participants were also provided with the handouts for these didactic modules.

For the online/CD-ROM arm, an I-TECH team member visited each clinic weekly for three weeks to bring computers and provide assistance with navigating the online/CD-ROM modules. Participants could use the computers for as long as they needed each week to complete two modules, which was generally two or three hours. Similarly, an I-TECH team visited each clinic weekly for three weeks to give participants two paper-based modules for participants to complete during the two-hour visit. Participants kept the paper-based materials, which they could read later, but the STI knowledge tests were only collected during the visits.

Additionally, all participants received a printed version of the Clinical Resource Guide, which includes the South Africa STI syndromic guideline algorithms.

Table 1. Overview of STI Curriculum and Learning Objectives

Module	Topics
1	STI Introduction and Patient History • Review the epidemiology of Sexually Transmitted Infections (STI) • Discuss characteristics of a sensitive patient encounter for STIs • Describe the importance of patient history to making an accurate STI diagnosis • List the most important patient history questions for a STI screen or complaint
2	STI Physical Exam and Counselling • Review importance of a physical exam to making the appropriate STI diagnosis • Discuss elements of both a male and female physical exam • Describe counselling topics related to STIs and how to discuss them sensitively
3	Male Urethritis Syndrome (MUS) • Identify the primary symptoms related to MUS • List the most important patient history questions for an STI visit • Ask questions in a manner that will elicit the responses needed • Accurately utilize the NDOH MUS syndromic algorithm • Recognize signs and symptoms that require urgent referral • Describe a targeted physical exam for MUS
4	Vaginal Discharge Syndrome (VDS) • Identify the primary symptoms related to VDS • List the most important patient history questions for a VDS visit • Describe a targeted physical exam for VDS • Ask questions in a manner that will elicit the responses needed • Accurately utilize the NDOH STI syndromic algorithm for VDS • Discuss appropriate approach to caring for children with suspected child abuse
5	Genital Ulcer Syndrome (GUS) • Identify the symptoms related to GUS • List the most important patient history questions for a GUS visit • Ask questions in a manner that will elicit the responses needed • Describe a targeted physical exam for GUS • Accurately utilize the NDOH GUS syndromic algorithm • Recognize signs and symptoms that require referral
6	Lower Abdominal Pain (LAP) • Identify the primary symptoms related to LAP • List the most important patient history questions for a LAP visit • Ask questions in a manner that will elicit the responses needed • Accurately utilize the NDOH LAP syndromic algorithm • Recognize signs and symptoms that require referral • Describe a targeted physical exam for LAP • Discuss appropriate approach to caring for the elderly

Outcomes

The outcome measure for the primary hypothesis was the number of STI management tasks completed during an unannounced SP encounter. SPs are widely used in medical and nursing education in the United States[xviii] and unannounced SPs are considered the gold standard for measuring the quality of care.[xix] Unannounced SPs have been used to measure the outcomes of several interventions for syndromic management of STIs in pharmacies[xx xxi] and clinics.[ix xxi xxii xxiii] Professional actors who were fluent in Setswana attended a three-day SP training and one-day pilot in September 2013. The pilot clinics were not included in the trial. Actresses were trained on a script for Vaginal Discharge Syndrome (VDS) that was based on a standard script but adapted to the actress's age and other personal characteristics. Similarly, male actors had scripts for Male Urethritis Syndrome (MUS). The following key elements of the script were identical for all actors of the same gender: presentation and emotional tone; history of present illness; past medical history; HIV and TB status; and medications. The standard scripts for VDS and MUS are in Appendices B and C, respectively.

After the clinic visits, the SPs answered five questions about the STI tasks completed by the clinicians:

1) Were you offered correct medications by the health care worker (HCW)?
2) Were you offered an HIV test?
3) Were you provided with male and/or female condoms?
4) Were you given partner notification slips?
5) Were you offered a genital exam?

The SPs' reports were verified with two sources of physical evidence that were saved in an envelope after the visits: 1) condoms provided; 2) medication slips. According to the Provincial Department of Health procedures, the SPs did not remove drugs from the clinics. At the point during the visit when a clinician would have dispensed the appropriate medications, the SP disclosed his/her identity and asked the clinician to record the drugs s/he prescribed on the medication slip, including the drug name, dose, mode of administration, frequency, and duration. All five elements of the medication had to be correct for medication dispensing to be considered correct. The correct treatment for a male SP was two drugs: 1) Cefixime, oral, 400 mg single dose; and 2) Doxycycline, oral, 100 mg twice daily for seven days. The correct treatment for a female SP was three drugs: 1) Cefixime, oral, 400 mg single dose; 2) Doxycycline, oral, 100 mg twice daily for seven days; and 3) metronidazole, 2 g immediately as a single dose.

Although each SP script was based on the same standard script, it was possible that the quality of acting varied across SPs. To prevent any potential bias, visits by specific SPs were balanced across study arms in each time period. No SP visited a particular clinic more than once, and pairing with other SPs was varied. The PHCs in each arm were randomly allocated to these grouping of SPs.

The secondary hypothesis relating to STI knowledge was measured by pre- and post-tests accompanying each module, each comprising five case-based, multiple choice questions. An exception was Module 4, which had four questions, because one of the questions was withdrawn. The pre- and post-test for each module contained the same questions but ordered differently.

Sample size calculation

Sample size was 10 PHCs per arm, for a total of 40 PHCs with 10 SP visits per facility. Calculations were conducted to estimate the power of a test for post-training differences across arms in the percentage of SPs with correct medications where correct medication was coded as a dichotomous pass/fail variable. The calculations were based on two time periods with five SP visits per time period and post-training percentages of 35% for the control or delayed intervention arm, 75% for the lecture-based classroom arm, and 60% for the other two delivery methods. Under three alternative assumptions for random effects of facilities and SPs (the standard deviation of the normal distribution used to generate random effects set to zero, .31, and .69) and 0.05 level of significance, the estimated power was at least 0.8.

Randomization

Forty PHC were randomized to four parallel arms (1:1:1:1 balance): Arm 1 was control or delayed implementation; Arm 2 was lecture-based classroom;

Arm 3 was online/CD-ROM; and Arm 4 was paper-based distance learning. Sites were randomized in strata to control for two characteristics of PHC: 1) subdistrict; and 2) and operating hours, meaning 24-hour services versus fewer hours.

Beginning with a list of the 40 clinics, a random number was generated between zero and one ("random1") and the list was sorted by that number. Each clinic was assigned a "facility ID" from one to 40 based on the order of random1. Then the list of clinics was sorted by the strata (operating hours and subdistrict) and facility ID. An intervention number from one to four was assigned to each clinic, beginning with number one for the 24-hour clinic in Madibeng with the lowest facility id. To allocate interventions to arms, a second random number was generated and the list of four interventions was sorted by that number.

The randomization was conducted on September 30, 2014, before the pre-training SP visits and knowledge tests.

Blinding

The research staff and the HCWs seen by SPs were not blinded during the data collection or the interventions.

Data management

A research coordinator or research assistant met each SP after each encounter to record the answers to the five questions on an SP Encounter Form, and verify the responses with the contents of the envelope. The research coordinator also conducted a debriefing and made notes on the SPs' experience. Please see Appendix C for these data collection tools. Data from the SP Encounter Form, Medication Slip, and SP Debriefing Questionnaire were entered using REDCap Software, Version 5.8.2© (Vanderbilt University, Nashville TN) and verified by a second individual who compared the entered data against the original paper forms and corrected where applicable. All medication data were checked by a clinician for accuracy. The total STI knowledge test scores for each module, time period, and clinic were entered on a Microsoft Excel® spreadsheet (Microsoft Corporation, Redmond, WA).

Statistical analysis

Descriptive statistics compared participation in the training program and the characteristics of clinicians across arms. The primary hypothesis was tested with the post/pre ratio of the number of tasks completed during SP encounters in the training arms relative to Arm 1, which served as a control (see below). The STI knowledge test scores were compared pre/post with a two-sample t-test. All analyses were completed with Stata® version 11 (Statacorp, 2009 College Station, TX).

Complete cases of SP encounters were analyzed as binomial experiments. We used a generalized linear model for the proportion of five tasks completed with main effects for arms, time period and their interaction, and controlling for the gender of the SP. The coefficient for arm was the ratio of STI tasks completed before training in the training arm to the control arm or relative risk (RR). The coefficient for Post was the RR of STI tasks completed post/pre in the control arm. The coefficient for Post*Arm was the ratio of RR (RRR) of the post/pre-change in the training program arm relative to the post/pre-change in the control arm. The analysis used a model with a Poisson family and log link to estimate the RR. All regression analyses were clustered on the clinic with robust standard errors to adjust for using the Poisson instead of the binomial family. Results are presented as RR with 95% confidence intervals (95% CI).

A sensitivity analysis was conducted that controlled for clinic operating hours. Another sensitivity analysis was conducted in which incomplete visits were coded as tasks not completed, and all SP encounters were included in this analysis.

The comparison of STI knowledge test scores was conducted with complete cases, where the unit of analysis was the facility-module. A complete case meant that at least one person at the clinic completed the pretest for a module and one person completed the post test. A sensitivity analysis was conducted in which an average score of zero was assigned to facility-modules when no one at a clinic completed a test for the module and all facility-modules were included in the analysis.

Human subjects review

The trial protocol was reviewed and approved by the South African Human Sciences Research Committee (REC 1/22/08/12). Following District and Sub-District Department of Health information sessions and approvals, all clinic managers were provided thorough information and asked to participate in an informed consent process on behalf of the clinic. If s/he agreed to participate in the trial, each clinician assigned to the PHC was also invited to participate in an informed consent process. The clinic manager and clinicians provided written informed consent to participate in the unannounced SP visits and the training program. The University of Washington Human Subjects Division determined that this study did not meet the regulatory definition of research under 45 CFR 46.102(d).

III. Results

Participant Flow

Figure 1 reports the flow for PHC and training participants. Among the 40 PHC, 11 were in Madibeng subdistrict, 15 in Moretele, and 14 in Rustenburg. Nine of the clinics provided 24-hour services and the rest operated fewer hours. One clinic manager in Arm 3 (Online/CD-ROM) refused to allow the training intervention after having initially consented due to staffing concerns but did allow the post-training SP encounters to occur. Pre- and post-tests conducted for each module were utilized to measure the number of clinicians initiating and completing them. An average of 31% of clinicians who consented to participate completed the pretest and 27% completed the posttest. Table 2 reports the number and percentage of participants for each arm and module. As shown, participation was lowest in the online/CD-ROM arm, which also had the largest participation gap between pretest (25%) and posttest (17%). Figure 2 reports the percentage of participants by clinic operating hours. As shown, participation on the pretest was 17% at the clinics with 24-hour services and 40% at other clinics.

The total number of SP encounters and the number of visits by individual SPs was similar across arms because of their balanced distribution. Thirty-two incomplete visits were not included in the main analysis. An incomplete visit could occur when the SP was not seen by a clinician despite waiting all day, or when the clinician did not complete the encounter. The SPs were instructed to refuse to provide specimens for HIV and urine tests and to refuse a genital examination; some clinicians did not complete the encounter in the absence of these test results or the examination. The reasons for incomplete visits by arm are reported in Figure 1.

Two actors (male 1 and female E) who visited the PHCs before training were not available after training. They were replaced by two actors (male 6 and female F) who used the same scripts as the actors they replaced, and whose visits were balanced across arms.

Figure 1. CONSORT Flow Diagram

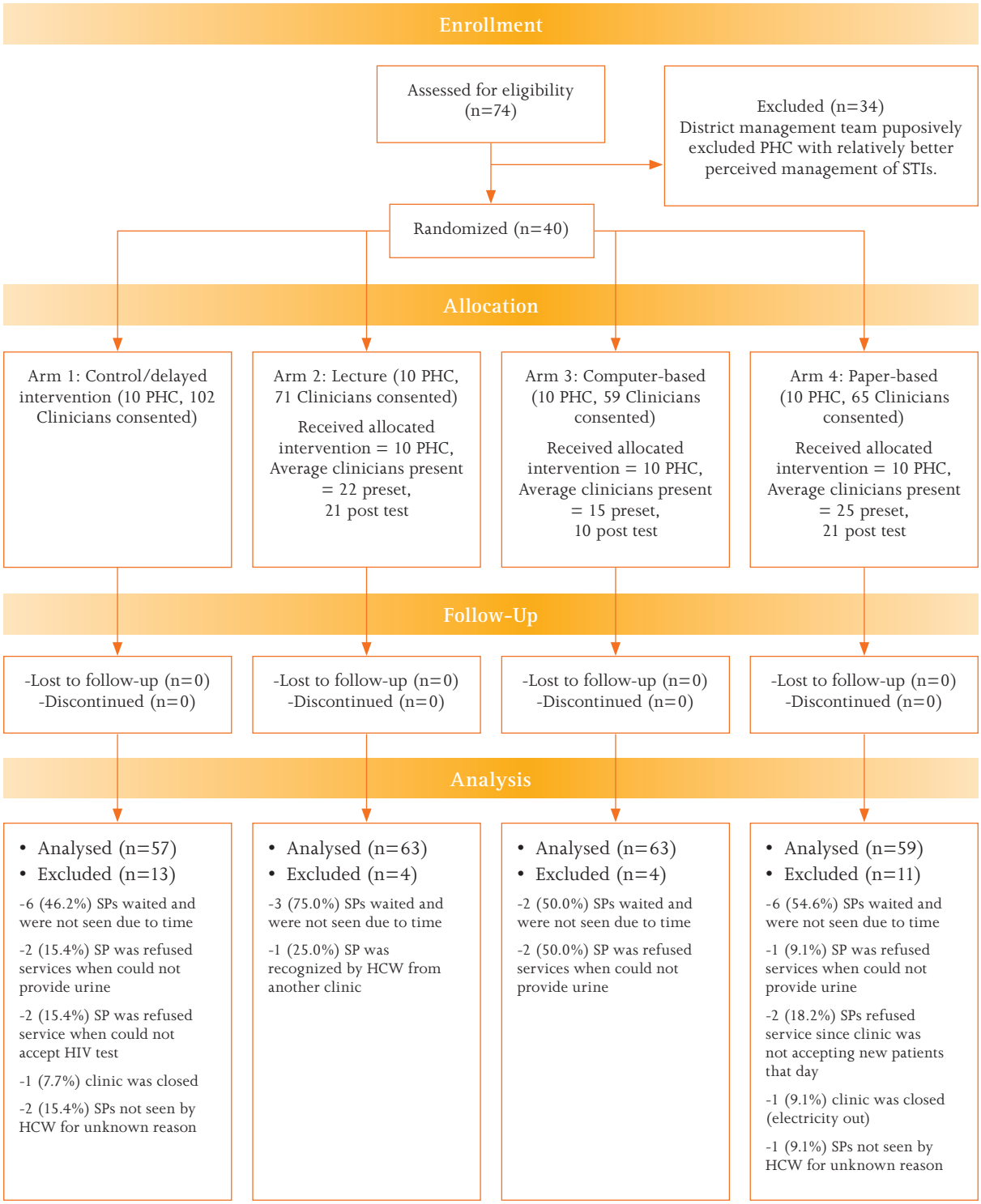
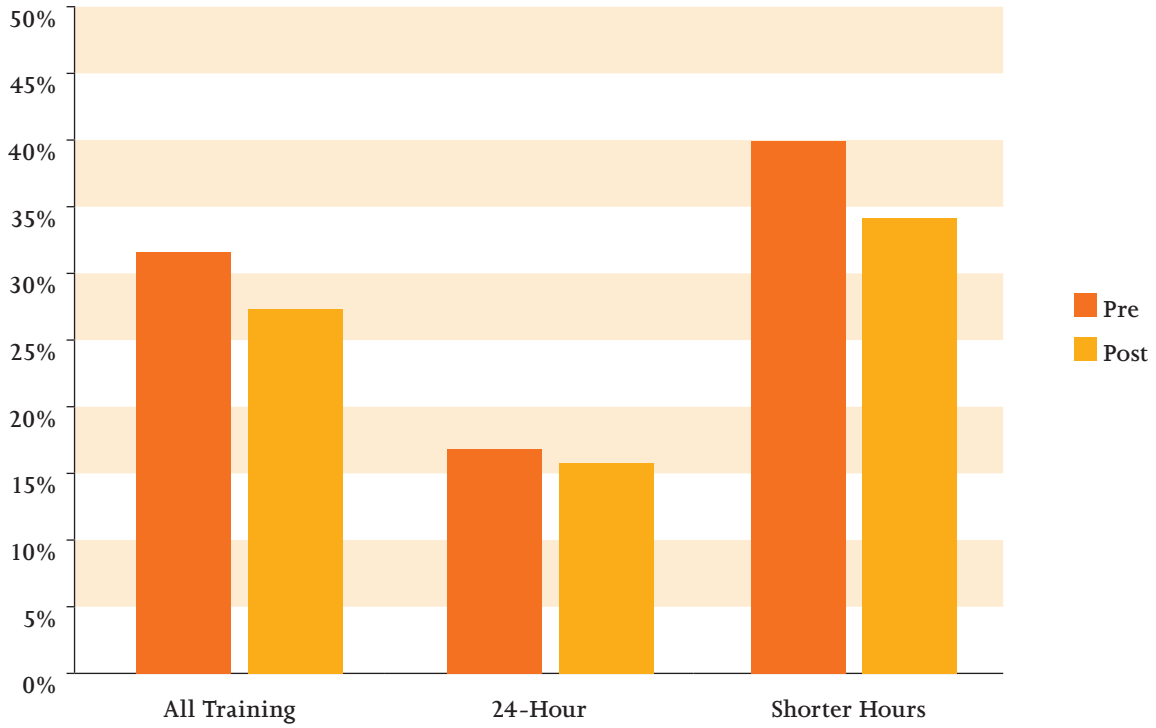


Table 2 Comparison of Clinicians Consented, Pretests Completed and Post Tests Completed Across Arms

	All Delivery Methods Combined N (%)		Lecture-Based N (%)		Online or CD-ROM Training N (%)		Paper-Based Training N (%)	
Clinicians Consented	195		71		59		65	
Module	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	82 (42.1)	70 (35.9)	26 (36.6)	24 (33.8)	20 (33.9)	16 (27.1)	36 (55.4)	30 (46.2)
2	78 (40.0)	61 (31.3)	26 (36.6)	25 (35.2)	20 (33.9)	9 (15.3)	32 (49.2)	27 (41.5)
3	62 (31.8)	58 (29.7)	29 (40.8)	27 (28.0)	16 (27.1)	13 (22.0)	17 (26.2)	18 (27.7)
4	58 (29.7)	53 (27.2)	30 (42.3)	27 (28.0)	9 (15.3)	6 (10.2)	19 (29.2)	20 (30.8)
5	45 (23.1)	40 (20.5)	12 (16.9)	12 (16.9)	10 (16.9)	8 (13.6)	23 (35.4)	20 (30.8)
6	43 (22.1)	38 (19.5)	11 (15.5)	11 (15.5)	12 (20.3)	9 (15.3)	20 (30.8)	18 (27.7)
Average	61 (31.5)	53 (27.5)	22 (31.5)	21 (29.6)	15 (24.6)	10 (17.2)	25 (37.7)	22 (34.1)

Figure 2. Tests completed as percentage of clinicians consented by facility operating hours



Stakeholder Engagement & Recruitment

Following funder and National Department of Health input and approval, the I-TECH program manager met with the District Management Team in May 2013 to identify the sub-districts for the trial. Subsequent meetings were held with the Madibeng sub-district in June 2013, Moretele in May 2013, and Rustenburg in September 2013, during which the management teams purposively selected the clinics that would be invited to participate. Clinic managers and clinicians were recruited and consented from August to October 2013, which was before pre-training for unannounced SP visits.

In a few cases, a clinician started work at the PHC or was temporarily assigned to it after the recruitment period. When the SP disclosed his/her identity at the end of the encounter, s/he showed the consent form to the clinician. If the clinician was not familiar with the consent form, the research coordinator or research assistant conducted the informed consent process with the clinician on the same day as the encounter. All SP data were removed for any clinician declining to consent.

For any clinics where any clinicians had declined to consent, a list of consented clinicians was provided to the actor visiting the clinic on that day. If the actor encountered a clinician who had not consented, they politely excused themselves from the visit and returned on another day.

Following the assessment, stakeholder meetings were held with each Sub-District, the District, National Department of Health, and the funder, to provide results and discuss next steps. Given the low rate of training, overall, the didactic National Department of Health 3-day STI training was offered to all nurses from the participating clinics, in collaboration with the North West Provincial STI coordinator and the Regional Training Centre.

Description of Sample and Baseline Outcomes

The majority of the SP encounters were with female clinicians (93%), and all but two clinicians were nurses (99.2%). Please see Table 3 for these descriptive statistics. Fewer of the SP encounters were in Madibeng (26.6%) than Moretele (36.5%) and Rustenburg (36.9%) because fewer of the clinics selected were in that sub-district.

Before training, the average number of STI tasks completed correctly was 1.63 (median=1, Interquartile range: 0, 3) among completed visits. As shown in Table 4, during completed pre-training visits, clinicians gave correct medications to 30.3% of SPs, offered an HIV test to 51.2%, provided male and/or female condoms to 22.2%, gave partner notification slips to 29.3%, and offered genital exams to 39.4%.

Despite the random assignment of PHCs to arms, there were differences in the percentages of tasks completed across arms before training. The percentages of SPs offered an HIV test and given condoms were higher in the control arm. In the lecture-based classroom arm, the percentage of SPs given partner notification slips was higher but the percentage offered a genital exam. Consequently, a simple comparison across arms post training would not accurately reflect the effects of the training delivery methods. The pre/post difference-in-difference analysis was needed.

Wait Time

Waiting time for the SPs to be seen at the clinic varied between 56 minutes and 13 hours pre training, and 50 minutes to 8.9 hours post training. The median wait time was 4.5 hours both pre and post training, and the average wait time was 4.7 hours at both times.

Table 3. Characteristics of Sample

Training delivery method					
	Arm 1	Arm 2	Arm 3	Arm 4	
	Control N (%)	Lecture N (%)	Online/ CD-ROM N (%)	Paper-Based N (%)	Total N (%)
Sample size	**70**	**67**	**67**	**70**	**274**
*Gender of Health Care Professional**					
Female	56 (94.9)	57 (90.5)	62 (98.4)	52 (88.1)	227 (93.0)
Male	3 (5.1)	6 (9.5)	1 (1.6)	7 (11.9)	17 (7.0)
*Profession**					
Nurse	59 (100.0)	62 (98.4)	63 (100.0)	58 (98.3)	242 (99.2)
Doctor	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.4)
Unknown	0 (0.0)	1 (1.6)	0 (0.0)	0 (0.0)	1 (0.4)
District					
Madibeng	20 (28.6)	20 (29.9)	12 (17.9)	21 (30.0)	73 (26.6)
Moretele	25 (35.7)	28 (41.8)	27 (40.3)	20 (28.6)	100 (36.5)
Rustenburg	25 (35.7)	19 (28.4)	28 (41.8)	29 (41.4)	101 (36.9)
SP visit completed	57 (81.4)	63 (94.0)	63 (94.0)	59 (84.3)	242 (88.3)
SP visit not possible	13 (18.6)	4(6.0)	4 (6.0)	11 (15.7)	32 (11.7)

SP Results

After training, the average number of STI tasks completed correctly was 1.73 (median=2, Inter-quartile range: 0, 3) among completed visits. As shown in Table 4, among these completed visits, clinicians gave correct medications to 31.5% of SPs, offered an HIV test to 59.3%, provided male and/or female condoms to 30.2%, gave partner notification slips to 27.9%, and offered genital exams to 43.0%.

There was no change in the number of STI tasks completed in the control arm, as shown by the ratio of post/pre relative risk of 1.00 (95% CI= 0.65, 1.55) in the top half of Table 5. When all training arms were combined, there was an 11% increase in the number of STI tasks completed (RR=1.11, 95% CI=0.86, 1.44), which was also an 11% increase when compared to the control arm in the ratio of relative risks (RRR=1.11, 95% CI=0.67, 1.84).

Looking at the effects across delivery arms, there was a 26% increase in STI tasks completed in the lecture-based classroom arm, a 17% increase in the paper-based distance-learning arm, and a 13% decrease in the online/CD-ROM arm. The results were similar when compared to the control arm. There was a 26% increase (RRR=1.26, 95% CI=0.77, 2.06) in the lecture-based classroom arm, 17% increase (RRR=1.17, 95% CI=0.59, 2.28) in the paper-based distance-learning arm, and a 13% decrease

(RRR=0.87, 95% CI=0.40, 1.90) in the online/CD-ROM arm. None of these changes were statistically significant.

Focusing on the medications, the clinician incorrectly prescribed ciprofloxacin instead of cefixime for 35 of 78 (45%) men with incorrect medications. The percentage of males prescribed ciprofloxacin was the same pre and post training. In contrast, the clinician incorrectly prescribed ciprofloxacin for four of 88 (4%) women with incorrect medications.

The results of comparing the effects of online/CD-ROM and paper-based distance-learning arms relative to lecture-based classroom arm were consistent with main results, as shown in the bottom half of Table 6. The post/pre ratios of the number of STI tasks completed was lower for online/CD-ROM and paper-based distance-learning arms than lecture-based classroom arm.

In sensitivity analyses, the results were the same when controlling for clinic operating hours. Clinics with 24-hour services were associated with a 16% decrease in the number of STI tasks completed (RR=0.84, 95% CI=0.58, 1.21). The results were substantially the same in the analysis of all SP encounters in which the incomplete visits were coded as tasks that were not completed.

There were a few notable changes between pre and post training in the performance of certain tasks within arms, and particularly in the lecture arm, as shown in Table 4. In the lecture arm, offering of HIV tests increased from 54.6% to 80%, condom provision rose from 27.3% to 40%, and genital exam offers rose from 30.3% to 50%; however, provision of partner notification slips fell from 48.5% to 40%. Changes in other arms were generally more limited. In the paper-based arm, there were small increases in HIV test offers, condom provision and provision of partner notification slips, but a small decrease in offers of genital exams. In the online arm, there were small decreases in the number of HIV tests offered and provision of partner notification slips, while completion of other tasks remained roughly the same. In the control arm, condom provision fell slightly, while provision of partner notification slips and offers of genital exams increased slightly, resulting in overall task completion remaining unchanged.

While all analysis was performed across all facilities, a breakdown of changes in task completion from pre to post training by sub-district is also provided in Table 5. While none of these changes were statistically significant, performance in Rustenburg did appear to improve more than in other sub-districts but this is likely because baseline performance was at a much lower level than in the other two sub-districts.

STI Knowledge Results

When all training delivery methods were combined, average test scores increased from 52.5% pretest to 65.7% posttest, an absolute increase of 13.2% ($p<0.001$)(see in Table 7). The increases ranged from 4.8% to 16.6% across modules and were statistically significant for five of six modules. Module 4 on vaginal discharge syndrome, for which the increase was not statistically significant, was the exception.

Looking across the delivery arms, the increase was greatest for the lecture-based classroom arm; the average test scores increased from 49.2% pretest to 67.7% posttest, an absolute increase of 18.5% ($p<0.001$). The increases were statistically significant for five of six modules. Average test scores increased in the online/CD ROM arm from 48.5% pretest to 62.1% posttest, an absolute increase of 13.6% ($p=0.004$). The increases were statistically significant for two modules. Average test scores in the paper-based distance-learning arm increased from 57.9% pretest to 65.1% posttest, an absolute 7.2% increase ($p=0.004$). The results were statistically significant for one module.

In sensitivity analyses, an average score of zero was assigned to facility-modules when no one at a clinic completed a test for the module. The results were substantially the same as the complete cases analysis but the average test scores were lower and fewer differences were statistically significant. This was especially true for the posttest scores, where scores were missing for 37 facility-modules, compared to the pretest, where scores were missing for 10 facility-modules.

Table 4. Bivariate Comparison of STI Care by Training Delivery Method: All Sub-Districts

	Training Delivery Method				
	Arm 1	Arm 2	Arm 3	Arm 4	
	Control N (%)	Lecture N (%)	Online/ CD-ROM N (%)	Paper-Based N (%)	Total N (%)
STI Care Pre Training					
Sample size	**29**	**33**	**34**	**32**	**128**
Were you offered correct medications?	10 (34.5)	11 (33.3)	11 (32.4)	8 (25.0)	30 (30.3)
Were you offered an HIV test?	18 (62.1)	18 (54.6)	17 (50.0)	16 (50.0)	51 (51.2)
Were you provided with condoms?	13 (44.8)	9 (27.3)	6 (17.7)	7 (21.9)	22 (22.2)
Were you given partner notification slips?	10 (34.5)	16 (48.5)	7 (20.6)	6 (18.8)	29 (29.3)
Were you offered a genital exam?	11 (37.9)	10 (30.3)	14 (41.2)	15 (46.9)	39 (39.4)
STI Care Post Training					
Sample size	**28**	**30**	**29**	**27**	**114**
Were you offered correct medications?	9 (32.1)	10 (33.3)	9 (31.0)	8 (29.6)	27 (31.4)
Were you offered an HIV test?	17 (60.7)	24 (80.0)	10 (34.5)	17 (63.0)	51 (59.3)
Were you provided with condoms?	10 (35.7)	12 (40.0)	5 (17.2)	9 (33.3)	26 (30.2)
Were you given partner notification slips?	11 (39.3)	12 (40.0)	5 (17.2)	7 (25.9)	24 (27.9)
Were you offered a genital exam?	13 (46.4)	15 (50.0)	12 (41.4)	10 (37.0)	37 (43.0)

Table 5: Comparison of STI Care Pre and Post Training by Sub-District

MADIBENG				
Task	Total (N=68)*	Pre (N=37)	Post (N=31)	p=
Were you offered an HIV test?	43 (63.2)	23 (62.2)	20 (64.5)	0.841
Were you provided with condoms?	21 (30.9)	9 (24.3)	12 (38.7)	0.201
Were you given partner notification slips?	21 (30.9)	12 (32.4)	9 (29.0)	0.762
Were you offered a genital exam?	22 (32.4)	11 (29.7)	11 (35.5)	0.613
Were you offered correct medications by the HCW?	37 (24.3)	9 (24.3)	11 (35.5)	0.314

MORETELE				
Task	Total (N=97)*	Pre (N=52)	Post (N=45)	p=
Were you offered an HIV test?	67 (69.1)	36 (69.2)	31 (68.9)	0.971
Were you provided with condoms?	33 (34.0)	19 (36.5)	14 (31.1)	0.574
Were you given partner notification slips?	40 (41.2)	23 (44.2)	17 (37.8)	0.520
Were you offered a genital exam?	53 (54.6)	27 (51.9)	26 (57.8)	0.564
Were you offered correct medications by the HCW?	35 (36.1)	20 (38.5)	15 (33.3)	0.600

RUSTENBERG				
Task	Total (N=77)*	Pre (N=39)	Post (N=38)	p=
Were you offered an HIV test?	27 (35.1)	10 (25.6)	17 (44.7)	0.079
Were you provided with condoms?	17 (22.1)	7 (18.0)	10 (26.3)	0.376
Were you given partner notification slips?	13 (16.9)	4 (10.3)	9 (23.7)	0.116
Were you offered a genital exam?	25 (32.5)	12 (30.8)	13 (34.2)	0.747
Were you offered correct medications by the HCW?	21 (27.3)	11 (28.2)	10 (26.2)	0.600

Table 6. The Effect of STI Training on STI Care as Measured by Unannounced Standardized Patient Visits

	Training Method							
	Training (all methods combined)		Lecture		Online or CD-ROM Training		Paper-Based Training	
Results	RR (CI)	P-value	RR (CI)	P-value	RR (CI)	P-value	RR (CI)	P-value
Hypothesis 1								
Control (change pre/post)	1.00 (0.65, 1.55)	0.995						
Training (change pre/post)	1.11 (0.86, 1.44)	0.423						
Change training/ change control (RRR)	1.11 (0.67, 1.84)	0.684						
Hypothesis 2								
Control (change pre/post)			1.00 (0.65, 1.55)	0.995	1.00 (0.65, 1.55)	0.995	1.00 (0.65, 1.55)	0.995
Arm (change pre/post)			1.26 (0.99, 1.60)	0.058	0.87 (0.46, 1.66)	0.680	1.17 (0.70, 1.95)	0.560
Change Arm / change control (RRR)			1.26 (0.77, 2.06)	0.365	0.87 (0.40, 1.90)	0.730	1.16 (0.59, 2.28)	0.658
Hypothesis 3								
Arm 3 (change pre/post)					1.26 (0.99, 1.60)	0.058	1.26 (0.99, 1.60)	0.058
Arm (change pre/post)					0.87 (0.46, 1.66)	0.680	1.17 (0.70, 1.95)	0.560
Change Arm / change Arm 3 (RRR)					0.58 (0.31, 1.07)	0.080	0.78 (0.50, 1.21)	0.261

Table 7. Effect of STI Training on Case-Based Test Results

	Training (all methods combined)					Lecture				
Module	N	Pre	Post	Change	P-value	N	Pre	Post	Change	P-value
1	22	57.2%	71.1%	13.9% (7.1%, 20.7%)	<0.001	9	51.3%	78.7%	27.4% (20.5%, 34.2%)	<0.001
2	21	53.7%	65.5%	11.8% (3.9%, 19.8%)	0.006	9	52.1%	73.9%	21.7% (11.6%, 31.9%)	0.001
3	22	57.9%	75.7%	17.8% (9.6%, 26.0%)	<0.001	10	63.5%	77.3%	13.8% (1.3%, 26.2%)	0.034
4	20	56.8%	61.7%	4.8% (-2.8%, 12.5%)	0.200	10	49.7%	62.5%	12.8% (-0.1%, 25.7%)	0.051
5	19	46.0%	62.5%	16.6% (6.0%, 27.1%)	0.004	7	43.3%	61.9%	18.6% (-12.7%, 49.8%)	0.196
6	18	40.9%	54.7%	13.8% (2.5%, 25.1%)	0.019	7	27.6%	45.2%	17.6% (-4.1%, 39.3%)	0.094
Total	122	52.5%	65.7%	13.2% (9.8%, 16.5%)	<0.001	52	49.2%	67.7%	18.5% (13.1%, 23.9%)	<0.001

	Online or CD-ROM Training					Paper-Based Training				
Module	N	Pre	Post	Change	P-value	N	Pre	Post	Change	P-value
1	3	74.0%	63.3%	10.7% (-6.1%, 2.7%)	0.958	10	60.6%	63.3%	2.8% (-5.7%, 11.2%)	0.480
2	2	52.0%	52.0%	0.0% (-50.8%, 50.8%)	1.000	10	55.5%	60.8%	5.3% (-7.9%, 18.5%)	0.387
3	5	53.2%	74.7%	21.4% (6.3%, 36.4%)	0.017	7	53.1%	74.0%	21.0% (-1.8%, 43.7%)	0.065
4	3	63.2%	54.2%	-9.0 %(-32.4%, 14.3%)	0.238	7	64.3%	63.7%	-0.6% (-9.3%, 8.1%)	0.873
5	5	38.0%	58.0%	20.0% (2.4%, 37.6%)	0.034	7	54.3%	66.3%	12.1% (1.5%, 22.8%)	0.031
6	4	31.7%	53.8%	22.1% (-32.8%, 76.8%)	0.290	7	59.5%	64.8%	5.2% (-6.6%, 17.1%)	0.320
Total	22	48.5%	62.1%	13.6% (5.0%, 22.3%)	0.004	48	57.9%	65.1%	7.2% (2.5%, 11.9%)	0.004

IV. Discussion

Despite poor training attendance, two of the STI training program delivery methods were associated with increases in the number of STI tasks completed, albeit not statistically significantly: lecture-based classroom training and paper-based distance learning. Surprisingly, the online/CD-ROM training was associated with a decrease in the number of STI tasks completed but this effect was also not statistically significant. Also of note, there was no change observed in the control arm pre or post training.

Given the low level of attendance for training, it is possible an adequate training threshold was not attained to result in statistically significant changes in STI syndromic management. Participation in the training program overall was only 31%, and participation in the online/CD-ROM delivery method was only 25%. Multiple factors are hypothesized as leading to this low training attendance. Despite multiple attempts to schedule and reschedule trainings, trainers would often arrive on site to provide facility-based training only to find that few participants were available or that the training had been cancelled. Low staffing levels, high clinic patient volumes, and conflicting priorities likely led to these training challenges. Additionally, some clinicians may have been on leave or off duty during the trainings, as suggested by the relatively low participation at clinics with 24-hour services.

Furthermore, the assessment design was based on 100% participation in training, with the expectation that any clinician who treated an SP post training would reflect the effects of the training program. Due to low training levels, SP encounters were not necessarily with clinicians who had participated in the training, and due to restrictions imposed by both study design and ethical approval requirements, we were unable to track whether or not SPs were seen by clinicians who had received the training.

Due to the randomization of clinic sites to the various training methods, participants did not self-select their preferred training method. As a result, individuals with greater computer literacy or preferences for distance-learning modalities were not necessarily those completing the online/CD-ROM or paper-based trainings. Additionally, the online/CD-ROM training was completed on site as opposed to maximizing its utility as a distance learning tool. The online/CD-ROM training was anticipated to only take one hour per module; however, in reality, participants required two to three hours. We hypothesize this was due to participants' lack of familiarity with computer-based training. Unfortunately, as a result, some participants did not have the time necessary to complete the training. Since no incentives were provided to complete trainings, clinicians may not have been motivated to participate in the offered trainings.

Given the increase in STI knowledge test scores, one possible interpretation is that the training programs were effective among participants but were insufficient to affect systemic changes. During follow-up stakeholder engagement meetings, district-wide stock outs of medications, condoms, and partner notification slips were reported. These systemic issues may have made it difficult for clinicians to implement knowledge learned. Improvements in areas not requiring systemic support, such as offering HIV tests, were noted among the didactic training participants; however, systemic issues affect delivery of services, regardless of training or HCW knowledge, and highlight the importance of a comprehensive approach to improving STI services and not providing training in isolation.

Limitations

The main limitation of the trial was the smaller-than-anticipated number of SP encounters. SPs were unable to complete 32 visits due to clinic wait times and logistical challenges. Ten SP visits per facility were spread across three time periods instead of the two envisioned in the sample size calculations, and the third set of post-training encounters was cancelled. Further, significant differences across arms in the STI tasks completed before training required a difference-in-difference analysis, which had larger standard errors and less power than a simple comparison across arms. As discussed above, low training levels attained at the facilities probably also reduced the likelihood of the assessment finding statistically significant changes between the pre- and post-training periods.

The similarity of the scripts across SPs of the same gender may have contributed to some clinicians suspecting the SP's identity before s/he disclosed. During the debriefings, 11 SPs (4.5%) reported that the clinician suspected his/her identity. In these

cases, the clinicians may have performed at a higher standard than their normal practice; however, were that the case, even their best practice left room for improvement.

Generalizability

Although the lecture-based classroom and paper-based distance-learning methods were associated with increases in the number of STI tasks completed, statistical tests did not show that these results were generalizable. However, the pre/post relative risk for the lecture-based classroom arm showed a trend toward statistical significance. Given the small sample size, the results could be characterized as absence of evidence rather than evidence of an absence.[xxiv]

V. Recommendations

Evidence from other studies has demonstrated that the effects of online learning are comparable to classroom methods in general,[xxv] and that educational outreach interventions have been effective in South Africa.[xiii xiv] Both the paper-based and the online/CD-ROM content could be provided in the future with delivery methods that play to their strengths. For example, allowing participants to self-select their preferred training method and complete the training as time allows or over a longer period of time would theoretically improve training uptake. This could be highly advantageous, specifically in settings with multiple shifts or high staff turnover, or as an orientation to new staff.

We recommend that future online/CD-ROM trainings provide more opportunities for learner engagement. Ally (2004) proposes a model with four types of interaction for online learning: 1) learner-interface; 2) learner-content; 3) learner-support; and 4) learner-context.[xxvi] For the STI training, the learner-interface interaction was limited by brief access to the computers during the I-TECH onsite visits. The learner-content interface was provided by high quality videos. The learner-support interface was missing because there was no interaction with other participants or faculty, such as an online community. Although the training was conducted at a clinic, the learner-context interface, which means supporting the participants to apply what they learned in real life, could also have been strengthened.

Additionally, strengthening clinic systems could further support putting learning into practice. For example, Colvin et al. provided "syndrome packets" with correct antibiotics, 10 condoms, a partner notification card, and an information leaflet in addition to training,[xxiii] and the STRETCH intervention included a management team at the clinics, in addition to educational outreach and revised guidelines.[xiv]

Unannounced SP visits are considered the gold standard for measuring the quality of care, and the quality of STI care seen during this assessment was low—an average of 1.63 of five STI tasks were completed pre training, and only 1.73 post training. These results for 40 facilities in three sub-districts may extend throughout the Bojanala Platinum district, which has an HIV prevalence rate higher than the national average[xxvii] and a highly mobile population that ebbs and flows with work in the mines. Additional operational research to improve STI care, as well as training combined with initiatives to improve systems, is certainly warranted.

This initial research on delivering on-site training should inform the design of future studies to improve on-site training participation. Future trainings should maximize learner interactivity and training methodology to accommodate clinicians with different schedules and learning needs. This process also suggests drawing on SP visits and similar assessments to strengthen learning opportunities.[xviii] The SP encounters created a teachable moment for the clinicians. In the future, a similar approach could be utilized to train clinicians by building in constructive feedback sessions immediately following the visit.

VI. Conclusion

The trial represents a success in many dimensions: the consent procedures were faithfully executed; the SPs were expertly trained; and the complicated logistics of the SP visits were mastered. The results showed an improvement in STI management for two of the three training delivery methods, specifically in areas in which the nurses could affect change without systemic intervention. Lessons learned include challenges related to provision of on-site facility-based training, the necessity of systemic intervention to support implementation of knowledge gained during training, and the importance of maximizing the strengths of various training methodologies.

Appendix A:
Female Vaginal Discharge Syndrome Case Standard Script

Case Background Information

PRESENTING SYMPTOMS:	Vaginal Discharge for past seven days
ACTUAL DIAGNOSIS:	Vaginal Discharge Syndrome
DIFFERENTIAL DIAGNOSIS:	Lower Abdominal Pain, Idiopathic Vaginal Discharge, Urinary Tract Infection
CLINICAL CONSULTANT:	Suzanne Jed, MSN, FNP-BC
CASE AUTHORS:	Tamara Owens, Med, Suzanne Jed, MSN, FNP-BC, Erushka Pillay, MM, Marcia Weaver, PhD
PATIENT NAME:	Each SP will use birth name for authenticity of case portrayal
PATIENT DEMOGRAPHICS:	Age: 20-63 years old Sex: Female Race: As actual Height: Average Weight: Average

MATERIALS AND EQUIPMENT NEEDED

- ID Card
- Watch
- Cell phone

TERMINOLOGY

Case Writing Notes (CWN) – These notes are inserted throughout the case as directives on how to write future versions of the case. CWNs are intended for the case authors, not the SPs.

PROFILE

The patient is a 20- to 63-year-old female who has come to the clinic because of a vaginal discharge which she has been experiencing for the past four days.

CASE GOAL

The goal of this case is to assess the knowledge and skills of a healthcare provider related to Vaginal Discharge Syndrome.

CASE EVALUATION OBJECTIVES

1. Demonstrate appropriate diagnosis and treatment of Vaginal Discharge Syndrome.
2. Demonstrate knowledge and skill regarding issuance of appropriate partner notification slips and recommendation of condom use.
3. Demonstrate knowledge of importance of testing for HIV when an STI is diagnosed.

CASE SUMMARY

You are a 20- to 63-year-old female patient who is coming to the clinic with a complaint of vaginal discharge for the past four days. This is the first time you have been to this clinic.

Your challenge as the standardized patient (SP) is three-fold:

- To appropriately and accurately respond to questions related to the symptoms and medical history of this case;
- To accurately recall the encounter during the debriefing session;
- To collect materials provided during the visit and turn them over to the coordinator.

PRESENTATION AND EMOTIONAL TONE

Present in a fairly relaxed state. You are walking and sitting normally. You can point to your vaginal area when describing your discharge.

Dress in a manner that would be considered appropriate, conservative, and similar to others in the area. Do NOT dress in a way that may be thought of as normal for a sex provider. You are well groomed.

Responding to Questions

You are responsive and answer all of the healthcare provider questions when asked. When the healthcare provider asks questions regarding sex or STIs, you

should act somewhat uncomfortable with the topic but not extremely so.

Changes in Demeanor during the Encounter
At the beginning of the encounter, you should present in a fairly relaxed state. You are walking and sitting normally.

During the middle of the encounter, when presented with questions regarding sex, condom use, or STIs, respond in a hesitant manner, somewhat uncomfortable with the topic but willing to respond. You are not shy about having multiple partners and do not think it is a problem but do not become argumentative about it. You are not uncomfortable discussing HIV testing. If discussed, you agree it is a good idea to know your HIV status and that of your partners.

At the end of the encounter, you should present grateful for a diagnosis and medication.

SP OPENING STATEMENT
CWN: The response for each case version will vary based on the typical terms used by lay people AND what is most comfortable for the specific SP portraying the role.

When asked by the healthcare provider (nurse, doctor, etc.), "why are you at the clinic today" or "how can we help you", your response should be, "I have noticed a liquid down there". Remember, at each clinic visit you must respond the same way each time.

If the healthcare provider says, "Tell me more about it" or "Can you tell me what has been going on?" Your response should be, "It is watery, a little yellowish."

HISTORY OF THE PRESENT ILLNESS
You have experienced a vaginal discharge for the past seven days. The discharge is watery and a little yellowish. It is not itchy. Sex is not painful. It does not smell bad. Prior to seven days ago you did not have any problems. You have never experienced a discharge like this before.

Associated Symptoms:
- No abdominal/stomach pain
- No nausea, vomiting, diarrhea or constipation
- You have not noticed a rash anywhere
- No pain on urination or frequent urination
- No blood in urine
- You have not had a fever or chills
- You do not have a cough or night sweats
- No vaginal bleeding
- No vaginal itching
- No pain with intercourse
- No vaginal burning
- No sore throat

Your Current Concerns Are:
You feel the liquid is uncomfortable and you are concerned your sex partner will notice it and question your commitment to the relationship. You would like to get it treated as soon as possible.

PAST MEDICAL HISTORY
Overall Health:
Your last doctor visit was approximately one year ago. The visit was for a bad cough. You were treated with medication and it went away. You are otherwise healthy, without any other symptoms.

You had all of the normal childhood diseases and vaccinations. You have no known drug allergies

CWN: The response inserted into the case regarding vaccinations should note that older SPs will not know if they have had vaccinations. The younger SPs will.

Prior Illness
No prior illnesses, including TB.

HIV/AIDS screening
CWN: The response inserted into the case version will depend on the age of the SP.

Childbearing SPs: If you have children under the age of five, you were tested for HIV at time of delivery and tested negative.

Post-childbearing SPs: If your children are older, you were tested one year ago and tested negative.

STI Screening
CWN: The response inserted into the case version will vary by SP.

You have not been treated for any previous STIs. You do not know if any of your partners have ever had any STIs or tested positive for HIV.

Allergies
None

Past Hospitalizations
You have never been hospitalized or had any surgeries.

MEDICATIONS

- Prescription drugs: You are currently not on any medications.
- Over the counter (OTC) drugs, herbal or traditional medications: None
- Illicit/street drugs: None

MENSTRUAL HISTORY

CWN: The response inserted into the case version will depend on the age of the SP.

Premenopausal

You started your period at age 12. You are currently on your menses, and all of your menses have been normal. You get your period every 28-30 days. It lasts four to five days. The flow is not too heavy or too light, and has remained the same. You use four to five pads a day—the big, thick ones. If asked, tampons were uncomfortable so you do not use them. You are due to start your period in three weeks. You get cramps with your period but not a lot of pain.

You currently are not taking any contraceptives.

Postmenopausal

Your last period was 15 years ago. During the menopausal phase, you experienced irregular periods, hot flashes, mood changes, fatigue, and weight gain. It lasted for two years and finally ended when you were 48 years old.

SEXUAL HISTORY

CWN: The response for each case version will vary based on the specific SP portraying the role. The basic sexual history for this patient should include:

- A main partner: The main partner may be a husband or not. The use of condoms with the main partner can vary.
- Additional Partners: Each SP should have additional partners. The number of partners can vary. The sex of the partner can vary, as can the use of condoms.
- Non-traditional sex experience: The use of sex toys will vary for each case version.

Please note that in some societies, woman expect something material from a relationship, which may come in the form of occasional gifts, money, clothing, etc. The SP should be consulted to put this into an appropriate context.

Also, the known HIV status of the partners, as well as the actual status (some positive and some negative) should vary.

You currently have a husband to whom you are married. He travels frequently and there are two other men with whom you have had sex in the past two months. When you had sex, you did not use a condom with your husband but you did with the other two men. They did not pay you money or provide you with any other items for having sex with them. One is someone you have known since you were a young girl and the other is a man you recently met. All partners have been male. You do not use any sex toys with the partners.

You do not tell the health care provider you have multiple partners unless you are specifically asked how many sex partners you have or how many partner notification slips you need.

If asked, you do not know the HIV status of the additional partners. Your main partner has told you he is HIV negative. None of your partners have told you they were recently treated for STIs.

Family Planning

You are currently not taking any form of birth control (shot or pill).

PATIENT'S LIFESTYLE/HABITS

CWN: The response for each case version will vary based on the specific SP portraying the role. Please note that tea and coffee is a preferred caffeine drink. If asked, the SP must be able to detail the last three month of activities.

- Alcohol: You drink beer once in a while but never more than one or two per day.
- Tobacco: You have never smoked.
- Caffeine: You drink a cup of tea two to three times per day on occasion.
- Diet: You eat a normal diet for the area (pap, meat, potato, etc.).
- Exercise: You do not exercise.
- Activities/hobbies: You enjoy spending time with your family and friends. Over the last three months, you have had a basic routine. You have not gone swimming.
- Stress: Money is lacking and a stressor.

FAMILY MEDICAL HISTORY

CWN: The response for each case version will vary based on the specific SP portraying the role. Burden of diseases and death in South Africa are due to car accidents, heart attack, diabetes, stroke, and hypertension-related illness.

SPs should make up the names for all family members (e.g., siblings, children, and partners).

- Parents: You and your mom are close and you talk to both parents on a regular basis. Your mother is 17 years older than you. Your father is 20 years older than you. Your parents are currently healthy with no medical problems other than "they are getting older".
- Siblings: You have one brother and one sister. Both are currently healthy with no medical problems.
- Children: You have three children, ages appropriate for your own age. They are all healthy and in school/doing well.
- Paternal grandparents: Deceased; died of old age.
- Maternal grandparents: Deceased; died of old age.

PERSONAL HISTORY

CWN: The response for each case version will vary based on the specific SP portraying the role.

- Birth date: Your birth date should be similar to your actual age but not the same.
- Birth Place: Your birth place should be near your actual birth place, but not the same.
- Living arrangements: You live at home with your husband and children. You have a large circle of friends and enjoy an active social life.
- Education: You have at least an 8th grade education.
- Religion: Christian

PHYSICAL EXAMINATION

If the health care provider follows the appropriate algorithm, they may request a physical examination.

- Real Physical Findings: There are no physical examination findings that are present at this visit.
- Vital Signs: If vital signs are requested, allow them to take your temperature, weigh you, check a blood pressure and pulse, as long as you do not find these to be invasive.
- Abdomen Exam: If an abdominal exam is performed, do not complain of pain when the health provider pushes down (touches) on your lower abdomen. Do not hold your abdomen too tightly (guard) or complain of pain when the health provider lets go after pushing down (rebound tenderness); however, if this action does cause you pain, please notify the healthcare provider.

Genital Exam

CWN: The response each SP gives to decline a genital exam must feel comfortable to them and be reasonably realistic of an excuse for not allowing the healthcare provider to examine them. The examples for declining the exam are:

- Does not feel comfortable with a male healthcare provider performing the exam
- Is in a hurry to get to work or another urgent matter
- Currently on menses

If a genital exam is requested, politely decline stating you need to attend to an urgent matter and ask if you can return at another time for the pap exam. If the provider continues to request the exam, gently refuse and request if there is any medication you can take for your symptoms.

Test/Medication

- HIV screening: The health provider should advise HIV screening. Politely decline or state you will return for HIV testing.
- Urine Sample: Please note that you may be asked to provide a urine sample. State that you cannot produce one at the moment. If the healthcare provider is persistent, politely decline.
- Blood Draw: Please do NOT allow blood to be drawn
- Medication: If medication is dispensed and you are expected to take in the office, you may politely decline and state you will take at a different time. DO NOT ingest any medication if provided in the office.

PATIENT RESPONSE TO SPECIFIC INTERVIEWING QUESTIONS

CWN: The response for each case version will vary based on the specific SP portraying the role.

How long have you had the discharge?

SP response: "Two days."

Can you describe the discharge?

SP response: "It's watery, a little yellowish."

Have you experienced any symptoms with the discharge?

SP response: "Like what?"

The healthcare provider should provide examples of the symptoms such as itching, burning, bleeding, etc. After the examples, you should

respond with, "I have not experienced any symptoms. It is not itchy and doesn't smell bad."

Have you noticed a rash, lesions in the vaginal area?

SP response: "No."

Have you experienced any abdominal pains?
SP response: "No."

Are you currently taking any medication?
SP response: "No."

Have you taken any medication in the past?
SP response: "No."

Are you allergic to any medications?
SP response: "No."

Have you noticed having a fever?
SP response: "No."

Have you had any medical problems in your past?
SP response: "No."

Have you had sex in the last three months?
SP response: "Yes."

How many partners have you had in the last three months?
SP response: "Three." (This number with vary based on the SP.)

What is the sex of your partners?
SP response: "Male."

Did you use a condom with your partners?
SP response: "Sometimes."
If the healthcare provider asks you to explain, you tell them that you have a main partner whom you have never used a condom. With your other partners you used condoms.

Is there any possibility that you may be pregnant?
SP response: "No, I am currently on my menses."

When was your last period?
SP response: "One week ago." (This response will vary based on the SP.)

Have you noticed any symptoms such as nausea, diarrhea, or constipation?
SP response: "No."

Are you married?
SP response: "Yes."

How long have you been married?
SP response: "Five years." (This response will vary based on the SP.)

Are you currently sexually active?
SP response: "Yes."

Do you use condoms with your husband?
SP response: "No."

Do you have children?
SP response: "No." (This response will vary based on the SP.)

How many sexual partners do you have?
SP response: "Three."
This is a closed-ended question, so your response should only provide the number of partners, and you should hesitate before giving the response. You are a married woman having sex outside the marriage, which make you feel slightly shy in responding but not ashamed.

Have you been screened for HIV/AIDS before?
SP response: "Yes."

Have you had TB before?
SP response: "No."

Have you been screened for TB before?
SP response: "No."

Have you been tested for STI before?
SP response: "No."

AT THE END OF THE ENCOUNTER

After the healthcare worker has completed the examination, you should do the following:

- Inform them that you are the unannounced SP.
- Hand them the letter.
- Do not provide feedback to the healthcare provider. The letter will re-explain the project. If the healthcare provider has questions, they should direct them to the facility manager.
- Ask them to complete the medication form.
- Place all forms, slips, and medication in the envelope.
- Thank them for their time and leave the facility.

Appendix B:
Male Uretheritis Syndrome Case

Case Background Information

PRESENTING SYMPTONS:	Pain on urination for three days
ACTUAL DIAGNOSIS:	Male Urethritis Syndrome
DIFFERENTIAL DIAGNOSIS:	Urinary Tract Infection
CLINCIAL CONSULTANT:	Suzanne Jed, MSN, FNP-BC
CASE AUTHORS:	Tamara Owens, Med, Suzanne Jed, MSN, FNP-BC, Erushka Pillay, MM, Marcia Weaver, PhD
PATIENT NAME:	Each SP will use birth name for authenticity Of case portrayal
PATIENT DEMOGRAPHICS:	Age: 20-60 years old Sex: Male Race: As actual Height: Average Weight: Average

MATERIALS AND EQUIPMENT NEEDED

- ID Card
- Watch
- Cell Phone

TERMINOLOGY

Case Writing Notes (CWN) – These notes are inserted throughout the case as directives on how to write future versions of the case. CWNs are intended for the case authors, not the SPs.

PROFILE

The patient is a 20- to 60-year-old male who has come to the clinic because he has been experiencing pain on urination for the past three days.

CASE GOAL

The goal of this case is to assess the knowledge, skills, and behaviours of a healthcare provider related to urethritis syndrome.

CASE EVALUATION OBJECTIVES

1. Demonstrate appropriate diagnosis and treatment of urethritis syndrome.
2. Demonstrate knowledge and skill regarding issuance of appropriate partner notification slips and recommendation of condom use.
3. Demonstrate knowledge of importance of testing for HIV when an STI is diagnosed.

CASE SUMMARY

You are a 20- to 60-year-old male patient who is coming to the clinic complaining of pain on urination for the past three days. This is the first time you have been to this clinic.

Your challenge as the standardized patient is three-fold:

- To appropriately and accurately respond to questions related to the symptoms and medical history of this case;
- To accurately recall the encounter during the debriefing session;
- To collect materials provided during the visit and turn them over to the coordinator.

PRESENTATION AND EMOTIONAL TONE

Present in a fairly relaxed state. You are walking and sitting normally. You are not in pain and have no noticeable discomfort.

Dress in a manner that would be considered appropriate, conservative, and similar to others in the area. Avoid extremely nice clothing or jewelry or any other items that make you memorable. DO NOT dress in a way that may be thought of as normal for a sex worker. You are well groomed.

Responding to Questions
You are responsive and answer all of the healthcare provider questions when asked. When the healthcare provider asks questions regarding sex, you are proud of your sexual encounters. If asked if you have sex with men, you are quick to respond that you do not but you are not insulted. When asked about previous STIs, you are quick to respond that you have never had any previously. You are proud of having tested for HIV a year ago and having a negative HIV status. You are not shy about not using condoms.

Changes in Demeanor During the Encounter
At the beginning of the encounter, you should present in a fairly relaxed state. You are walking and sitting normally.

At the end of the encounter, you should present grateful for a diagnosis and medication and eager to move on to your next activity for the day.

SP OPENING STATEMENT
CWN: The response for each case version will vary based on the typical terms used by lay people AND what is most comfortable for the specific SP portraying the role.

When asked by the healthcare provider (nurse, doctor, etc.), "why you are at the clinic today" or "how can we help you", your response should be "I feel burning when I urinate". Respond in a way that is most comfortable for you. Remember, at each clinic visit you must respond the say way each time.

If the healthcare provider says, "Tell me more about it" or "Can you tell me what has been going on?" your response should be, "it happens every time I urinate."

HISTORY OF THE PRESENT ILLNESS
You have are experiencing burning when you urinate for the past three days. The burning sensation occurs every time you urinate. You have not noticed any urethral discharge (liquid from your penis). You do not feel like you need to urinate more than normal. Prior to three days ago, you did not have any problems. You have never experienced a discharge from your penis before.

Associated Symptoms:
- No trouble swallowing or sore throat
- No nausea, vomiting, diarrhoea, or constipation
- No abdominal pain
- You have not noticed a rash anywhere
- You have not noticed a fever or chills
- You do not have a cough or night sweats
- No urethral bleeding
- No urethral itching
- No pain with intercourse
- No blood in urine
- You do not feel like you have to drink all of the time

Your Current Concerns Are:
You are most concerned about getting treatment so that you no longer have this feeling every time you urinate.

PAST MEDICAL HISTORY
Overall Health
Your last doctor visit was one year ago for HIV testing during a campaign. You tested negative. You rarely go to the doctor. You are otherwise healthy, without any symptoms.

You were last tested for HIV one year ago and it was negative. You have not been treated for any previous STIs. You do not know if any of your partners have ever had any STIs or tested positive for HIV.

You had all of the normal childhood diseases and vaccinations. You have no known drug allergies.

CWN: The response inserted into the case regarding vaccinations should note that older SPs will not know if they have had vaccinations but the younger SPs should. The HIV status of the SP partners can vary (some positive and some negative).

Prior Illness
No prior illness, including TB.

HIV/AIDS screening
CWN: The response inserted into the case version will depend on the age of the SP.

You were tested one year ago during a campaign. You tested negative.

STI Screening
CWN: The response inserted into the case version will depend on the age of the SP.

You have not been treated for any previous STIs. You do not know if any of your partners have ever had any STIs or tested positive for HIV.

Allergies
None.

Past Hospitalizations
You have never been hospitalized or had any surgeries.

MEDICATIONS
Prescription Drugs
You are currently not on any medications.

Over the counter (OTC) drugs or traditional /herbal remedies
None.

Illicit/Street Drugs
None.

SEXUAL HISTORY
CWN: The response for each case version will vary based on the specific SP portraying the role. The basic sexual history for this patient should include:

- A main partner: The main partner may be a wife or not. The use of condoms with the main partner can vary.
- Additional Partners: Each SP should have additional partners. The number of partners can vary. The sex of the partner can vary, as can the use of condoms.
- Non-traditional sex experience: The use of sex toys will vary for each case version.

You are sexually active. Three weeks ago, you ended one relationship with a previous girlfriend. As of two weeks ago, you have a new girlfriend with whom you have had vaginal sex. You have never had sex with a male. You are not currently using condoms because you don't like the way they feel. You did not use condoms with your previous girlfriend either. You do not know if your current partner is using contraception. You don't think she is hoping to fall pregnant.

You do not tell the health care provider you have multiple partners unless you are specifically asked how many sex partners you have or how many partner notification slips you need.

If asked, you do not know the HIV status of the additional partners. Your current girlfriend has told you she is HIV negative. None of your partners have told you they were recently treated for STIs.

Please note that in some societies that woman expect something material from a relationship. The material/tangible something may come in the form of occasional gifts, money, clothing, etc. The male SP should be consulted to put this into am appropriate context.

Also, the SP should vary the known HIV status of their partners.

PATIENT'S LIFESTYLE/HABITS
CWN: The response for each case version will vary based on the specific SP portraying the role. Please note that tea and coffee is a preferred caffeine drink.

- Alcohol: You drink beer on the weekends with your friends.
- Tobacco: You have never smoked.
- Caffeine: You drink a cup of tea on occasion.
- Diet: You eat a normal diet for the area (Pap, meat, potatoes, etc.).
- Exercise: You do not exercise.
- Activities/hobbies: You like to play soccer, watch TV, and spend time with friends and family. You have not gone swimming. Over the last three months, your activities have been routine.
- Stress: Your work is somewhat stressful.

FAMILY MEDICAL HISTORY
CWN: The response for each case version will vary based on the specific SP portraying the role. Burden of diseases and death in South Africa are due to car accidents, heart attack, diabetes, stroke, and hypertension-related illness. SPs will need to create names for parents, siblings, children, and partners.

- Parents: You and your mom are close, and you talk to both parents on a regular basis. Your mother is 20 years older than you. Your father was 25 years older than you. Your mother has high blood pressure and your father is deceased (dead). He died in a car accident several years ago.
- Siblings: You have one brother and one sister, both of whom are currently healthy with no medical problems.
- Children: You have one child who lives with the mom's family. This is a child from a previous relationship. You see the child on occasion.
- Paternal grandparents: Deceased; died of old age
- Maternal grandparents: Deceased; died of old age. There is no one in your family with diabetes. You don't know if anyone had heart problems or not, and there is no family history of cancer.

PERSONAL HISTORY

CWN: The response for each case version will vary based on the specific SP portraying the role.

- Birth date: Your birth date should be similar to your actual age but not the same.
- Birth Place: Your birth place should be near your actual birth place but not the same.
- Living arrangements: You live at home with your family. You have a large circle of friends and enjoy an active social life.
- Education: You have at least an 8th grade education.Religion: Christian

PHYSICAL EXAMINATION

If the healthcare provider follows the appropriate algorithm, they will ask to conduct a physical exam, including a genital exam.

Real Physical Findings

There are no physical examination findings that are present at this visit.

Vital Signs

If vital signs are requested, allow them to take your temperature, weigh you, and check your blood pressure and pulse, as long as you do not find these to be invasive.

Abdomen Exam

If an abdominal exam is performed, do not complain of pain unless the medical provider is actually hurting you.

Genital Exam

CWN: The response each SP gives to decline a genital exam must feel comfortable to them and be reasonably realistic of an excuse for not allowing the healthcare provider to examine them. The examples for declining the exam are: does not feel comfortable with a female healthcare provider performing the exam; or, is in a hurry to get to work or another urgent matter.

If a genital exam is requested, politely decline, stating that you need to attend to an urgent matter and ask if you can return at another time for the pap exam. If the provider continues to request the exam, gently refuse and request if there is any medication you can take for your symptoms.

TEST / MEDICATION

HIV screening

The healthcare provider should advise for HIV screening. You may decline or state you will return for HIV testing.

Urine Sample

Please note that you may be asked to provide a urine sample. State that you cannot produce a sample at the moment. If the healthcare provider is persistent, politely decline.

Blood Draw

Please DO NOT allow blood to be drawn.

Medication

If medication is dispensed and you are expected to take it in the office, you may politely decline and state you will take at a different time. DO NOT ingest the medication if provided in the office.

PATIENT RESPONSE TO INTERVIEWING QUESTIONS

CWN: The response for each case version will vary based on the specific SP portraying the role.

How long have you had the burning sensation?

SP response: "Three days."

Have you noticed a discharge?

SP response: "No."

Have you experienced any other symptoms with the burning sensation?

SP response: "Like what?"

The healthcare provider should provide examples of the symptoms, such as itching, burning, bleeding, etc. After the examples, you should respond with, "I have not experienced any symptoms."

Have you noticed a rash or lesions in the genital area?

SP response: "No."

Have you experienced any abdominal pains?

SP response: "No."

Are you currently taking any medication?

SP response: "No."

Have you taken any medication in the past?

SP response: "No."

Are you allergic to any medications?

SP response: "No."

Have you noticed having a fever?

SP response: "No."

Have you had any medical problems in your past?

SP response: "No."

Have you had sex in the last three months?

SP response: "Yes."

How many partners have you had in the last three months?

SP response: "Two." (This number with vary based on the SP.)

What is the sex of your partners?

SP response: "Female."

Did you use a condom with your partners?

SP response: "No."

If the healthcare provider asks you to explain, you tell them that you have never used a condom with your girlfriends.

Have you noticed any symptoms such as nausea, diarrhea, or constipation?

SP response: "No."

Are you married?

SP response: "No."

Are you currently sexually active?

SP response: "Yes."

Do you use condoms with your girlfriend?

SP response: "No."

Do you have children?

SP response: "Yes." (This response will vary based on the SP.)

How many sexual partners do you have?

SP response: "One."

This is a closed-ended question, so your response should only give the number of partners.

Have you been screened for HIV/AIDS before?

SP response: "Yes."

Have you had TB before?

SP response: "No."

Have you been screened for TB before?

SP response: "No."

Have you been tested for STI before?

SP response: "No."

AT THE END OF THE ENCOUNTER

After the healthcare worker has completed the examination, you should do the following:

- State to them, "I am the unannounced SP".
- Hand them the letter
- Do not provide feedback to the healthcare provider. The letter will re-explain the project. If the healthcare provider has questions, they should direct them to the facility manager.
- Ask them to complete the medication form.
- Place all forms, slips, and medication in the envelope.
- Thank them for their time and leave the facility.

Appendix C:
Data Collection Tools

Standardized Patient Encounter Form

Standardized Patient Encounter Background Data

Date _____ Time Period _____ Record # _____

Clinic ID # _____ Standardized Patient ID # _____

Time left I-TECH vehicle? _____ Time left facility? _____

Standardized Patient Encounter Checklist

Were you offered medications by the HCW? ☐ Yes ☐ No

If yes, was the medication slip completed by the HCW? ☐ Yes ☐ No

Comments _____

Were you offered an HIV test? ☐ Yes ☐ No

Were you provided with condoms? ☐ Yes ☐ No

Were you given partner notification slips? ☐ Yes ☐ No

Medication Slip

Date _____ Time Period _____ Record # _____

Clinic ID # _____ Standardized Patient ID # _____

Thank you for the visit.
Please tell me what medication you would prescribe for me today.
Please write clearly and neatly.
PLEASE DO NOT SIGN OR STAMP THIS FORM

Drug or Treatment Name	Dose	Oral, IM or IV?	Frequency (times per day/week)	Duration (no. of days or weeks)

Please write the number of partner notification slips provided: _____
To maintain confidentiality for the study, please do NOT sign or stamp this form.

Standardized Patient (USP) Debriefing Questionnaire

Date _____ Time Period _____ Record # _____

Clinic ID # _____ Standardized Patient ID # _____

Please document the general comments from the USP.

1. Did you encounter any problems? (Write down the USP comments.)

_____

_____

2. Do you feel the healthcare worker knew you were an "unannounced standardized patient?"

☐ Yes ☐ No

3. Please describe what happened when you disclosed that you are a patient actor.

_____

_____

4. Do you feel the training session you received prepared you for the visit today?

☐ Yes ☐ No

5. Do you believe you needed additional information for your clinic visit?

☐ Yes ☐ No Please describe if Yes

_____

_____

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Provider Information Sheet

I-TECH is conducting an evaluation of STI care at clinics in Madibang, Moretele, and Rustenberg Subdistricts in collaboration with the North West Province Department of Health.

The patient actor who visited your health facility today is collecting data for the evaluation. As explained during the consent process, all data will be analyzed in groups of facilities rather than by individual clinician. No information about an individual will ever be shared with a clinic supervisor or with other sub-district or district officials.

Performance reviews for clinicians will continue to be conducted with your supervisor through the process of the Department of Health. Under the circumstances, it is not necessary or appropriate to ask the patient actor for feedback on his/her visit to your facility today.

Thank you for your consideration.

In case of any questions, please contact these people at the I-TECH-South Africa office:

Makati (Gladys) Mema
Program Coordinator
email: gmema@itech-southafrica.org,
office: 012 433-0100

Erushka Pillay
Program Manager
email: epillay@itech-southafrica.org
office: 012 433 -0100

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