The Effect of Three Methods of Delivering Clinic-Based STI Training on STI Syndromic Management in South Africa: A Cluster Randomized, Controlled Trial

Marcia Weaver, Erushka Pillay, Suzy Jed, Julia DeKadt, Sean Galagan, Jay Gilvydis, Makati (Gladys) Mema, Evasen Naidoo, Gabrielle O'Malley, Albert Bakor

Abstract

Introduction. The South African National Department of Health (NDOH) updated the national guidelines for syndromic management of sexually transmitted infections (STI) in 2009 and sought to train health professionals on them. I-TECH designed six STI modules for training at primary health care clinics (PHC), 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 for each 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 by 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 the 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), which was also a 11% increase relative to the control arm in the ratio of RR (RRR=1.11, 95% CI=0.67, 1.84). 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% pretest 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.

Conclusion. The trial showed an improvement in STI management for two of the three training delivery methods, but did not provide generalizable evidence of their effectiveness. The training program content and lessons learned could be used to improve the effectiveness and coverage of the delivery methods in the future.

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.[1, 2,3 4, 56, 7, 8, 9] 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.[10] 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.[11]

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,[12] as well as an update on the revised national guidelines. The NDOH supported a decentralized approach to in-service training, which is implemented at the clinic level, such as the educational outreach of the Practical Approach to Lung Health in South Africa (PALSA)[13] and for the Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) intervention.[14] 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, [9 15 16 17] 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 the test among 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 District Management Team selected three subdistricts for the trial: Madibeng, Moretele, Rustenberg. They purposively selected the 40 clinics with greater 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 doctors and nurses assigned to the PHCs.

Intervention

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 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 clinic-based location and time allocated to training was the same for all three delivery methods. All participants received a printed version of the Clinical Resource Guide. For the lecture-based classroom arm, an I-TECH trainer visited each clinic once a week for three weeks to teach two modules per week and give participants the handouts for those modules. For the online/CD-ROM arm, an I-TECH team visited each clinic weekly for three weeks to bring computers for the participants to use during the visit, 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.

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[18] and unannounced SP are considered the gold standard for measuring the quality of care.[19] Unannounced SP have been used to measure the outcomes of several interventions for syndromic management of STIs in

pharmacies[20 21] and clinics.[21 9 22 23] 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 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. 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 vaginal discharge syndrome and male urethritis syndromes 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 HCW?

2) Were you offered an HIV test?

3) Were you provided with male and/or female condoms?

4) Where 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, 400mg single dose, and 2) Doxycycline, oral, 100 mg twice daily for 7 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 7 days, and 3) metronidazole, 2 g immediately as a single dose. The clinician also recorded the number of partner notification slips s/he gave the SP on the medication slip.

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, the five male and five female SPs were distributed in 10 combinations with one visit per SP to 10 clinics across three time periods: pre training, and one and five months post training. Within each time period, all males and females were grouped with each of the other actors of the same gender twice, and all males and females were grouped with each other member of the opposite gender two or three times. The PHCs in each arm were randomly assigned to one of the 10 combinations, so that the SPs were balanced across arms in each time period.

The secondary hypothesis for STI knowledge was measured by tests with five, case-based, multiple choice questions for each module. The pretest and post-test for each module was the same, but the order of the questions was different. An exception was module 4, which had four questions, because one of the questions was withdrawn.

Sample size calculation

Sample size was given at 10 PHC per arm or a total of 40 PHC and 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. The calculations focused on the 15% difference between the lecture-based classroom arm and the other delivery methods. Under three alternative assumptions for the random effects for 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 vs. 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 "facilityid" 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 facilityid. 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 facilityid. 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 staff and participants 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 the 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 D 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 comparing the entered data against the original paper forms. 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 the 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 relative risks (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 the 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

A. 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, with the rest operating 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 were conducted for each module, and thus 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 post test. 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. There were two exceptions. 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.

Recruitment

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 to purposively select the PHC that would be invited to participate. Clinic managers and clinicians were recruited from August to October 2013, which was before the pretraining 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 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.

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 were in that subdistrict.

Before training, the average number of STI tasks completed correctly was 1.63 (median=1, Inter-quartile range: 0, 3) among completed visits. As shown in Table 4, among these completed 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. The percentage of SPs given partner notification slips was higher and percentage offered a genital exam was lower in the lecture-based classroom arm. 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.

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 5. 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.

STI Knowledge Results

When all training delivery methods were combined, average test scores increased from 52.5% pretest to 65.7% post-test, an absolute increase of 13.2% ($p<0.001$), as shown in Table 6. 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 was the exception, for which the increase was not statistically significant.

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% post-test, 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% post-test, 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% post-test, 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.

IV. Discussion

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. These results were disappointing in light of evidence that the effects of online learning are comparable to classroom methods in general,[24] and evidence that educational outreach interventions have been effective in South Africa.[13 14]

Given the increase in STI knowledge test scores, one possible interpretation is that the training programs were effective among participants, but the delivery methods were not effective at reaching all the clinicians. Participation in the training program overall was only 31%, and participation in the online/CD-ROM delivery method was only 25%. Some clinicians may have been off duty during the trainings, as suggested by the relatively low participation at PHC with 24-hour services. With high PHC patient volumes and low staffing levels other clinicians would have had to work extra hours to make-up for time devoted to at onsite training. In addition, clinicians received no incentives for the onsite trainings, in contrast to off-site trainings for which travel-related expenses and food are generally provided.

Given the low-level of training attendance, it is possible a high enough training threshold was not attained to cause facility-level changes in STI syndromic management, such as ordering supplies of condoms or partner notification slips. In addition, the clinic-

level 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. In practice, the SP encounters were not necessarily with the clinicians who participated in the training.

The limited evidence of the effectiveness of the training program may reflect less on the training content and more on the delivery methods. Both the paper-based and the online/CD-ROM content could be taught in the future with delivery methods that play to their strengths. A participant could access the paper-based content whenever and wherever s/he wanted. If the PHC had sustainable access to computers, participants could access the online/CD ROM clinic whenever they are at the PHC. Clinic managers could use these methods to target clinicians who manage patients with STIs. In settings with multiple shifts or high staff turnover, the methods could also train clinicians who work on shifts outside normal training hours and new staff as soon as they arrive, rather than waiting to schedule and fund a lecture-based classroom training.

Future online/CD-ROM trainings would however, need to provide more engagement with learners. Ally proposes a model with four types of interaction for online learning: 1) learner-interface, 2) learner-content, 3) learner-support, and 4) learner-context.[25] 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 PHC, the learner-context interface, which means supporting the participants to apply what they learned in real life, could also have been strengthened. For example, to support putting learning into practice, Colvin et al. provided “syndrome packets” with

correct antibiotics, 10 condoms, a partner notification card, and an information leaflet in addition to training.[23] The STRETCH intervention included a management team at the clinics, in addition to educational outreach and revised guidelines.[14]

According to the results of the unannounced SP visits, which are considered the gold standard for measuring the quality of care, the quality of STI care was low. An average of 1.63 out of five STI tasks were completed pretraining, and 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[26] and a highly mobile population that ebbs and flows with work in the mines. Although the low attendance for the STI training sessions was disappointing, additional operational research to improve STI care is warranted.

This initial research on delivering onsite training should inform the design of studies to improve onsite training participation. Future trainings should combine lecture-based classroom methods with paper-based or online/CD-ROM methods to accommodate clinicians with different schedules and learning needs. This operations research also planted the seed for creating an activity for the learner-context interface using SPs, which are primarily a method of training doctors and nurses.[18] The SPs encounter created a teachable moment for the clinicians. Given that they are required to disclose at the end of the visit to avoid taking medications, the SPs could give a handout to the clinicians that briefly explains the STI tasks. Or given that the research coordinator or research assistant visited the PHC after the encounter to remove the medical record, s/he could be trained to provide constructive feedback to the clinician based on the SP debriefing.

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. The second 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.

The similarity of the scripts across SPs of the same gender may have contributed to some clinicians suspecting the SPs 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, but 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, the statistical tests did not show that the results were generalizable. The post/pre relative risk for the lecture-based classroom arm however, 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.[27]

V. Conclusion

The trial represents a success for the Bojanala Platinum District and I-TECH South Africa 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 training materials are well-designed and could continue to serve as a resource of South Africa National Department of Health in the future. The training materials were delivered as planned, albeit with lower than anticipated participation. The results showed an improvement in STI management for two of the three training delivery methods, even though the trial did not provide generalizable evidence of their effectiveness. The training program content and lessons learned from the trial could be used to improve the effectiveness and coverage of the delivery methods in the future.

Acknowledgments

We are grateful to Harnik Gulati who is the I-TECH South Africa country team lead, Linda Campbell, Elizabeth M. Frick, Anya Nartker, and Liz Scott for developing the training materials, Tamara Owen for training the SPs, Fulufhelo Malamatso and Sipho Mazibuko for leading the field teams, and the talented actors and actresses of Morgeez Casting Agency who served as SPs. This study and the activities detailed were developed and conducted by the University of Washington and I-TECH with funding from Cooperative Agreement U91HA06801-06-00 from the US Department of Health and Human Services, Health Resources and Services Administration (HRSA). 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.

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

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)

Table 3. Characteristics of Sample

	Training delivery method				
	Arm 1 Control N (%)	Arm 2 Lecture N (%)	Arm 3 Online/ CD-ROM N (%)	Arm 4 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)

Table 4. Bivariate comparison of STI care by training delivery method

	Training delivery method				
	Arm 1 Control	**Arm 2 Lecture**	**Arm 3 Online/ CD-ROM**	**Arm 4 Paper-based**	**Total**
	N (%)	N (%)	N (%)	N (%)	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)
Where 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. The effect of STI Training on STI Care as Measured by Unannounced Standardized Patient Visits
*** Analysis of complete cases, i.e. visit completed**

			Training Method					
	Training (all methods combined)		Lecture		Online or CD-ROM training		Paper-based training	
Sample size	57		63		63		59	
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						
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 6. 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

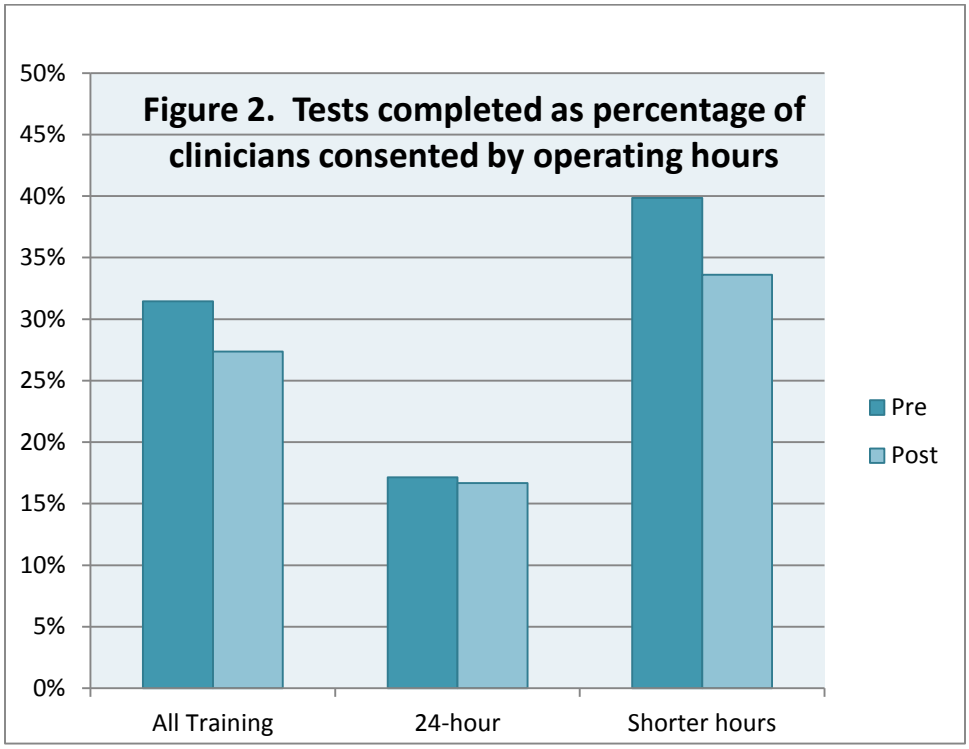
Figure 2. Tests completed as percentage of clinicians consented by operating hours
50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
All Training
24-hour
Shorter hours
Pre
Post

Figure. CONSORT Flow Diagram

Appendices

A. CONSORT Checklist
B. Female Vaginal Discharge Syndrome Case
C. Male Urethritis Syndrome Case
D. Data Collection Tools
    i. Standardized patient encounter form
    ii. Medication slip
    iii. Standardized patient debriefing questionnaire
    iii. Provider Information Sheet

References

[1] Boonstra E, Lindbaek M, Koulman E, Ngome E, Romoren M, Sundby J. Syndromic management of sexually transmitted diseases in Botswana's primary healthcare: quality of care aspects. *Tropical Medicine and International Health,* 2003; 8(7): 604-14.

[2] Voeten HACM, Otido JM, O'Hara HB, Kuperus AG, Borsboom GJJM, Ndinya-Achola JO, et. al. Quality of sexually transmitted disease management in Nairobi, Kenya: a comparison among different types of health care facilities. *Sexually Transmitted Infections*, 2001; 28(11): 633-42.

[3] Otieno FO, Ndivo R, Oswago S, Ondiek J, Pals S, McLellan-Lemal E, Chen RT, Chege W, Gray KM Cohort Study Evaluation of syndromic management of sexually transmitted infections within the Kisumu Incidence*. Int J of AIDS STDs,* 2014; DOI: 10.1177/0956462414523260

[4] Mbofana FS, Brito FJ, Saifodine A, Cliff JL. Syndromic management of sexually transmitted diseases at primary care level, Mozambique. *Sexually Transmitted Infections,* 2002; 78 (1): E2.

[5] Iipinge SN, Pretorius L. The Delivery and Quality of Sexually Transmitted Infections Treatment by Private General Practitioners in Windhoek Namibia. *Global Journal of Health Science*, 2012; 4 (5): 2012.

[6]Steen R, Soliman C, Mujyambwani A, Twagirakristu J-B, Bucyana S, Grundmann C, et. al. Notes from the field: practical issues in upgrading STD services based on experience from primary health care facilities in two Rwandan towns. *Sexually Transmitted Infections*, 1998; 74 (supplement 1): S159-65.

[7] Harrison A, Karim S A, Floyd K, Lombard C, Lurie M, Ntuli N, et. al. Syndrome packets and health worker training improve sexually transmitted disease case management in rural South Africa: randomized controlled trial. *AIDS*, 2000; 14: 2769-2779.

[8] Martin D, Kouman E, Masatu M, Klepp K-I. Clinicians' perspective on a training programme in syndromic management of sexually transmitted infections in Northern Tanzania. *International Journal of STD & AIDS*, 2005; 16: 697-701.

[9] Hanson S, Engvall J, Sunkutu R M, Kamanga J, Mushanga M, Hojer B. Case management and patient reactions: a study of STD care in a province of Zambia. *International Journal of STD and AIDS*, 1997; 8: 320-328.

[10] World Health Organization. Guidelines for the management and treatment of sexually transmitted diseases, 2003. http://www.who.int/reproductive-health/publications/mngt_stis/ (accessed 12 Mar 2013).

[11] Lewis DA, Maruma E. Revision of the national guideline for first-line comprehensive management and control of sexually transmitted infections: what's new and why? *South Afr J Epidemiol Infect* 2009; 24(2):06-09.

[12] HIV and AIDS and STI Strategic Plan for South Africa, 2007-2011. Available online at: http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/externaldocument/2007/20070604_sa_nsp_final_en.pdf Accessed on March 26, 2014.

[13] Fairall LR, Zwarenstein M, Bateman ED, Bachmann M, Lombard C, et al. Effect of educational outreach to nurses on tuberculosis case detection and primary care of respiratory illness: pragmatic cluster randomized trial. *British Medical Journal*, 2005; 331: 750:754.

[14] Fairall L, Bachmann MO, Lombard C, Timmerman V, Uebel K, et al. Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial. *Lancet,* 2012; 380: 889-898.

[15] Weaver MR, Myaya M, Disasi K, Regoeng M, Matumo HN, Madisa M, Puttkammer N, Kilmarx, Marrazzo J. Routine HIV Testing in the Context of STI Syndromic Management: Evaluation of a Training Program in Botswana. *Sexually Transmitted Infections*, 2008; 84 (4): 259-264.

[16] O'Hara HB, Voeten HACM, Kuperus AG, et al. Quality of health education during STD case management in Nairobi, Kenya. *Int J STD AIDS* 2001;12: 315–23.

[17] Wang D, Operario D, Hong Q, Zhang H, Coates TJ. Intervention to train physicians in rural China on HIV/STI knowledge and risk reduction counseling: preliminary findings. *AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV*, 2009; 21:4, 468-472.

[18] Passiment M, Sacks H, Huang G. Medical Simulation in Medical Education: Results of an AAMC Survey. Washington, DC: American Association of Medical Colleges, 2011.

[19] Luck J, Peabody JW. Using standardized patients to measure physicians' practice: validation study using audio recordings. *BMJ,* 2002;325:679–83.

[20] Mugo PM, Duncan S, Mwaniki SW, Thiong'o AN, Gichuru E, Okuku HS, van der Elst EM, Smith AD, Graham SM, Sanders EJ. Cross-sectional survey of treatment practices forurethritis at pharmacies, private clinics and government health facilities in coastal Kenya: many missed opportunities for HIV prevention Mugo PM. *Sex Transm Infect,* 2013;89:583–589.

[21] Garcıa PJ, Carcamo CP, Garnett GP, Campos PE, Holmes KK (2012) Improved STD Syndrome Management by a Network of Clinicians and Pharmacy Workers in Peru: The PREVEN Network. *PLoS ONE* 7(10): e47750. doi:10.1371/journal.pone.0047750.

[22] Bachmann MO, Colvin E, Nsibande D, Connolly C, Curtis B. Quality of primary care for sexually transmitted diseases in Durban, South Africa: Influences of patient, nurse, organizational and socio-economic characteristics. *International Journal of STD & AIDS*, 2004; 15: 388-394.

[23] Colvin M, Bachmann MO, Horman RK, Nsibande D, Nkwanyana NM, Connolly C, Reuben EB, Effectiveness and cost effectiveness of syndromic sexually transmitted infection packages in South African primary care: cluster randomised trial. *Sex Transm Infect,* 2006; 82:290–294.

[24] US Department of Education. (2010). Evaluation of Evidence-Based Practices in Online Learning: A Meta-Analysis and Review of Online Learning Studies (pp. 1-94). Washington DC: DOE Office of Planning, Evaluation, and Policy Development.

[25] Ally M. "Foundations of Educational Theory for Online learning. In Theory and Practice of Online Learning. Anderson T and Elloumi F (eds). Athabasca AB, Athabasca University, 2004. Available online at http://cde.athabascau.ca/online_book/copyright.html Accessed on March 17, 2014.

[26] Government of South Africa, National Department of Health, Directorate of Epidemiology & Surveillance. The 2011 National Antenatal Sentinel HIV & Syphilis Prevalence Survey in South Africa, 2012. Available online at http://www.healthlink.org.za/indicators/HIV_AIDS/antenatal_2011.pdf Accessed online on March 31, 2014.

[27] Altman DG, Bland JM. Absence of evidence is not evidence of absence. *British Medical Journal*, 1995; 311: 384.