EFFECTIVE SCREENING WITH SELF-COLLECTED VAGINAL SWABS

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Author Note

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Abstract

Problem Urine specimens detect up to 10% fewer infections compared to vaginal specimens for Sexually Transmitted Infections (STI) screening. An annual data report from January 2022 to January 2023 from a reproductive health clinic in Baltimore revealed 92% use of urine specimen and 8% use of vaginal specimen for the screening of chlamydia (CT), gonorrhea (GC), and trichomonas (TV). Assessment of the workflow of the clinic revealed that urine specimen collection is the preferred method due to its convenience and insufficient supply of vaginal swabs. **Purpose** A Quality Improvement (QI) project was performed to improve the detection of CT, GC, and TV among sexually active women aged 14-50 years at a reproductive health clinic in Baltimore City by implementing and measuring adherence to self-collection of vaginal specimens for testing. **Methods** The following structural and workflow changes were implemented at the clinic: incorporation of self-collected vaginal swabs into the CT, GC, and TV testing workflow, supply order of vaginal swabs, display of self-collection diagrams in the clinic's exam rooms and bathrooms, and integration of self-collection training module into the Employee Training system. Self-collected vaginal specimens were collected for CT, GC, and TV testing instead of urine samples unless a patient declines to self-swab. Weekly chart audits and run charts were conducted to monitor practice adherence. **Results** Two hundred and two (n=202) eligible participants were screened for CT, GC, and TV. Hundred and thirty-four self-swab and 68 provided urine specimen indicating 66% practice adherence. Participants that declined self-swabbing reported personal preference with urine collection. **Conclusion** Implementation of self-collected vaginal swabs for STI screening is achievable through efforts from both staff and patients. Efforts are needed to address personal discomfort with self-swabbing and sustainability of the implementation.

Keywords: STI screening, Self-collected Vaginal Swabs, CT, GC, TV testing

EFFECTIVE SCREENING WITH SELF-COLLECTED VAGINAL SWABS

Sexually transmitted infections (STIs) pose a significant public health concern worldwide, necessitating accurate and reliable diagnostic tools for timely and effective treatment. In 2023, the Centers for Disease Control and Prevention (CDC) reported over 2.4 million cases of sexually transmitted infections (STIs) in the United States. Effective screening is crucial to timely treatment and prevention of complications. Since 2009, the Center for Disease Control and Prevention (CDC) has recommended the use of vaginal swabs as ideal due to its sensitivity in detecting STIs and studies have shown that urine specimens detect up to 10% fewer infections compared to vaginal specimens (Aaron et al., 2023).

The site for this Quality Improvement (QI) project is a reproductive health clinic in Baltimore, Maryland. The clinic relies heavily on urine specimens rather than vaginal for STI screening. A data report from January 2022 to January 2023 from the clinic indicated 92% use of urine specimen and 8% use of vaginal specimen for the screening of chlamydia (CT), gonorrhea (GC), and trichomonas (TV). Assessment of the workflow of the clinic revealed that urine specimen collection is the preferred method by both patients and providers due to its convenience and ability to ease the clinic's workflow and insufficient supply of vaginal swabs (Figure 1).

Available Knowledge & Specific Aims

An evidence search was performed to compare the sensitivity between vaginal and urine specimens in detecting STIs and determine what is best for practice. The following keywords: “Vaginal swab”, “Urine”, “STI”, and “Sensitivity vs. Specificity” were used in CINAHL and PubMed databases (Figure 3). CINAHL database was used to research articles using Boolean

search phrases: ((Vaginal swab) AND (Urine) AND (STI)). This search yielded 26 results. Inclusion criteria of publications dated from 2017 to 2024, English language, and human participants were applied. The incorporation of the inclusion criteria resulted to ten remaining articles. The remaining articles were reviewed to detect relevance to the goal of the QI project, and this yielded four remaining articles. Abstract, level and quality of evidence for each article were reviewed and it resulted in one remaining article. After a full review and systematic search, the remaining one article was chosen to compare the sensitivity of vaginal swab and urine sample in detecting STI. PubMed database yielded 46 results. The articles were reviewed for relevance to the PICO outcome and peer-reviewed, and it resulted in 26 remaining articles. Date of publication from 2017 to 2024 were applied and it yielded 20 remaining articles. Abstract, level and quality of evidence, limitations for each article were reviewed and it yielded six remaining articles. The remaining articles were fully reviewed and chosen to compare the sensitivity of vaginal swab and urine sample in screening and detecting STI as outlined in (Appendix A). The studies were reviewed for their implication on practice. All the studies provided clear inclusion criteria. The intervention was consistent in all the studies, and it proved higher sensitivity with vaginal swab compared to urine specimen in detecting STI as summarized in (Appendix B). Aaron et al, and Gottlieb et al are both systematic reviews that found significantly higher sensitivity with vaginal swab compared to urine specimen in detecting chlamydia, gonorrhea, and trichomonas. Eligible participants in both reviews were adult/adolescent women with and without symptoms which are the target participants for the QI project. Lunny et al, another systematic review incorporated randomized control trials into the review and found that self-collected vaginal swabs are as sensitive (0.92 (95% CI 0.87–0.95)) compared to provider collected endocervical swabs in detecting STI. Additionally, Krause et al, a quasi-experimental retrospective study and Chinnok et al, a prospective observational cohort study showed that detection rates of chlamydia and gonorrhea collected through vaginal swabs were noninferior compared to those collected endocervical. The settings for all the studies are similar ranging from ED, health clinics, STD clinics, and OB/GYN clinics. Based on the consistent findings of all seven studies and levels of

evidence, it is supported that vaginal specimens have a higher sensitivity compared to urine specimens in detecting STI. Based on the consistent findings of all seven studies and level of evidence, it is proven that vaginal swab has a higher sensitivity compared to urine sample in detecting chlamydia, gonorrhea, and trichomonas. Increasing the rate of vaginal swab collection for STI testing at the reproductive clinic is the best clinical practice to improve patient outcomes and STI screening.

The purpose of this Quality Improvement project is to improve the detection of Chlamydia, Gonorrhea, and Trichomonas among sexually active women aged 14-50 years at a reproductive health clinic in Baltimore City by implementing and measuring adherence to self-collection of vaginal specimens for testing.

Rationale (Framework)

The MAP-IT model was used to guide the development of this QI project, mapping out desired goals and changes with a GANTT Chart and producing a comprehensive plan with timelines (Figure 6). The Promoting Action on Research Implementation in Health Services (PARIHS) model (Figure 4) was used to aid in achieving the desired outcomes of the project. PARIHS model is a framework that argues that a successful implementation is a function of three core elements: the importance of clarity about the nature of the evidence being used, the quality of the context, and the type of facilitation needed to ensure a successful change process (White et al, 2021).

Evidence- Clinical studies have shown that vaginal swabs are more sensitive than urine specimens for detecting STIs like chlamydia and gonorrhea, and trichomonas especially in women. The extensive research performed by the Quality Improvement Project Lead (QI-PL) was presented to the clinic's staff to increase their knowledge on increased sensitivity with vaginal specimens in screening for STIs. The training module contains data on sensitivity with vaginal specimen versus urine in detecting STI.

Context- The Organizational Culture Assessment Questionnaire was used to assess the culture of the clinic. The clinic culture supports change, innovation, and patient-centered care. The staff were receptive to change.

Facilitation- The presence of a supportive practice coordinator whose job is to oversee the flow of the clinic and monitor changes suited the role of a facilitator in ensuring a successful implementation. The practice coordinator troubleshooted barriers, offered refreshers on how to explain the self-swab process to patients and addressed patient concerns.

Methods

Context

The clinic provides family planning and STI testing/counseling services to women and men. The common population/demographic that seeks services at the clinic is sexually active women from ages 14 to 50 who lives in Baltimore City. A urine specimen is the standard collection for STI screening (Figure 2). The Organizational Culture Assessment Questionnaire (OCAQ) was used to assess the culture of the clinic. OCAQ is a framework developed by Dr. Parsons to assess the culture of an organization and it argues that all organizations must carry four crucial functions to survive which are managing change, achieving goals, coordinating teamwork, and building a strong culture (Sashkin & Rosenbach, 2020).

Managing change- From previous quality improvement projects, staff members were flexible and adaptable when changes were necessary. Staff believed that they could influence their workplace through ideas and involvement and their concerns during periods of change are heard and taken into consideration.

Achieving goals- Staff members have clearly defined goals that relate to the goal and mission of the clinic. They participate in defining specific goals.

Coordinated Teamwork- Staff members work together collaboratively, preferring cooperation over completion. Managers at all levels work together as a team to achieve results for the organization.

Customer orientation- Staff members give the highest priority and support to meeting the needs of patients. The clinic always looks for new and better ways to cater to patients. Overall, OCAQ revealed that staff are flexible with practice changes, participate in achieving a defined goal, and collaborate to improve patient outcomes.

Based on interviews with the clinic manager, sponsor of the clinic, and staff, urine is the standard specimen collected for STI screening due to its convenience and ease of workflow. QI projects on improving STI screening with vaginal swabs were performed in the past and were unsuccessful due to lack of monitoring of vaginal swabs supply and non-adherence to practice change.

Intervention

The QI project was implemented over a 15-week period from September 2024 to December 2024. The goal for the implementation was 100% of vaginal specimen collection for all eligible participants screened at the clinic by the end of Week 15. In the months preceding project implementation, the QI Project Lead (QI-PL) mobilized an interdisciplinary team of stakeholders at the clinic to plan the following structure and workflow changes: incorporation of self-collected vaginal swabs into the STI testing workflow, supply of vaginal swabs, display of self-collection diagrams in the clinic's exam rooms and bathrooms, and integration of self-collection training module into the Employee Training system.

Several strategies and tactics were used to accomplish the structural changes and attain the goals of the QI project. One strategy was the modification of the STI testing workflow. Sexually active women aged 14-50 years seeking STI screening at the clinic were offered vaginal swabs to self-collect specimens. A medical assistant escorted participants from the waiting room to the exam room after check-in. After verification of personal identifiers, a vaginal swab was handed to participants to self-collect. The medical assistant instructed patients on how to properly self-swab vaginal specimens and the diagram displayed in the room was used as a resource. After collection, the medical assistant took the vaginal specimen to the lab for testing (Figure 5). Another strategy was the training of the clinic's staff on how to properly instruct participants on specimen collection. Staff were required to complete the online training module and pass the post-test with a score of 100% to show proof of competency. Self-collection diagrams were ordered by the clinic's manager and displayed in the exam rooms and bathrooms (Appendix C). The practice coordinator was designated as the person responsible for the ordering and monitoring of the supply of vaginal swabs. A weekly count of vaginal swabs was performed by the practice coordinator to ensure availability. The threshold to order more swabs was weekly count below 100 swabs. Vaginal swabs were ordered and placed in all exam rooms.

Measures

Count audit of vaginal swabs, completion of online training module and chart audit were measured (Figure 8). The count audit was done by the practice coordinator. A weekly count was done to ensure availability and keep track of the supply. The count was recorded in the clinic's STI supplies folder and a new order was placed when the count was below 100 vaginal swabs. The practice coordinator also audited employees that completed the training module. CAL system records module completion by employees and it was accessible to the practice

coordinator to view. Practice coordinator ensured that the module was completed by all employees. Weekly, the Quality Improvement Project Leader/QI-PL (Nafissatou Salami) reviewed eligible participants charts in EHR (Epic) and recorded findings into an electronic REDCap audit tool. When auditing charts, QI-PL ensured that only women from age 14-50 seeking STI screening charts were reviewed. Data was collected through weekly reports that were run through Epic. When running reports, eligible participants and "Visit type" were checked. Visit type was specifically STI screening. Epic generated the report of eligible participants with STI visit type that got screened. A week time frame was entered in to view the number of eligible participants that got screened that week. The report specified the number of vaginal and urine specimens that were collected for all participants for that week. Data is then retrieved and entered into REDCap by the QI-PL using side by side screen method in a private room at the clinic. There were no barriers to data collection. Participant's' data were protected using HIPAA rules and guidelines. The facilitator for data collection was Epic report generator. The generator gives all the data that is required for the data collection.

Ethical considerations

The QI project was conducted ethically and not harmful to participants and anyone involved. Participants' data were retrieved and entered into REDCap (secure and encrypted database) by the QI-PL using side by side screen method in a private room at the clinic. Data were protected using HIPAA rules and guidelines. There was no hard copy paper of participants' data to minimize violation of privacy. Protected health information was de-identified by coding the data via the REDCap database and removing patient identifiers after data collection. The QI project was reviewed and approved by the Human Research Protection Office (HRPO) and was classified as non-human subject's research.

Results

Data was collected for 15 weeks from September 4th, 2024, to December 20th, 2024. A total of 202 eligible participants were screened for chlamydia, gonorrhea, and trichomonas. These participants were seeking STI screening at the clinic without symptoms. Out of 202 eligible participants, 134 self-swab and 68 provided urine specimens with an age range of 16 to 46 years indicating a 66% (n= 134) overall adherence (Figure 10). The median age is 25 (Figure 11). Staff stated that the 68 participants that opted for urine specimens were not comfortable with self-swabbing despite education given to them on the increased sensitivity with vaginal specimens in screening for STI.

Analysis

Descriptive statistics were employed to analyze and measure the impact of the QI project. A run chart was performed to track the progress of the implementation, monitor practice adherence, and predict trends and patterns over time (Figure 9). The 15 data points on the x-axis represents weeks of data collection and the y-axis represents the percentage of vaginal specimens collected. There are no shifts, trends, or runs noted. At the beginning of implementation (Week 1 to Week 3), the percentage of practice adherence was lower than the median. At the beginning of Week 4, a default order of vaginal swab in Epic was introduced to increase vaginal specimen collection rate. Every participant that come in for chlamydia, gonorrhea, and trichomonas screening are offered vaginal swab for specimen collection unless they decline. This promoted an increase in vaginal collection rate as shown from Week 5 to Week 10. Hundred percent of practice adherence was achieved on Week 8. The goal of the QI project was only achieved that week. After Week 10, a steady decrease in collection rate was noted and it was due to barriers

such as personal discomfort with self-swabbing from participants and lack of participation from medical assistants in offering self-collection swabs. The overall practice adherence was 66% which is below the median (80%). The target goal of 100% collection rate was not met.

Discussion

The implementation of self-collected vaginal swabs for the screening of chlamydia, gonorrhea, and trichomonas demonstrates a notable change in specimen collection practice at the reproductive health clinic. Prior to implementation, urine specimens accounted for 92% of all STI testing, with only 8% of tests using vaginal swabs. After 15 weeks of implementation, there is a notable increase in the use of vaginal specimens to 66%, with urine specimens declining to 34%. This shift shows promising progress toward the clinic's goal of achieving a 100% uptake of vaginal swab specimens. The transition to self-collected vaginal swabs is guided by evidence indicating its sensitivity for detecting chlamydia, gonorrhea, and trichomonas particularly in women. Numerous studies support the use of vaginal swabs as the preferred specimen type over urine, due to higher organism load in the vaginal canal, which increases the likelihood of detection especially in asymptomatic individuals. Our findings support these clinical recommendations and reflect that implementation strategies can meaningfully influence provider practices and patient outcomes.

Despite these gains, the 100% target was not met, and several barriers were identified that may have contributed to this gap. Patient discomfort and hesitancy around vaginal collection emerged as a primary obstacle. Some patients expressed concerns about the physical process or lack of confidence in their ability to properly collect the sample. These concerns may have deterred them from selecting the vaginal swab option, even when it is presented as self-collected and non-invasive. In addition, inconsistencies among clinic staff in promoting and educating

patients about the self-swab method affects the fidelity of the implementation. While some staff members were highly engaged and consistently recommended vaginal swabs, others reverted to familiar practices and offered urine collection as the default. Variations in approach likely contributed to the continued use of urine specimens in over one-third of cases. These findings underscore the critical role of staff training, buy-in, and standardized workflows in sustaining new clinical practices.

Moving forward, addressing both patient and staff barriers will be essential. Patient education materials that emphasize the accuracy, safety, and ease of self-collection may help reduce discomfort and increase acceptance. Simultaneously, reinforcing staff training and accountability measures can promote consistency and adherence to best practices. Incorporating feedback loops, audits, or incentives may further enhance compliance and engagement. To ensure the continued success of self-collected vaginal swabs as the primary STI screening method, several sustainability strategies must be implemented (Figure 7). A key sustainability effort involves increasing patient awareness and comfort with self-collection. This can be achieved through educational materials like developing culturally sensitive pamphlets, posters, and digital content explaining the benefits and ease of self-collected vaginal swabs. Another key sustainability effort will be standardizing staff training and accountability through mandatory training by incorporating training sessions into onboarding and routine staff development to reinforce knowledge on best practices and patient counseling. Furthermore, implementing workflow checklists to ensure that vaginal swabs are the default recommendation and that urine specimens are used only when clinically necessary. Embedding self-collection as a standard practice within clinic policies will support long-term sustainability. Integrating electronic health

record (EHR) prompts to remind providers and staff to offer vaginal swabs first will also aid in sustainability efforts.

While the implementation of self-collected vaginal swabs led to a notable shift in specimen use, several factors may have affected the internal validity of the project. These include sources of bias, imprecision in data collection, and variability in implementation, which could have influenced the outcomes. Patients were not randomly assigned to specimen type, which could introduce selection bias. Staff may have been more likely to offer vaginal swabs to certain patients such as older patients or those perceived to be more comfortable with their bodies, resulting in non-representative uptake rates. Differences in how consistently staff promoted and instructed patients on self-collection introduced variability in implementation. Some staff may have defaulted to urine collection out of habit or uncertainty. Documentation of specimen type within patient records may have been subject to inconsistent charting. If vaginal swabs were performed but not accurately coded, this would affect the accuracy of reported percentages. The timeframe between implementation and measurement may have been too short to capture full workflow changes. This could result in temporal bias, where early adoption may not reflect long-term trends or outcomes.

The increase from 8% to 66% in vaginal swab utilization marks a notable change, but sustainability efforts are necessary to achieve the 100% goal. A multi-faceted approach that addresses patient concerns, enhances staff adherence, and institutionalizes best practices will be key to ensuring the long-term success of this initiative. By embedding these changes into clinic culture and operations, the clinic can continue to optimize STI screening outcomes while maintaining patient-centered care.

Conclusion

This quality improvement project to increase the use of self-collected vaginal swabs for STI testing represents an advancement in aligning clinical practice with evidence-based guidelines. The project has improved the screening of chlamydia, gonorrhea, and trichomonas, contributing to better patient outcomes and more effective public health interventions. The value of this initiative to the healthcare profession lies in its focus on evidence-informed decision-making, patient-centered care, and workflow optimization. It also promotes a more proactive, preventive approach to reproductive health. From a healthcare delivery and quality standpoint, the project enhances clinical practice by standardizing a superior testing method and integrating it into routine care. These improvements reduce missed diagnoses, improve treatment timeliness, and help curb transmission of infections in the community. The focus on staff training, patient education, and data-driven feedback also contributes to a culture of continuous quality improvement. This project demonstrates that even small but targeted changes in clinical workflows can yield significant improvements in quality of care. It reinforces the importance of aligning practice with evolving evidence, engaging both patients and staff in the process, and using structured frameworks like PARIHS to guide implementation. Other clinics and health systems can adopt similar approaches to enhance the effectiveness of STI screening and contribute to broader goals in reproductive and public health. Overall, this initiative exemplifies how thoughtful, data-informed quality improvement can elevate standards of care, promote equity, and build more responsive and resilient health systems.

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Appendix A

Evidence Review of Sensitivity Comparison between Vaginal and Urine Specimen in detecting STI

Citation #1: Aaron, K. J., Griner, S., Footman, A., Boutwell, A., & Van Der Pol, B. (2023). Vaginal Swab vs Urine for Detection of Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis: A Meta-Analysis. Annals of family medicine, 21(2), 172–179. http					**Level and Quality** **III-B**
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
Provide a synthesis of the evidence on the diagnostic assay sensitivity for female vaginal swabs vs urine samples among commercial assays for chlamydia, gonorrhea, and trichomoniasis.	Meta- Analysis Systematic review	**Search strategy:** The review strategy was based on published frameworks, including the PRISMA and QUORUM guidelines for systematic reviews and meta-analysis of diagnostic tests and reporting. **Eligible Participants:** Symptomatic and asymptomatic adult	**Intervention protocol:** The estimation of diagnostic sensitivity of commercially available assays for vaginal swabs compared to urine specimen from women in testing Chlamydia, Gonorrhea, and Trichomonas.	Higher test sensitivity with vaginal swab specimen compared to urine specimen. **Measures:** RealTime CT/NG polymerase chain reaction (PCR) assay (Abbott Laboratories); Amplicor PCR assay, and cobas PCR assay (Roche Diagnostics) Transcription-mediated amplification and hybridization	**Statistical Results:** 20 studies contributed 30 comparisons of CT detection. Pooled sensitivity estimates from the studies were 94.1% for vaginal swabs and 86.9% for urine specimens (P <.001). For NG, 10 studies contributed 16 comparisons. The pooled sensitivity

		and/or adolescent women **Excluded:** Pediatric **Setting:** Primary care settings, community health organizations, and clinics specializing in sexually transmitted disease, obstetrics and gynecology, or family planning in UK, USA, and Canada. **Homogeneity:** 50% for chlamydia and gonorrhea and 66% for trichomonas which indicates moderate to high homogeneity. **Inclusion criteria:** Studies that evaluated commercially available NAATs for CT, NG, and TV presented data for adolescent and/or		protection assay (Hologic); ProbeTec strand displacement amplification, MAX CTGCTV, and CTGCTV2 real-time PCR assays (Becton, Dickenson and Company); Dx CT/NG/MG real-time PCR assay (Bio-Rad Laboratories, Inc); CT/NG Xpert Rapid real-time PCR and Xpert TV PCR (Cepheid	estimates were 96.5% for vaginal swabs and 90.7% for urine specimens (P <.001). Nine studies contributed nine comparisons of TV performance with vaginal swabs and urine. Pooled sensitivity estimates were 98.0% for vaginal swabs and 95.1% for urine specimens (P <.001). **Conclusion:** Overall, 6% lower sensitivity of urine specimen compared to vaginal specimen in testing for Chlamydia, Gonorrhea, and Trichomonas.

		adult women; included sensitivity data obtained from the same assay on both a urine specimen and a vaginal swab; used a reference standard other than the test being evaluated; and were published in English. **Data extraction:** The titles and abstracts of studies identified by the search were screened by all authors and studies that did not meet eligibility criteria were removed. Abstracts had to describe a population of sexually active adolescent or adult women and a relevant commercially based assay for CT, NG, or TV to be considered further. The full-text			

		reports of all potentially relevant studies were obtained and assessed independently for eligibility, based on the defined inclusion criteria.			
Citation #2: Krause, A., Miller, J. B., Samuel, L., & Manteuffel, J. J. (2022). Vaginal Swabs Are Non-inferior to Endocervical Swabs for Sexually Transmitted Infection testing in the Emergency Department. The western journal of emergency medicine, 23(3), 408–411. http					**Level and Quality** **II-B**
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**

Prove that vaginal swabs aren't inferior to endocervical swabs in detecting Chlamydia and Gonorrhea by comparing the detection rate for both. **Hypothesis:** STI detection rates using vaginal swabs in the ED would be equivalent to the pre-implementation protocol that used only endo-cervical swabs collected by clinicians.	Quasi-Experimental Retrospective	**Sampling Technique:** Convenience **Eligible Participants:** Women who received testing for Chlamydia and Gonorrhea in the nine Emergency Departments (Eds) during the study period. Those women were both symptomatic and asymptomatic of STIs. **Setting:** Nine Eds in the metropolitan Detroit, Michigan, area. **Excluded:** Men **Accepted:** 22,291 encounters **Control:**	**Control Protocol:** Endocervical swabs collected by clinicians using the Aptima Unisex Swab Specimen Collection Kit (Hologic, Inc., Marlborough, MA). **Intervention Protocol:** Vaginal swabs collected by patients or clinicians. Clinicians would perform the vaginal swabs if the patient had any STI symptoms, if asymptomatic patients requested that the clinician collect the swabs, or if the patient was unable to perform the swab herself. Patients who collected their own vaginal swabs were provided instructions on how	**Dependent Variable:** Vaginal swabs collected by both patients and clinicians for STI testing in the ED resulted in chlamydia and gonorrhea detection rates similar to those from using endocervical swabs collected by clinicians. **DV Measure:** Testing was performed by transcription-mediated amplification using the Aptima Combo 2 assay on the Panther platform (Hologic). Data was pooled from the electronic health record (I) across the Henry Ford Health System.	**Statistical Results:** The rate of detection of Chlamydia was 7.5% pre-implementation and 7.6% post-implementation (between-group difference, 0.1 percentage points; 95% CI: −0.7, 0.4; P <.01 for non-inferiority). The rate of detection of gonorrhea was 3.1% pre-implementation and 3.6% post-implementation (between-group difference, 0.5 percentage points; 95% CI: −0.8, 0.04; P < 0.1 for non-inferiority). **Conclusions:** The results of this study showed that detection rates of chlamydia and gonorrhea collected through vaginal swabs were non-inferior to

		11,732 encounters used endocervical swabs collected by clinicians. **Intervention:** 10,559 encounters self-swab by patients. **Power Analysis:** Power of 95% and alpha = 0.05 were estimated. Analysis consisted of non-inferiority testing for proportion with a non-inferiority margin of one percentage point absolute difference in detection rates of STI.	to perform the intravaginal swabs per MDHHS and CDC policies prior to collection by either a nurse or clinician. **Treatment fidelity:** Specimens for testing for Chlamydia and Gonorrhea were collected using the Aptima Vaginal Swab Specimen Collection Kit (Hologic) following manufacturer's instructions.		those collected endocervical.

Citation #3: Lunny, C., Taylor, D., Hoang, L., Wong, T., Gilbert, M., Lester, R., Krajden, M., & Ogilvie, G. (2017). Self-Collected versus Clinician-Collected Sampling for Chlamydia and Gonorrhea Screening: A Systemic Review and Meta-Analysis. PloS one, 10(7), e013277					**Level and Quality** **I-B**
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**

Compare self-collected vaginal samples to clinician collected cervical samples for Chlamydia and Gonorrhea screening.	Meta- Analysis Systematic review	Randomized control trials, Quasi-randomized trials, cross-sectional observational studies. **Eligible Participants:** Adult asymptomatic and symptomatic women **Setting:** Health clinics in US and Europe **Search strategy:** The databases searched included the Cochrane Database of Systematic Reviews, Web of Science, Database of	**Intervention Protocol:** Estimation of sensitivity and specificity of self-collected swab compared clinician collected swabs for the screening of chlamydia and Gonorrhea. **Treatment fidelity:** Validity was assessed using the Quality Assessment of Diagnostic Accuracy Studies (Quadas) checklist.	**Dependent Variable:** For the detection of chlamydia, self-collected vaginal swabs and clinician collected swabs have similar sensitivity and specificity. For the detection of gonorrhea, self-collected vaginal swabs and clinician collected swabs have similar sensitivity and specificity. **DV Measure:** NAAT testing was used to detect sensitivity and specificity. NAAT used : PCR (Abbott LCx and Roche Amplicor), SDA (Becton Dickinson ProbeTec ET), TMA (Aptima, GenProbe Aptima Combo 2 [AC2], and Aptima	**Statistical Results:** Self-collected vaginal vs clinician-collected cervical samples: Chlamydia in women. Six studies comparing self-collected vaginal to clinician-collected cervical samples were included (n = 1806) When the studies were pooled, sensitivity was 0.92 (95% CI 0.87–0.95), and specificity was 0.98 (95% CI 0.97–0.99). Self-collected vaginal swabs vs clinician collected cervical samples: Gonorrhea in women. One cross-sectional study (n = 309) compared self-collected vaginal samples to clinician-collected cervical samples was included. The reported sensitivity was 0.98

		Abstracts of Reviews of Effects, EMBASE, and PubMed/Medline (January 1990 and June 2013). **Inclusion criteria:** Studies were included if they: (a) used a clinician-collected specimen as their reference standard, (b) included both positive and negative test results and (c) used a NAAT platform of: polymerase chain reaction testing (PCR), strand displacement amplification (SDA), transcription-mediated amplification (TMA), or ligase chain reaction (LCR). **Exclusion criteria:** (A) The time period between self- and		Neisseria gonorrhea assay), and LCR (Abbott LCx [LCx] assay)	(95% CI 0.88–1.00) and the specificity was 0.97 (95% CI 0.94–0.99) **Conclusions:** The high sensitivity and specificity of vaginal self-collected swabs compared to swabs collected by clinicians supports the use of vaginal swab self-collection for chlamydia and gonorrhea testing.

		clinician-collected samples was longer than three weeks (because of potential change in the disease status of the patient), (b) participants were known to be positive for disease before enrolment in the study, (c) any combined test result (e.g. urine and vaginal combined as self-collected), (d) more than 20 percent of included patients dropped out of the study, I authors did not reply to our request for additional data, (f) the study did not include a NAAT.			
Citation #4: Gottlieb, M., Williams, C. J., & Pierre, V. A. (2023). What Is the Accuracy of Vaginal Swab Versus Urine for Detection of Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis? Annals of emergency medicine, 82(4), 517–519. https://doi.or					**Level and Quality** **III-B**
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**

The purpose of this meta-analysis is to determine the sensitivity between vaginal swab specimen and urine specimen in detecting chlamydia, gonorrhea, and trichomonas.	Meta- Analysis Systematic review	**Eligible Participants:** Adult and adolescent women **Setting:** STD and Obstetrics clinics in Australia, Canada, France, Germany, Sweden, Ukraine, UK and USA. **Search strategy:** The authors searched PubMed, EBSCO, Scopus, and the Cochrane Central Register of Controlled Trials from January 1, 1995, through December 31, 2021. **Inclusion criteria:** Inclusion criteria required studies to have evaluated commercially available nucleic acid	**Intervention protocol:** Estimation of sensitivity of vaginal swabs compared to urine for chlamydia, gonorrhea, and trichomonas.	Higher test sensitivity with vaginal swab specimen compared to urine specimen in detecting Chlamydia, Gonorrhea, and trichomonas in women.	**Statistical results:** 20 studies for Chlamydia were reviewed. Vaginal swab sensitivity is 94% and urine sample sensitivity is 86.9%. Odd ratio is 2.69. Ten studies were reviewed for Gonorrhea. Sensitivity for vaginal swab is 96.5% and 90.7% for urine sample. Odd ratio is 3.68. Nine studies were reviewed for Trichomonas. Sensitivity for vaginal swab is 98.0% and 95.1% for urine sample. Odd ratio is 2.48. **Conclusions:** This study found significantly higher sensitivity for vaginal swabs than urine for the detection of chlamydia,

		amplification tests for the relevant infections, include data on the sensitivity from the same assay on both urine specimens and vaginal swabs. **Exclusion criteria:** Pediatric testing data			gonorrhea, and trichomoniasis.

Citation #5: Pickett, M., Visotcky, A., Brazauskas, R., Ledeboer, N., Drendel, A (2021). Can a Clean Catch Urine Sample Be Used to diagnose Chlamydia and Gonorrhea in Adolescent Females? Journal of Adolescent Health, 69(4), 574-578. https://doi.org/10.1016/j.jadohealt					**Level and Quality** **III-B**
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**

The purpose of this study is to determine the sensitivity and specificity of clean catch urine for chlamydia and gonorrhea in women.	Prospective cohort study	**Sampling Technique:** Convenience **Eligible Participants:** Adolescent and young adult females aged 14-22 years. **Setting:** Children's hospital Emergency Department and an Adolescent Medicine clinic at Children's hospital. **Accepted:** Women aged 14-22 years requiring chlamydia and gonorrhea testing.	**Intervention Protocol:** Samples of vaginal swab, clean catch urine, and dirty urine were collected from the eligible participants and analyzed using Hologic's Aptima Combo2 Assay.	**Dependent Variable**: Clean catch urine is noninferior to dirty urine. Sensitivity and specificity of vaginal swab is higher than clean catch urine	**Statistical Results:** For chlamydia, 59 participants were positive by vaginal swab. The sensitivity of clean urine to diagnose chlamydia was 86.2% (95% CI: 74.8%–93.1%) and specificity was 98.8% (95% CI: 96.5%–99.8%). The sensitivity of dirty urine to diagnose chlamydia was 89.8% (95% CI: 79.2%–95.6%), and the specificity was 99.6% (95% CI 97.6%–100%). For gonorrhea, 18 participants were positive by vaginal swab. The sensitivity of clean urine to diagnose gonorrhea was 94.4% (95% CI: 72.4%–100%) and specificity was 99.7% (95% CI: 98.0%–100.0%). The

		Intervention: Vaginal swab, clean urine test sample and dirty urine.			sensitivity of dirty urine to diagnose gonorrhea was 100% (95% CI: 79.3%–100%) and specificity was 99.7% (95% CI: 98.0%–100%). **Conclusions:** Clean urine samples may be an alternative option to diagnose chlamydia and gonorrhea in women but not sensitive compared to vaginal swabs.

Citation #6: Van Der Pol, B., Taylor, S. N., Mena, L., Lebed, J., McNeil, C. J., Crane, L., Ermel, A., Sukhija-Cohen, A., & Gaydos, C. A. (2020). Evaluation of the Performance of a Point-of-Care Test for Chlamydia and Gonorrhea. JAMA network open, 3(5), e204819. https					**Level and Quality** **III-B**
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**

The purpose of this study is to evaluate the clinical performance of a point-of-care (POC) molecular diagnostic assay for the detection of chlamydia and gonorrhea.	Cross-sectional study	**Sampling Technique:** Convenience **Eligible Participants:** Women and men seeking STI screening or diagnosis at 11 clinics in geographical locations. **Setting:** STI, HIV, family planning, and obstetrics and gynecology clinics. **Excluded:** 341 participants who had taken antibiotics effective against chlamydia or gonorrhea within the past 28 days.	**Intervention protocol:** Participants were categorized as symptomatic if they reported abnormal discharge, dysuria, genital itching, pelvic pain, or discomfort during intercourse. Women were asked to provide 4 vaginal swabs: 3 clinician-collected swab samples using collection and transport devices approved for use with the 3 commercially available nucleic acid amplification tests (NAATs). Women were randomized such that one-half collected their own swab samples for the experimental assay prior to any other swab samples, while the remainder had the	A composite infection status was used to classify participants as infected if 2 or more comparator results were positive, as not infected if 2 or more comparator samples were negative, and as unevaluable if 1 result was invalid and the other 2 results did not agree with each other.	**Statistical results:** Swab samples from 1523 women, 817 (53.6%) of whom presented with symptoms, and 922 men, 308 (33.4%) of whom were symptomatic, were tested. For chlamydia, sensitivity of the new POC assay was 96.1% (95% CI, 91.2%-98.3%) for women and 92.5% (95% CI, 86.4%-96.0%) for men. For gonorrhea, sensitivity estimates were 100.0% (95% CI, 92.1%-100.0%) for women and 97.3% (95% CI, 90.7%-99.3%) for men. For chlamydia, specificity of the new POC assay was 99.1% (95% CI, 98.4%-99.5%) for women and 99.3% (95% CI, 98.4%-99.7%) for men. For gonorrhea, specificity

		Accepted: 2445 people comprised of 1523 women and 922 men. **Intervention:** Four vaginal swabs were collected from women and first-catch urine sample was obtained from men.	experimental assay swab samples collected by a clinician as the last vaginal sample taken. The comparator assay swab sample collection order was randomized. Men provided a first-catch urine sample that was aliquoted into 4 transport devices: 1 for the new POC assay and the other 3 for the comparator NAATs. **Treatment fidelity:** Comparator assays, chosen because they are the 3 most commonly used chlamydia and gonorrhea diagnostic assays in the United States, were performed in a central laboratory in compliance with the		estimates were 99.9% (95% CI, 99.5%-100%) for women and 100% (95% CI, 95.5%-100%) for men. **Conclusions:** The self-obtained vaginal swab samples were associated with performance equivalent to laboratory-based molecular diagnostics, which can support use of this POC assay in many settings. The availability of an easy-to-use, rapid (30-minute) molecular test for accurate detection of chlamydia and gonorrhea has the power to facilitate testing and treatment in a single patient visit for these STIs.

			manufacturers' instructions for use. Technologists performing any given assay (binx or comparator assays) were blinded to the results of the other assays.		
Citation #7: Chinnock, B., Yore, M., Mason, J., Kremer, M., Farshidpour, L., Lopez, D., & Castaneda, J. (2021). Self-obtained vaginal swabs are not inferior to provider-performed endocervical sampling for emergency department diagnosis of Neisseria gonorrhoeae and Chl					**Level and Quality** **III-B**
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**

The purpose of this study is to determine whether self-obtained vaginal swabs have noninferior sensitivity for the diagnosis of Chlamydia and Gonorrhea compared to provider-performed endocervical sampling.	Prospective observational cohort study	**Sampling Technique:** Convenience **Eligible Participants:** Female patients 18 years and older who were judged by the treating practitioner to need Chlamydia and Gonorrhea testing. **Setting:** Emergency Department at an Academic urban hospital. **Excluded:** Patients were excluded from if incarcerated, if an acute psychiatric	**Intervention Protocol:** Self-obtained vaginal swabs collection (SOVS) occurred without any direct assistance from ED personnel. Patients were given a handout describing the sample collection method. Testing for Chlamydia and Gonorrhea was performed using a 90-minute runtime NAAT assay (Cepheid Xpert CT/NG) by the hospital central laboratory.	Primary outcome measure examined the noninferiority of SOVS sensitivity for Chlamydia and Gonorrhea with noninferiority being demonstrated if sensitivity was 90% or above. The sensitivity measurement for the primary outcome was a patient-specific composite measure, not organism-specific. Thus, a true positive was defined as concordant chlamydia/gonorrhea positive with both SOVS and PPES testing. **Measure:** Manufacturer-reported sensitivity	**Statistical results:** SOVS had a sensitivity of 95% (95% CI = 88% to 99%) for the detection of NG/CT when compared to PPES, with three false-negative CT and one false-negative NG patients. Examining organism-specific results, SOVS had a sensitivity of 97% (95% CI = 87% to 100%) for NG and 94% (95% CI = 84% to 99%) for CT. **Conclusions:** Self-obtained vaginal swabs were found to be noninferior to provider-performed endocervical sampling for the diagnosis of Neisseria gonorrhoeae/Chlamydia trachomatis using a rapid nucleic acid amplification test in the ED.

		condition precluded understanding instructions or giving informed consent, not English or Spanish proficient, or treated for Chlamydia and Gonorrhea within the previous 4 weeks **Accepted:** 515 patients **Control:** The provider performed endocervical sampling (PPES) was performed during standard speculum pelvic examination. **Intervention:** For self-obtained vaginal swabs, patients were given		for PPES for the Cepheid Xpert NG/CT assay is 99% for NG and 96% for CT.	

		instructions using a one-page handout describing the sample collection method.			

Appendix B

Evidence Synthesis

Project Title: **Increased Rate of Vaginal Swab Testing for the Detection of STI**			
PICOT: **In sexually active women aged 14-50 attending Planned Parenthood Baltimore clinic, does increased collection of vaginal swab for the testing of STI compared to collection of urine sample, result in early detection of STI and efficient screening?**			
JHNEBP Model Level	**Total Number of Sources**	**Author and Quality Rating of each study**	**Synthesis of Findings**
Level 1 Experimental study · Randomized Controlled Trial (RCT) · Systematic review of RCTs with or without meta-analysis	1 systematic review of RCT (Lunny et al.)	Lunny et al., B	Lunny et al found that self-collected vaginal swabs are as sensitive compared to clinician collected cervical samples in detecting chlamydia and gonorrhea. For chlamydia, sensitivity was 0.92 and specificity was 0.98 and for gonorrhea, sensitivity was 0.98 and the specificity was 0.97.
Level II Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis	1 Quasi-experimental study (Krause et al.)	Krause et al., B	Krause et al showed that detection rates of chlamydia and gonorrhea collected through vaginal swabs were non-inferior to those collected endocervical. The rate of detection of Chlamydia was 7.5% pre-implementation and 7.6% post-implementation. The rate of detection of gonorrhea was 3.1% pre-implementation and 3.6% post-implementation.

Level III Non-experimental study · Systematic review of a combination of RCTs, quasi-experimental, and non-experimental studies, or non-experimental studies only, with or without meta-analysis · Qualitative study or systematic review of qualitative studies with or without meta-synthesis	2 Systematic reviews of experimental studies with meta-synthesis (Aaron et al., Gottlieb et al.) 2 cohort studies Prospective and observational. (Pickett et al., Chinnock et al.) 1 cross-sectional study. (Van Der Pol et al.)	Aaron et al., B Gottlieb et al., B Pickett et al., B Chinnock et al., B Van Der Pol et al., B	Aaron et al compared sensitivity of Vaginal swab to Urine sample in detecting chlamydia, gonorrhea, and trichomonas and found that overall urine sample has 6% lower sensitivity than vaginal swab. Gottlieb et al also compared the sensitivity between vaginal and urine samples in detecting chlamydia, gonorrhea, and trichomonas. It found that vaginal swab has a higher sensitivity compared to urine sample. Vaginal swab sensitivity is 94% and urine sample sensitivity is 86.9% in detecting chlamydia. Sensitivity for vaginal swab is 96.5% and 90.7% for urine sample in detecting gonorrhea. Sensitivity for vaginal swab is 98.0% and 95.1% for urine sample in detecting trichomonas. Pickett et al found that clean catch urine may be an alternative in detecting chlamydia and gonorrhea in women but not as sensitive as vaginal swab. The sensitivity of clean urine to diagnose gonorrhea was 94.4%. The sensitivity of clean urine to diagnose chlamydia was 86.2%. Chinnock et al found out that self-obtained vaginal swabs were noninferior to provider collected endocervical swabs in detecting chlamydia and gonorrhea. SOVS had a sensitivity of 95% in detecting chlamydia and gonorrhea. Van Der Pol et al evaluated the clinical performance of a point-of-care (POC) molecular diagnostic assay for the detection of chlamydia and gonorrhea. It found that the POC assay is as efficient as the laboratory based

			molecular diagnostics in detecting chlamydia and gonorrhea.
Level IV Opinion of respected authorities and/or reports of nationally recognized expert committees/consensus panels based on scientific evidence			

Figure 1

Clinic's STI screening Root Cause Analysis/Fishbone Diagram

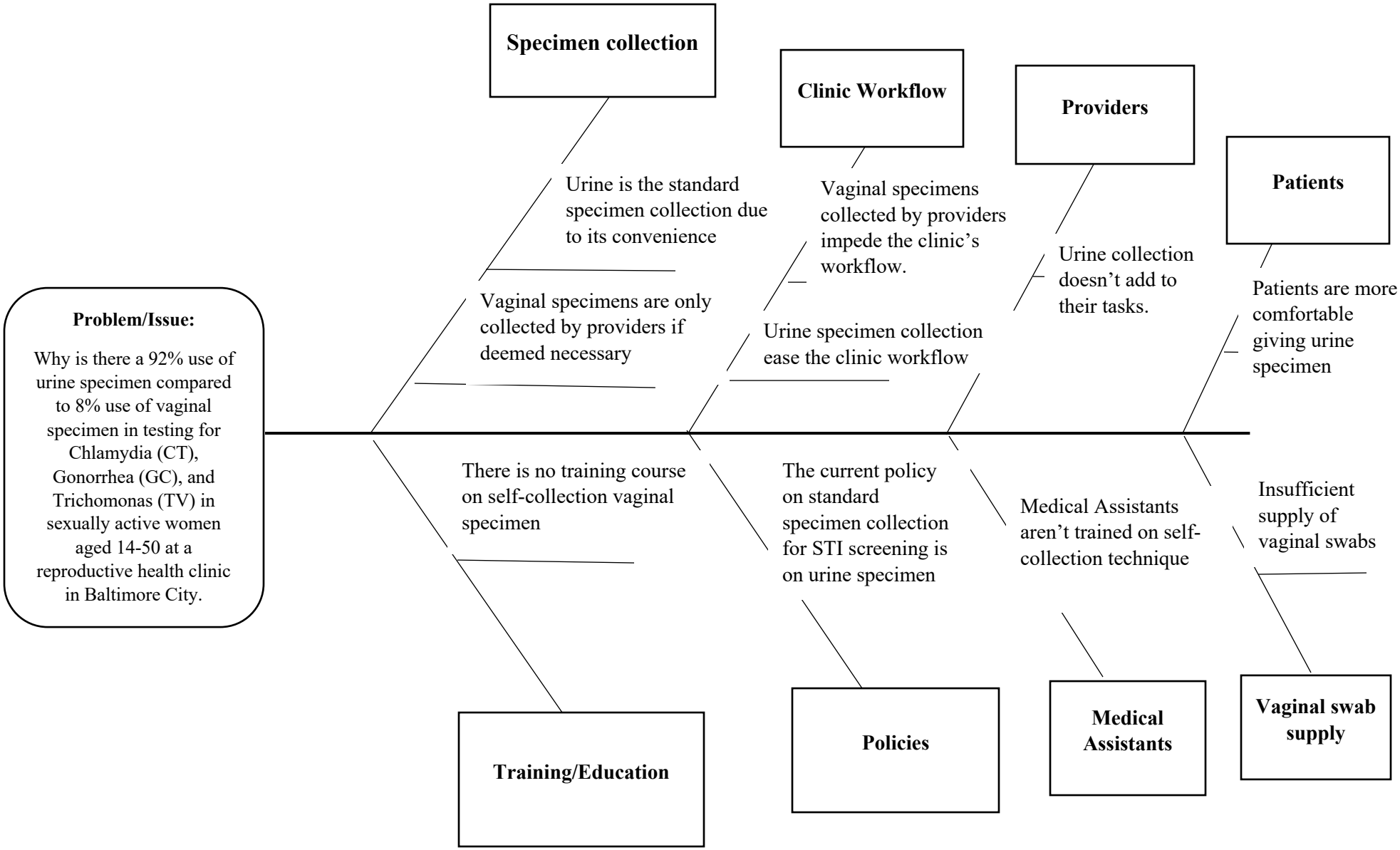


Figure 2

Current Process of STI Screening at the Clinic

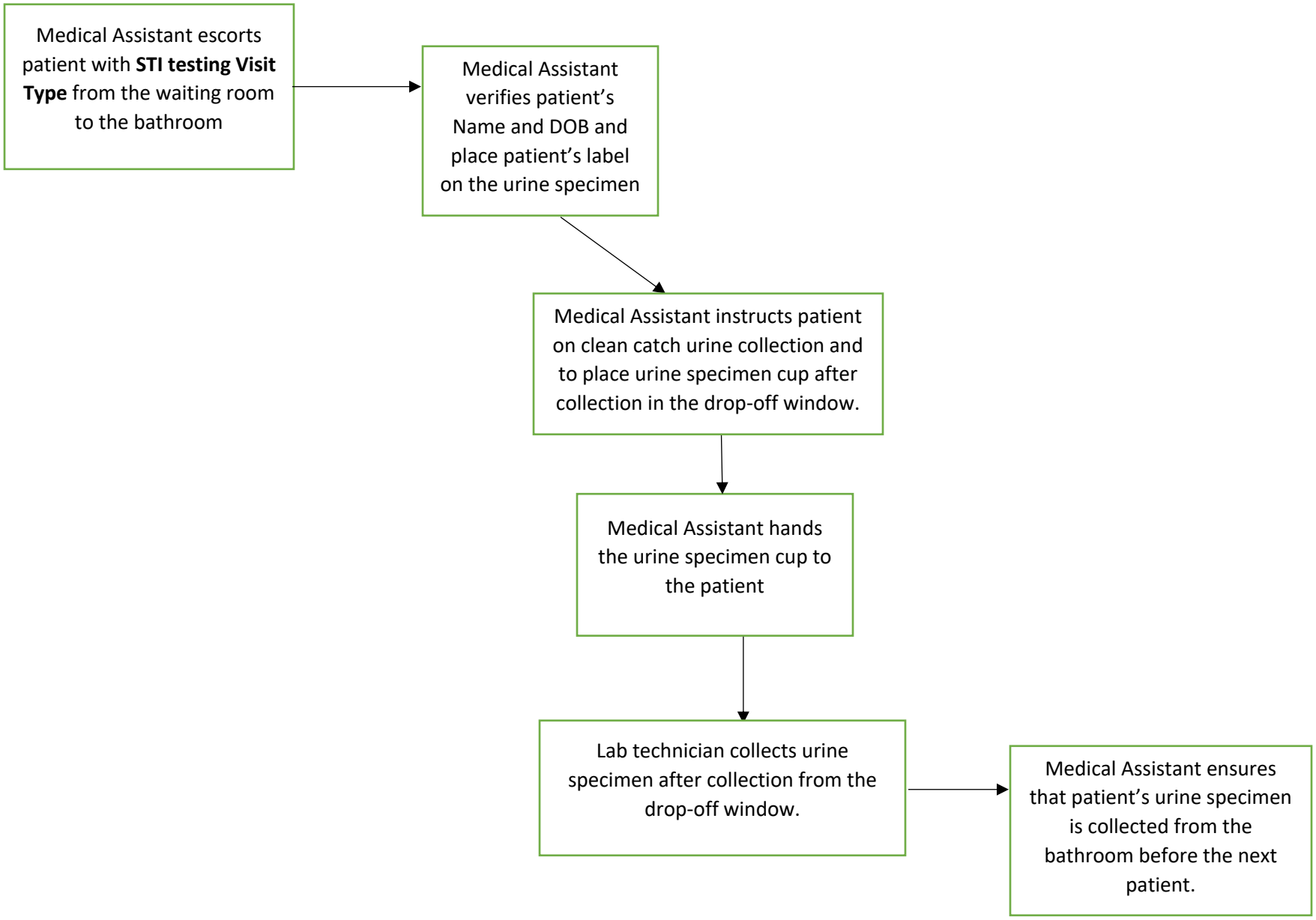


Figure 3

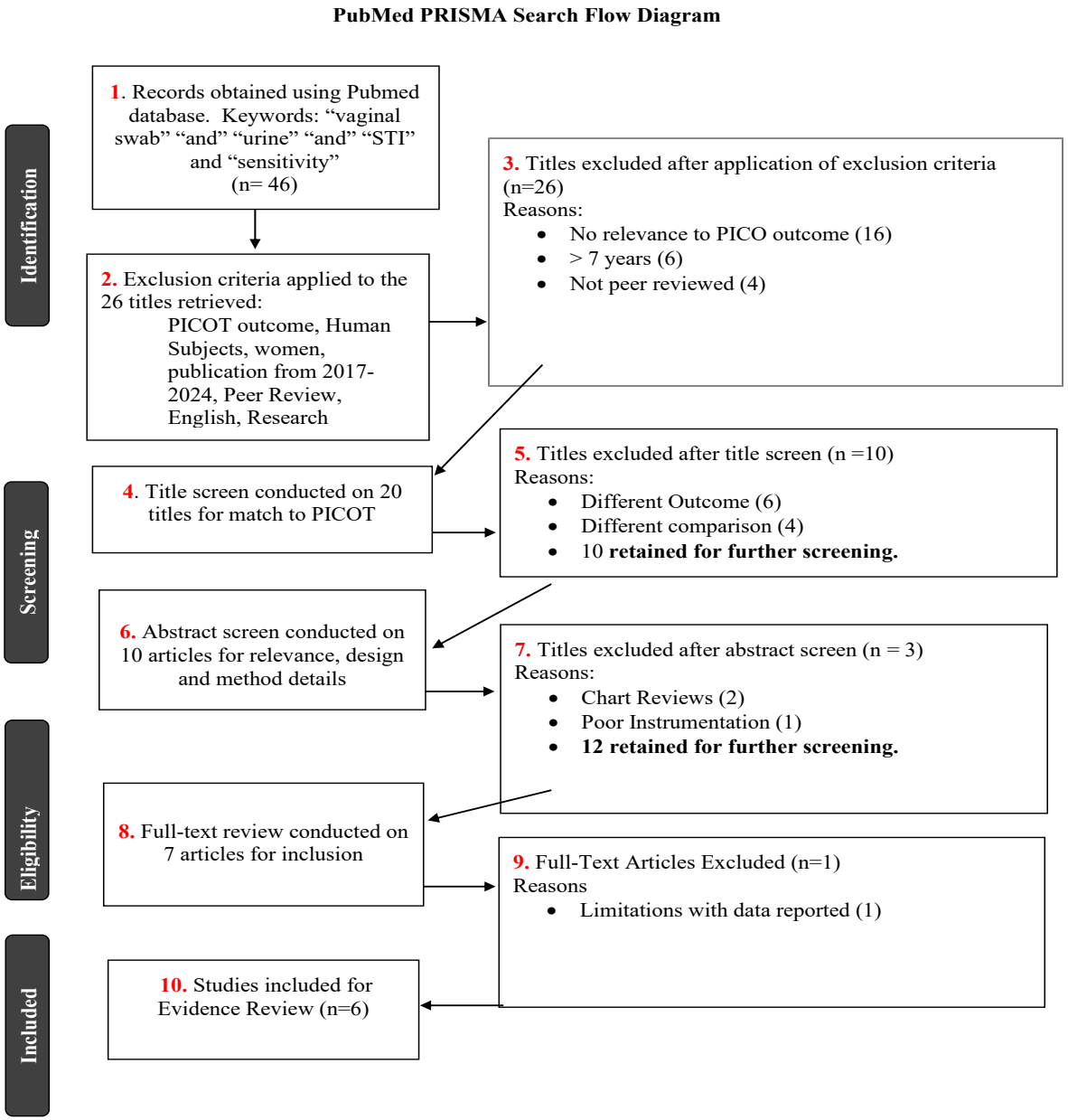

PubMed PRISMA Search Flow Diagram
Identification
Screening
Eligibility
Included
1. Records obtained using Pubmed database. Keywords: "vaginal swab" "and" "urine" "and" "STI" and "sensitivity" (n= 46)
2. Exclusion criteria applied to the 26 titles retrieved: PICOT outcome, Human Subjects, women, publication from 2017-2024, Peer Review, English, Research
3. Titles excluded after application of exclusion criteria (n=26)
Reasons:
No relevance to PICO outcome (16)
> 7 years (6)
Not peer reviewed (4)
4. Title screen conducted on 20 titles for match to PICOT
5. Titles excluded after title screen (n =10)
Reasons:
Different Outcome (6)
Different comparison (4)
10 retained for further screening.
6. Abstract screen conducted on 10 articles for relevance, design and method details
7. Titles excluded after abstract screen (n = 3)
Reasons:
Chart Reviews (2)
Poor Instrumentation (1)
12 retained for further screening.
8. Full-text review conducted on 7 articles for inclusion
9. Full-Text Articles Excluded (n=1)
Reasons
Limitations with data reported (1)
10. Studies included for Evidence Review (n=6)

Figure 4

PARIHS Theoretical Framework

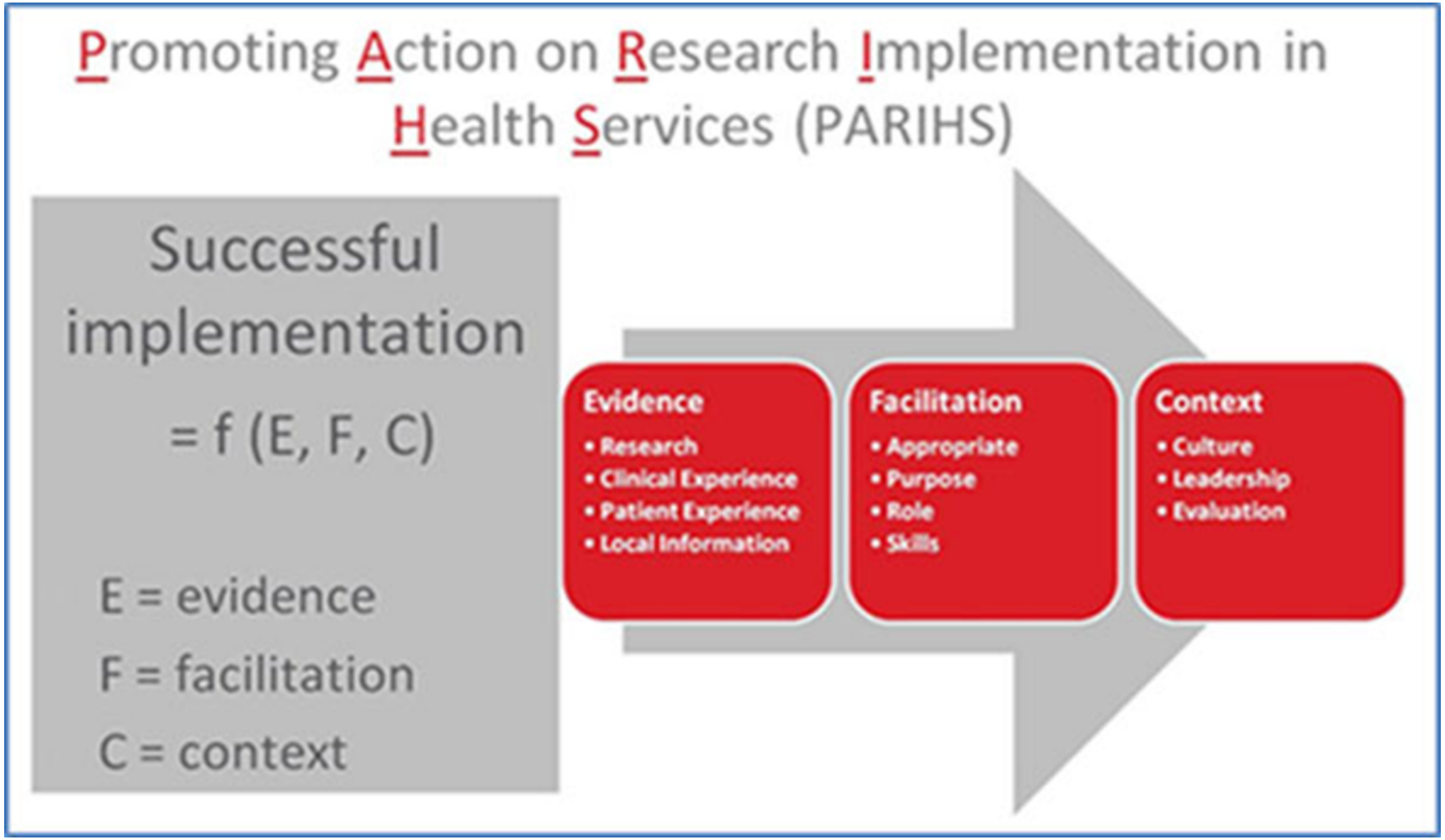


Figure 5

Desired Process of STI Screening at the Clinic

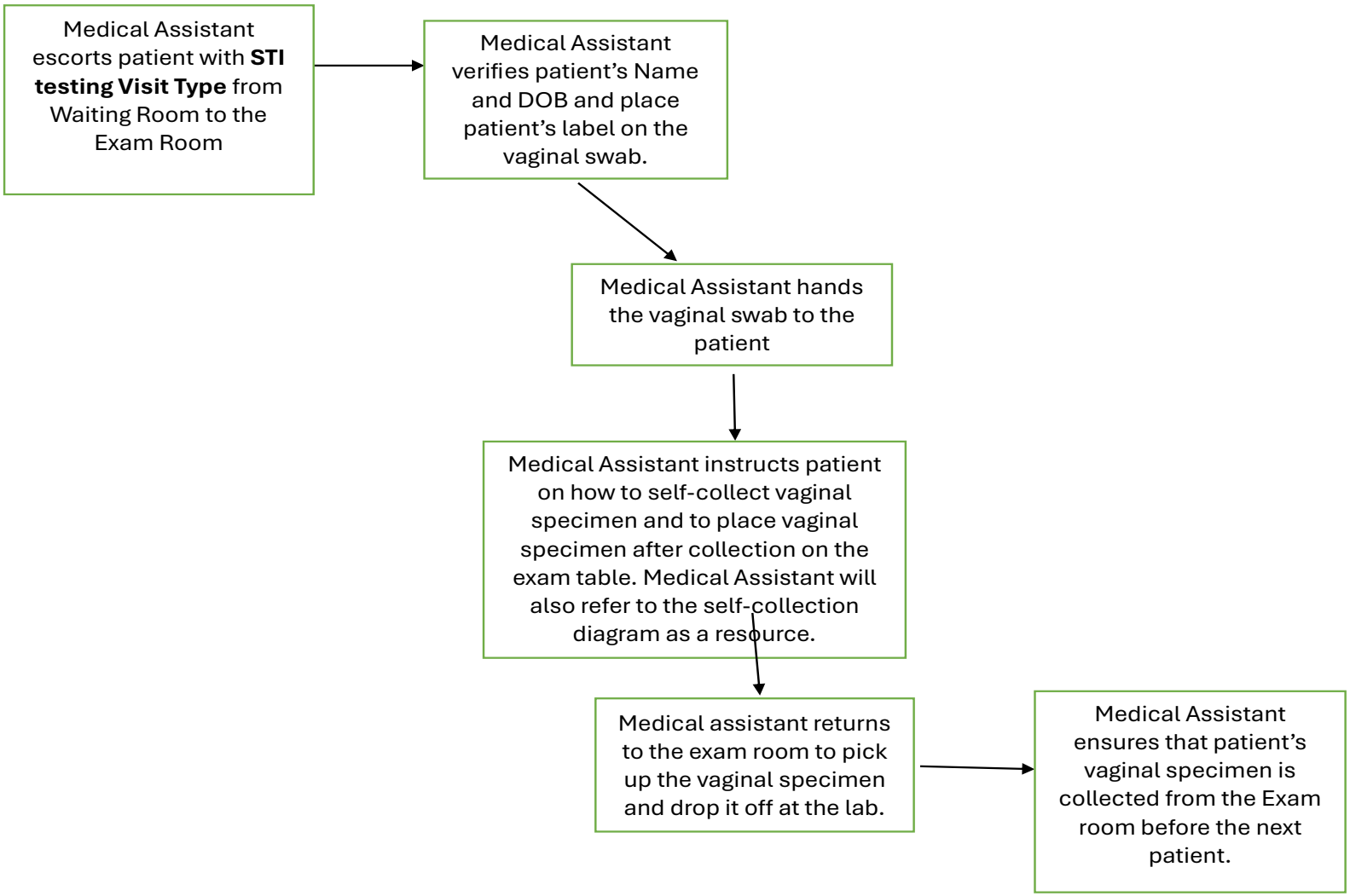


Figure 6

Project Timeline GANTT Chart

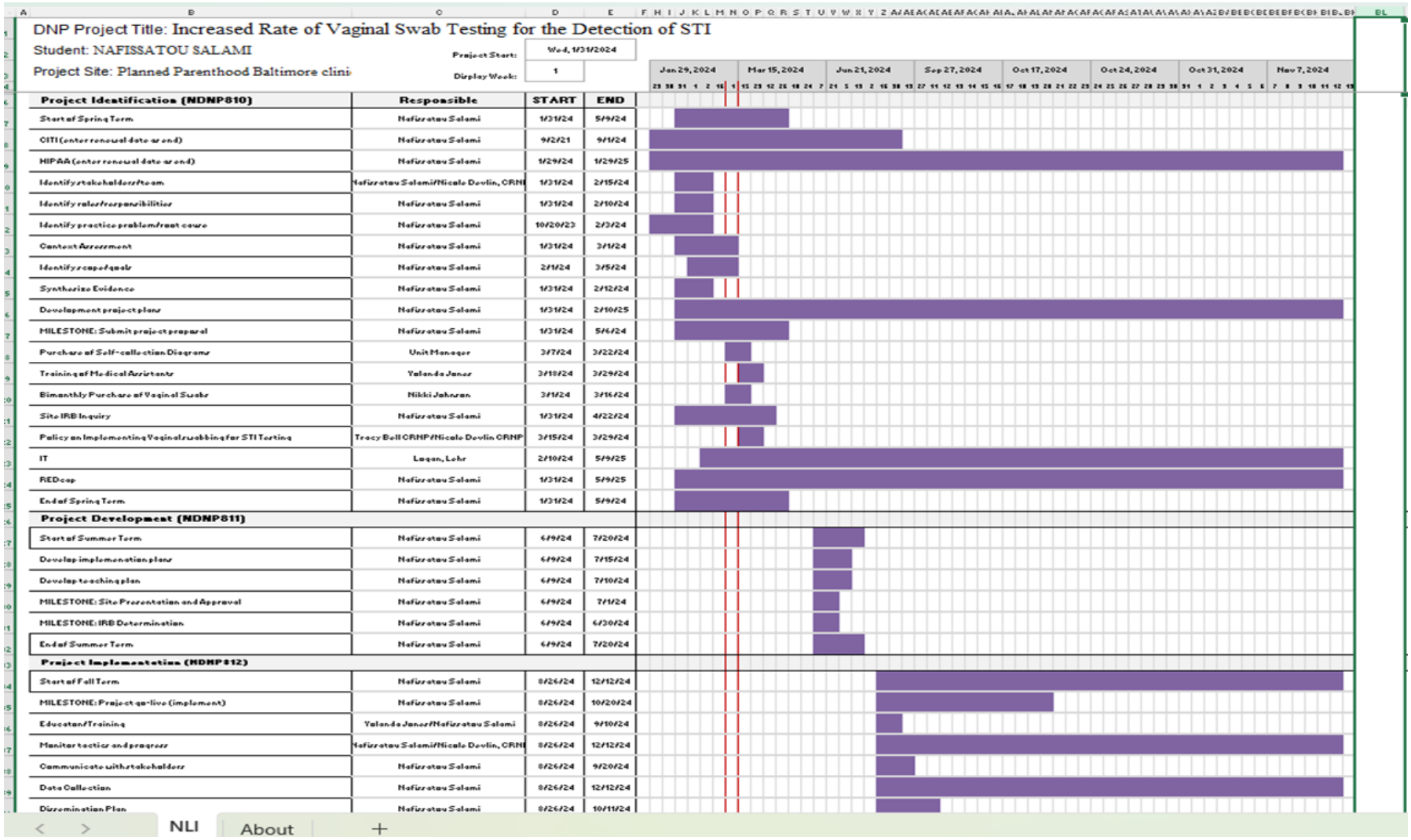


Figure 7

MOCHA/ Sustainability Planning Worksheet

Areas for Consideration	Notes
Measurement • What will we continue to measure? • What will we stop measuring? • What will we do if we see a negative signal (i.e., special cause variation)?	Continuous chart audits will be done to measure the success of the implementation. The quality assurance manager runs monthly reports of STI screening to ensure adherence of the use of vaginal swabs. The percentage of vaginal swab versus urine specimen will be measured. If there is a special cause variation, the root cause will be addressed, and modifications and changes will be applied where it fit.
Ownership • Who will own the new standard work? O Is he or she engaged and onboard with the improvement?	The Director of clinical services will own the implementation. She is responsible for ensuring that there is an adherence to the new standard of work. She is engaged in all the clinical services that occur at the clinic including STI testing. She will ensure that the implementation is ongoing, and the clinic staff adhere to the new practice change.

Communication and Training • How will we communicate about the change and who will be the messengers? • How will we support individuals in the new "right way"? • What type of training will we use?	Changes will be communicated through emails and periodic meetings between key stakeholders and healthcare professionals and updates will be discussed to ensure ongoing adherence to change. There will be an ongoing online refresher course that will be required for healthcare professionals to complete to remain competent.

Hardwiring the Change
• How will we make it hard to do the wrong thing and easy to do the right thing?
  o Can we reduce reliance on human memory?
• How will we standardize?
  o Do we need new documentation and resources?
	The default specimen collection will be vaginal swab for all women seeking STI testing at the clinic unless they refused. When a medical assistant orders the STI test on Epic, the default specimen type will pop as vaginal swab and can be changed to urine if a patient decides to give a urine specimen.

Assessment of Workload
• Are our changes increasing the overall workload to the system?
  o If so, how can we decrease the workload?
  o If not, how will we communicate about what is changing and not changing?
	The implementation is not affecting the clinic's workload. All healthcare professionals at the clinic have a weekly meeting where the workflow of the clinic and concerns are discussed. The meeting will be a great opportunity for staff to discuss the progression of the change and any concerns will be addressed.

Figure 8

Measurement Instruments/tools

Measures					
Measure/Tool	**Measure Type**	**Measure Source**	**Metric**	**Calculation**	**Copyright**
Chlamydia Screening in sexually active women between age 14-50	Process	National Committee for Quality Assurance Measure 0033	Number of sexually active women between age 14-50 screened for chlamydia	Numerator: Sexually active women between age 14-50 screened for chlamydia Denominator: Total number of women screened for STI testing	Yes
Staff that showed competency on training module	Structure	CAL system tracking record	Number of staff that successfully completed the training module and showed competency	Numerator: Number of staff that showed competency on training module Denominator: Total number of staff that are required to complete the training module	No
Monthly supply of vaginal swabs	Structure	Tracking supply folder of vaginal swabs	Number of vaginal swabs allocated monthly	Numerator: Number of vaginal swabs allocated monthly Denominator: Total number of vaginal swabs used	No

Sexually active women from age 14-50 that self-collected their vaginal specimen for STI testing	Outcome	Chart audits	Total number of sexually active women from age 14-50 that self-collected their vaginal specimen for STI testing	Numerator: Number of sexually active women from age 14-50 that self-collected their vaginal specimen for STI testing Denominator: Number of sexually active women from age 14-50 screened for STI through the collection of urine specimen	No

Figure 9

Practice adherence Run Chart

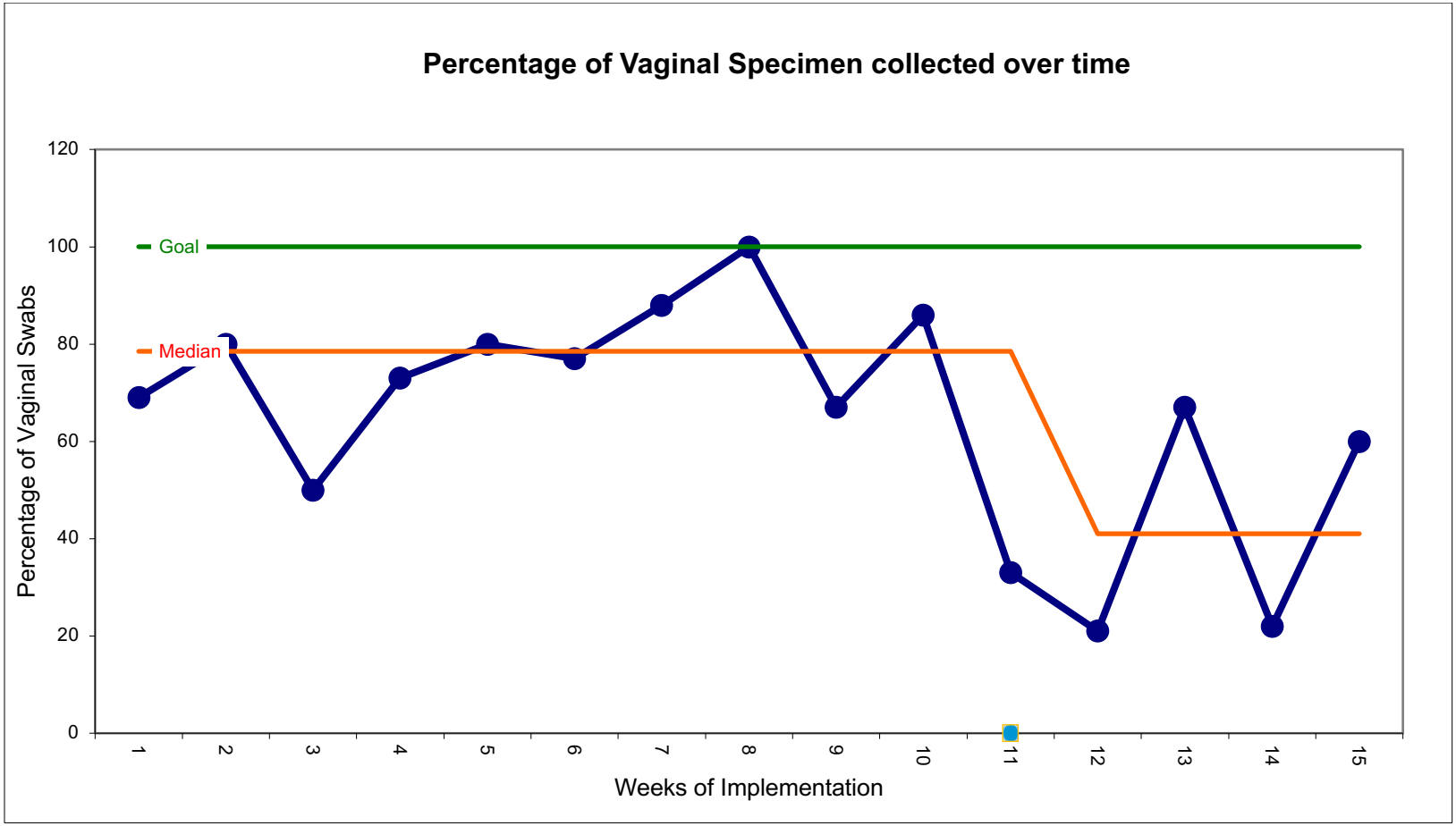


Figure 10

Number of Vaginal specimens versus Urine over a 15-week period

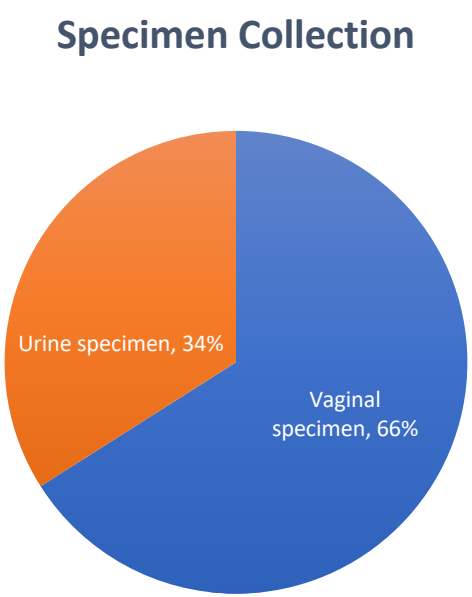
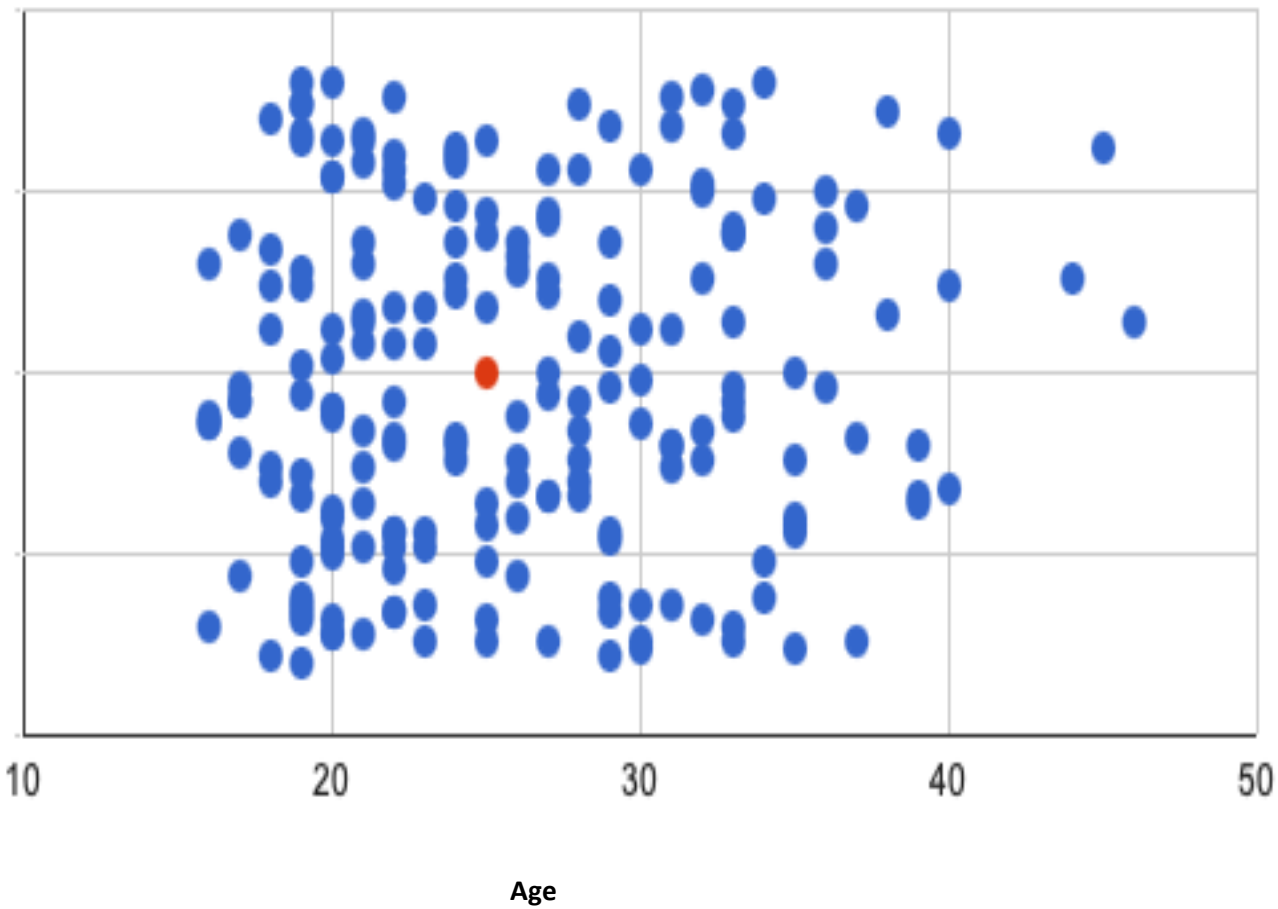


Figure 11

Scatterplot of Age Percentile



Appendix C

Self-collection Diagram

Aptima™ Multitest Swab Specimen Collection Kit

Anogenital skin lesion collection procedure guide

HOLOGIC

Collection for female and male anogenital skin lesion specimens

Partially open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. **If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit.** Hold the swab, placing thumb and forefinger in the middle of the shaft covering the black score line. Do not hold the shaft below the score line.

Swab specimen collection guide for:

- *Herpes simplex virus (HSV) types 1 & 2*

Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion.

If needed, expose the base of the lesion to access fluid.

Break at score line

While holding the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the shaft. The swab will drop to the bottom of the vial. Discard the top portion of the shaft.

Tightly screw the cap onto the tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for the specimen location.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

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