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Guideline for Screening of Trichomonas Vaginalis Infections in the Correctional Setting

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Abstract

Objective: This guideline project focused on creating a screening guideline for T. vaginalis that would benefit healthcare providers in a correctional healthcare setting for incarcerated females entering the facility.

Methods: A literature review was conducted. The PubMed and MEDLINE search engines, were used to obtain medical, biomedical and life sciences literature, and CINAHL for nursing and allied health resources, Governmental agency sites, such as the Centers for Disease Control and Prevention (CDC), were also explored. Guideline recommendations were extrapolated from the literature review, and then rated by, stakeholders.

Results: Several overarching themes were identified. Screening of asymptomatic women for *T. vaginalis* is appropriate in settings such as sexual health services in geographical areas of high prevalence and for women with associated risk factors. All females arriving through the inmate reception center in a correctional facility should be tested. An opt-out testing strategy can decrease the prevalence of *T. vaginalis* by increasing overall testing while maintaining inmates' right to refuse the test. Pair testing for *T. vaginalis* is to be implemented as an adjunctive method to current screening efforts for Chlamydia/Gonorrhea. Nucleic acid amplification tests (NATT) are the preferred screening method for *T. vaginalis*. Based on statistical computations, the stakeholders agreed on screening recommendations.

Conclusion: Effective screening of incarcerated females entering correctional healthcare settings is cost-effective and improves inmate patient health. Early detection of *T. vaginalis* during can prevent transmission in custody and the general population, improving population health.

Keywords: trichomonas vaginalis screening, sexually transmitted disease/infection, incarceration, jail, correctional, opt-out, testing

Guideline for Screening of *Trichomonas Vaginalis* Infections in the Correctional Setting

Trichomoniasis is a common sexually transmitted infection (STI) caused by a parasitic protozoan, *Trichomoniasis vaginalis* (*T. vaginalis*; Freeman et al., 2010). Trichomoniasis infection is a significant cause of concern at local, state, and national levels due to the high prevalence of infection and deficits in definitive guidance for screening. It is the most common curable STI worldwide and is often asymptomatic (Craig-Kuhn et al., 2019). However, while often asymptomatic, trichomonas infections can be associated with vaginitis, cervicitis, urethritis, low birth weight, preterm delivery, and endometritis. When untreated, these infections may increase the risk of contracting other STIs, such as herpes simplex virus (HSV) and human immunodeficiency virus (HIV; Craig-Kuhn et al., 2019).

Gap in Practice

T. vaginalis is estimated to be the most prevalent non-viral STI, affecting 2.6 million people in the United States (Centers for Disease Control and Prevention [CDC], 2022). The overall national prevalence of this infection is higher in women (2.1%) when compared to men (0.5%). Nationwide, trichomoniasis prevalence in correctional facilities is higher than in the general population, affecting 9%-32% of incarcerated women (CDC, 2022). These rates document that the female incarcerated population is disproportionately affected and at high risk for infection.

At the state and local levels, the prevalence of trichomoniasis varies according to setting. Javanbakht et al. (2014) found that of women in Southern California identified as high-risk, the highest trichomoniasis prevalence was among those testing through jail (22%), followed by STI clinics (17%), and was lowest among women using home-test kits (7%). The female correctional facility in Southern California currently houses approximately 2,000 people. Applying the same

trichomoniasis prevalence rate of 22% among incarcerated women, at any given time, an estimated 440 incarcerated women are likely to be infected. Given the high prevalence of trichomoniasis, the financial impact of this widespread infection is significant. In 2018, $173.74 million was spent nationally on diagnostic testing and treatment of trichomoniasis infection, with $220 per female patient and $153 per male patient (Lewis et al., 2021).

Despite the high burden of disease and adverse reproductive sequelae, trichomoniasis receives limited public health attention (Freeman et al., 2010). Unlike chlamydia, trichomoniasis is not a reportable disease, and there are no recommendations for general screening (CDC, 2021). The absence of reporting requirements, routine screening programs, and limited use of sensitive diagnostic tests have led to a sub-optimal understanding of trichomoniasis in the United States (Freeman et al., 2010). This lack of public health attention, surveillance, and the absence of existing recommendations for general screening lead trichomoniasis to be considered a *neglected STI* (Muzny, 2018, p. 218). Given the high prevalence of the infection among incarcerated females, developing definitive, streamlined guidelines for screening in the incarcerated setting may decrease the disproportionate number of infections (see Appendix A). Using a guideline may also reduce the prevalence of trichomoniasis in the community and decrease the disease burden related to this infection.

Literature Review

A comprehensive literature search was conducted using evidence-based practices to find strategies to best incorporate trichomoniasis screening in the correctional setting. A systematic search was conducted across three different disciplines, in multiple peer-reviewed databases including both PubMed and MEDLINE for medical, biomedical and life sciences literature and, CINAHL for nursing and allied health. Governmental organization websites such as the CDC

were also reviewed. Years of publication were limited from 2013 to 2023 to assure the literature was recent and relevant.

The search was conducted using the keywords “trichomonas screening,” “trichomonas dual testing,” “trichomonas prevalence,” and “trichomonas and HIV.” A complete reference was obtained for the items with content that discussed evidence-based testing practices. Studies were selected based on the hierarchy of research focusing on systematic reviews, randomized controlled trials, and nonrandomized controlled studies. Over 300 articles were retrieved from the initial search. Boolean connectors were then used to narrow the search results. Studies selected for inclusion included relevant trichomoniasis screening information and STI screening and were based in a correctional setting, preferably in a female facility. Studies were appraised using the *Johns Hopkins Evidence Level and Quality Guide* (see Appendix B). Permission was requested and received to utilize the *Johns Hopkins Evidence Level and Quality Guide* (see Appendix C). Two recurrent themes emerged from an in-depth review of these items: trichomoniasis and STI screening and paired testing. From these themes, it was possible to extrapolate evidence-based practices for optimal trichomoniasis screening strategies that were applied within an incarcerated female population, as noted in Appendix D, the Evidence Table for Literature.

Trichomoniasis and STI Screening

Many items included in the literature review addressed the theme of access to general trichomoniasis and STI screening, some specifically in the incarceration setting. The current recommendation by the CDC (2021) on trichomoniasis screening was only for asymptomatic and symptomatic HIV-infected women during initial visits and yearly after that. There were no other firm recommendations for screening in different populations. The CDC suggested, albeit with

less assertion, that trichomoniasis screening *might* be considered for persons in high-prevalence settings such as correctional facilities and individuals with high-risk factors (Patel et al., 2018). Two publications, including a systematic review with meta-analysis, revealed a link between this infection and HIV in women and that diagnosis and treatment of trichomoniasis might be a potential tool to reduce new HIV infections and identify other STIs (Javanbakht et al., 2014; Masha et al., 2019). Krieger et al. (2019) conducted a retrospective study among the incarcerated population and recommended routine opt-out screening to increase the identification of both symptomatic and asymptomatic STIs. Based on the systematic review of the management of STIs in the correctional setting, Spaulding et al. (2022) recommended the following: (a) STI screening should be performed as early as possible upon arrival to jail, (b) preferably using point-of-care testing, (c) opt-out testing is preferred to opt-in screening for STI, and (d) when insufficient funds are allocated for full-scope STI testing, prioritize test selection based on local infection epidemiology and potential consequences of a missed diagnosis.

Paired Testing

Multiple authors also highlighted the concept of paired testing, the performance of multiple tests on a single specimen to optimize information gleaned. A quality improvement project by Dang et al. (2021) integrated paired testing of chlamydia and gonorrhea with routine pregnancy tests upon entry to the jail system. This resulted in a 4.7-fold increase in the number of STIs screened and a comparable number of detected infections. Nucleic acid amplification tests (NAATs) to screen for trichomoniasis can be combined with chlamydia/gonorrhea on broad testing platforms that utilize urine and endocervical samples (Van Der Pol, 2016).

The information obtained from the literature documented that screening recommendations underscored the need to expedite screening using point-of-care tests upon

entry into correctional facilities; the advantages of the use of routine opt-out testing; and the importance of resource allocation, when necessary, which utilized local epidemiology and thoughtful test selection to initiate timely and relevant testing. Routine testing utilizing NAATs for trichomoniasis has the potential to detect a significantly higher number of infections in comparison to wet mount tests. It can be combined with chlamydia/gonorrhea on broad testing platforms, optimizing urine and endocervical samples to test for multiple infections concurrently. Finally, prompt screening can bolster patient and community cure rates and decrease community prevalence.

Project Question

Can a *Trichomonas vaginalis* screening guideline benefit healthcare providers in a Southern California correctional healthcare setting in screening incarcerated females entering the facility when recommendations are supported by critically appraised published literature, reviewed and rated by stakeholders in recommendations for implementation?

Objectives

- Reviewed peer-reviewed sources for strategies supporting accurate screening and diagnosis of *T. vaginalis* in a female correctional facility.
- Supported the data by grading the evidence using the Johns Hopkins nursing evidence-based practice evidence level and quality and quality grading protocol (Dang et al., 2022).
- Explained the process of rating the recommendations to the stakeholders in an educational meeting.
- Sought support from stakeholders to rate the recommendations.

- Recommended using the *T. vaginalis* guideline to screen females entering the correctional facility to support healthcare providers.

Framework

The Agency for Healthcare Research and Quality (AHRQ) program responds to the mission for quality improvement in healthcare, emphasizing implementation research and translating research into practice (Battles et al., 2014). The AHRQ (2018) National Quality Measure Clearinghouse (NQMC) Domain Framework supported the development of the trichomoniasis guideline project established by evidence-based recommendations and supported by the literature (see Appendix E). This framework included organizational measures consistent with historical relevance, clarifying the purpose and use of the measure for developers and users, streamlining the search and retrieval of measures within the NQMC, and accommodating the expanding range of measures over time.

The AHRQ (2018) NHRQ framework further subdivided the healthcare delivery measure and population health measure into three parallels: quality measure, related measure, and efficiency measures. The AHRQ's NHRQ framework emphasized healthcare delivery and population health measures. In addition, the healthcare delivery measure was used to assess the performance of the healthcare delivery system, including clinicians, healthcare teams, and health insurance providers in charge of the care of their patients. The AHRQ-NHRQ framework, and clinical efficiency measures was selected in developing the guideline because the selected guideline should be practical and efficient.

Methods

This project aimed to create a screening guideline for *T. vaginalis* that would benefit healthcare providers. First, the facility's environment was examined considering the project's

success utilizing the Strengths-Weaknesses-Opportunities-Threats (SWOT) tool (see Appendix F). The SWOT analysis provided an understanding and identification of potential vital factors to develop an improvement plan or strategy (Eizaga Rebollar et al., 2020). A risk management plan was developed to help identify how likely the specific events may occur, their possible impact on the project, and ways to mitigate the identified risks (see Appendix G). Furthermore, an organization readiness tool was used to determine how responsive the correctional setting was to a new change (see Appendix H). The setting scored above 50, indicating that the organization was prepared to implement a change. The budget was also taken into consideration, which allowed for differentiation and understanding of the direct and indirect costs of developing and implementing the guideline and how to handle both areas (see Appendix I).

Population

The guideline was geared towards screening for trichomonas in the racially, ethnically, and economically diverse incarcerated female population aged 18 years and older who arrived in the correctional facility. The guideline assists licensed healthcare providers in screening for trichomoniasis in women entering the correctional system. The guideline had inclusion and exclusion criteria for the reviewed evidence and no further inclusion/exclusion criteria for the patient population.

Setting

The proposed guideline was developed for a female correctional facility in Southern California. The correctional health organization comprises many healthcare professionals, including medical and mental health providers, dentists, nurses, and pharmacy, laboratory, and clerical personnel who oversee coordinated medical services for incarcerated individuals. The stakeholders included a team of 8-15 individuals (project lead; the university-provided librarian;

registered nurses; nurse practitioners; physician assistants; clinical pharmacist; and physicians). The guidelines will be used in correctional, detention, and custodian facilities where medical providers are located at entry points and upon release.

Measurement and Analysis

The librarian and the project lead searched databases and retrieved literature from three relevant disciplines: biomedical, medicine, and nursing. The project lead reviewed and graded 51 articles. Recommendations and rationales were extrapolated from the review of the literature. A survey tool was created that facilitated the compilation of the recommendations and rationales, and a shared folder had the literature and evidence table accessible for review. Given that the project lead created the recommendation tool, it had no established reliability or validity. Since the tool was used to answer the research question, the tool had face validity, and thus, the data was determined as reliable.

Procedure

The data collection for developing the guideline was based on descriptive statistics of the grading of literature, recommendations formulated by the project lead, and the ratings by the stakeholders. The recommendations for practice were based on graded evidence-based literature and documented on the recommendation form (see Appendix J). A dashboard was created to organize the ratings by the stakeholders (see Appendix K). The project lead scheduled a meeting with the stakeholders, where participants were educated on the project, expectations, and the project's time frame (see Appendix L). Additionally, an email was provided to the stakeholders after the initial meeting with the link to the survey and a link to a shared folder containing the articles and the evidence table (see Appendix M). A university-provided statistician was consulted to ensure that the study design and statistical analyses were appropriate and the most

efficient way to answer the research question. After identifying all the activities and tasks required for the guideline, a project timeline was developed, represented by a GANTT chart (see Appendix N). The GANTT chart was used to visualize the tasks required for a project as building blocks. The chart provided time estimates of multiple tasks.

Statistical Analysis

The data was organized using an Excel spreadsheet to facilitate the use of the Statistical Package of the Social Science (SPSS) software for advanced statistical analysis. Using SPSS, descriptive statistics could be computed, and frequencies for each variable were analyzed to extrapolate the mean, median, and mode. The statistician assisted in analyzing the data using Friedman's two-way ANOVA by rank. Friedman's test identified differences between the stakeholders' recommendation ratings. The nonparametric Friedman Test was used with ranked data; this test is preferred when the data are not rigorous, like interval data, if there are concerns about extreme deviation from a normal distribution, or if there is a considerable difference in the number of subjects for the groups (MacFarland & Yates, 2016). In addition, a chi-square value was calculated to determine how the stakeholders rated the recommendations differently.

Ethical Considerations

Before initiating the project, the lead ensured that ethical principles were maintained to safeguard the individuals involved. Additionally, the project lead completed the Human Subject Training to reinforce training about protecting people and data (see Appendix O). The proposal was submitted to the institutional review board through the university's Graduate Nursing Review Committee for review, and approval was obtained before proceeding with the project.

Results

Project Outcomes

The raw data of ratings submitted by stakeholders was extrapolated from the survey software tool. Thirteen stakeholders participated in the survey. Although 13 people were recruited, only 11 stakeholders completed the entire survey. There were five recommendations rated by 11 stakeholders, four rated by 12 stakeholders, and three rated by all 13 stakeholders.

The literature review yielded five recommendations. Based on the evidence, the stakeholders rated the recommendations from one to four, with one being poor, two being fair, three being good, and four being excellent. Figure 1 contains a bar graph of the five recommendations based on the stakeholder's ratings. Friedman's two-way ANOVA by ranks (a nonparametric test) was performed. A chi-square value was also calculated to determine how and if the stakeholders rated the recommendations differently (see Table). The stakeholders' consistently rated the five recommendations similarly and there was no significant difference, $X^2(4)= 5.887, p=.208$. Based on statistical data, Recommendation Four received the highest stakeholder acceptance, 92.31%. Recommendation Two and One obtained stakeholder acceptance of 84.62% and 81.82 % respectively. Recommendation Three and Five had the lowest stakeholder acceptance percentages, 76.92%, and 66.67% respectively (see Figures 1 and 2).

Discussion

The stakeholders supported the recommendations based on the literature review. The stakeholders agreed that prompt screening of *T. vaginalis* upon arrival to the correctional setting is key to reducing *T. vaginalis* complications. As the result of stakeholders' ratings, guidelines were grounded on this rating of reliable literature. After analyzing and interpreting the findings,

reliable guidelines for screening trichomoniasis infections in the correctional setting were recommended (see Appendix P).

The recommendations were reviewed with their rationales. Recommendation One noted that screening of asymptomatic women for *T. vaginalis* is appropriate in settings such as sexual health services in geographical areas of high prevalence and women with associated risk factors. The first recommendation opens the door for screening patients regardless of symptoms and makes it appropriate to screen patients in the correctional setting as an area of high prevalence. The rationale for this rating was that the recommendation is strongly supported by two systemic reviews, two with meta-analysis, and six randomized control trials. Therefore, this recommendation should be utilized as a first step.

The second recommendation was to perform universal testing for *T. vaginalis* for all females upon arrival to the reception area of the correctional facility. Due to high morbidity levels, correctional facilities are recognized as effective sites to improve public health through STI control. The rationale for this rating included two systemic reviews, two with meta-analysis, six randomized control trials, one interventional trial, and one prospective cohort trial that endorsed this recommendation. As a function of such positive support, this recommendation should be utilized for universal screening of *T. vaginalis* in females arriving in the correctional setting.

The third recommendation used an opt-out testing strategy that can decrease the prevalence of *T. vaginalis* by increasing overall testing while maintaining inmates' right to refuse the test. Opt-out testing is likely to be a more accurate estimate of the prevalence of the infection and, therefore, better able to ensure treatment of those testing positive. It may eventually reduce the potential spread of infections in the community when individuals are released from

incarceration. The rationale for this rating included two systemic reviews, two with meta-analysis, one randomized control trial, and one interventional trial provided support for this recommendation. Therefore, this recommendation should be utilized to increase the number of tests for *T. vaginalis* in females arriving in the correctional setting.

The fourth recommendation is for paired testing for *T. vaginalis* to be implemented as an adjunctive component of current screening efforts for Chlamydia/Gonorrhea. This will streamline testing with minimal additional work for nursing staff collecting samples. The rationale for this rating included two systemic reviews, two with meta-analysis, one randomized control trial, and one prospective study that endorsed this recommendation. Therefore, this recommendation should be utilized to increase the number of tests for *T. vaginalis* in females arriving in the correctional setting, with minimal effort by the nursing staff.

The final recommendation goes hand in hand with Recommendation Four, as it advocates the use of NATT as the preferred screening method for *T. vaginalis.* NATT offers the highest sensitivity for the detection of *T. vaginalis*. NATT has a sensitivity of 88%-100% from material in vaginal or endocervical swabs and in urine samples from women and also has a specificity of 95%-100% depending on the specimen and reference standard. Additionally, NATT can be used in paired testing as the technique is already in place for chlamydia/gonorrhea testing in the correctional setting. The rationale for this rating was the support from two systemic reviews, two with meta-analysis, one randomized control trial, and one prospective study endorsed this recommendation.

The project question was answered with a positive response, noting that a properly supported *T. vaginalis* screening guideline can benefit healthcare providers in a Southern California correctional healthcare setting in screening incarcerated females entering the facility.

The results concluded that *T. vaginalis* screening guidelines in the correctional setting would be essential in improving the care provided to this patient population. The guideline would be sustainable after the completion of the project. There are established guidelines and successful streamlined screening for other STI of high prevalence in correctional settings. Formulating structured and evidence-based practice guidelines for trichomonas screening implemented in incarceration settings can ultimately reduce the disparate prevalence of the infection among female incarcerated populations and the overall financial burden associated with the high prevalence of infections.

Summary

Key Findings

This guideline development project identified a robust collection of relevant articles and the recommendations were based on a solid literature review. The guidelines will be used in correctional, detention, and custodian facilities where medical providers are located at entry points and upon release. This guideline has the potential for sustainability in the future since similar guidelines are already successfully in place in the correctional setting. There is a gap as far as treatment initiation and completion prior to release into the community, and this needs to be further investigated. Possible treatment initiation by nursing instead of waiting for the provider to provide treatment may be one potential solution for the patient to receive prompt treatment prior to release from the facility.

Limitations

The guideline was directed toward a single clinical site serving the incarcerated female urban patient population; thus, the findings are not generalizable to other similar patient populations or clinical settings with differing patient populations, trichomonas prevalence rates,

or clinical practice patterns. However, with minimal adjustments, the guideline can be used to address the needs of any setting and not limited to a type of facility or patient population. The incarcerated population is a protected patient population; therefore, custody interference may occur to complete the screening process. Challenges from nursing staff are also possible since completing an additional step can be daunting. Monetary limitations may also pose a threat to the longevity of the program. However, cost-effectiveness can be proven with data showing how this would limit costs related to infection complications and treatment cost reduction by preventing future HIV infections. There were challenges within the team. Initially, 13 stakeholders were invited to review and rate the recommendations. However, data was missing for two stakeholders, so changing the number of stakeholders to 11 did not impact the statistical data. The stakeholders who did not participate missed the opportunity to provide their input to the recommendations.

Conclusion

The lack of guidelines for screening of *T. vaginalis* in correctional facilities leaves incarcerated females with untreated infections and vulnerable to infection complications. Investing in a structured approach to trichomoniasis screening within correctional health services closes the gap between evidence-based and current practices. Additionally, the screening guideline plays a fundamental role in improving healthcare and patient outcomes by helping providers make the best evidence-based decisions for their patients in a time-efficient manner. Given the well-known correlation between correctional facilities and medically underserved communities, effective screening in correctional facilities should reflect what is medically appropriate to improve population health and that of the incarcerated. The data presented can provide an opportunity to reevaluate our current efforts regarding the control of *T. vaginalis.*

Continuing to ignore the alarming rates of *T. vaginalis* is a disservice to our patients and our ability to improve their sexual and reproductive health as well as the surrounding community.

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Table

Chi-Square Results for Stakeholders Answers (N=11)

Related-Samples Friedman's Two-Way Analysis of Variance by Ranks Summary

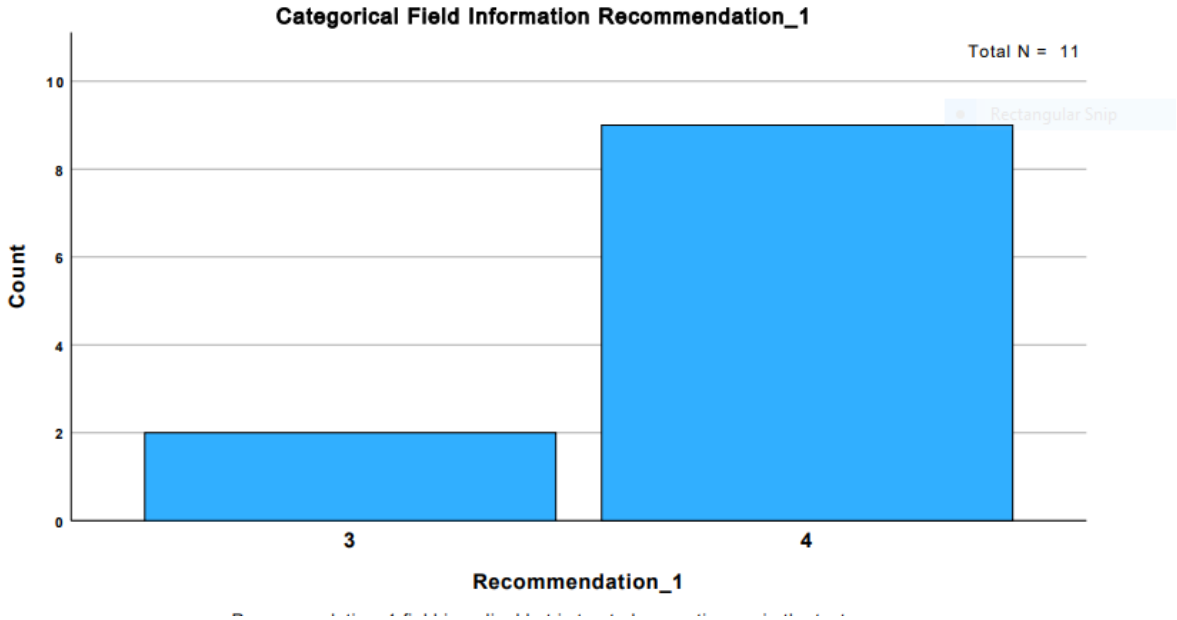
Total N	11
Test Statistic	5.887
Degree Of Freedom	4
Asymptotic Sig.(2-sided test)	.208

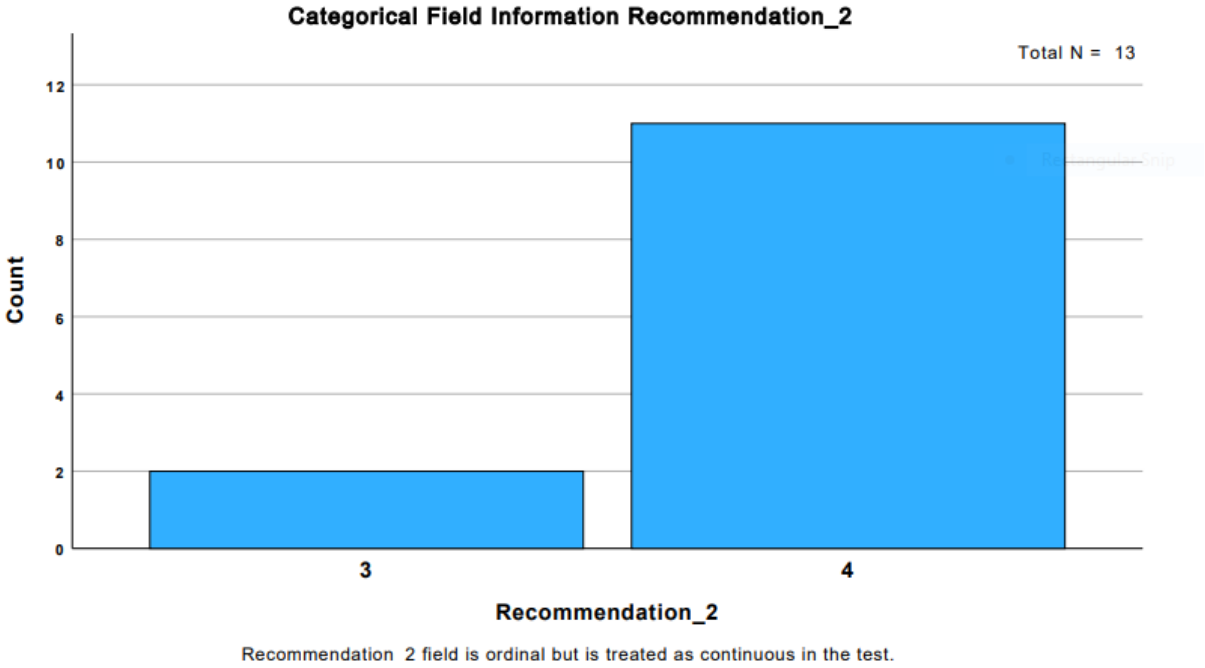
$$X^2(4) = 5.887, p = .208$$

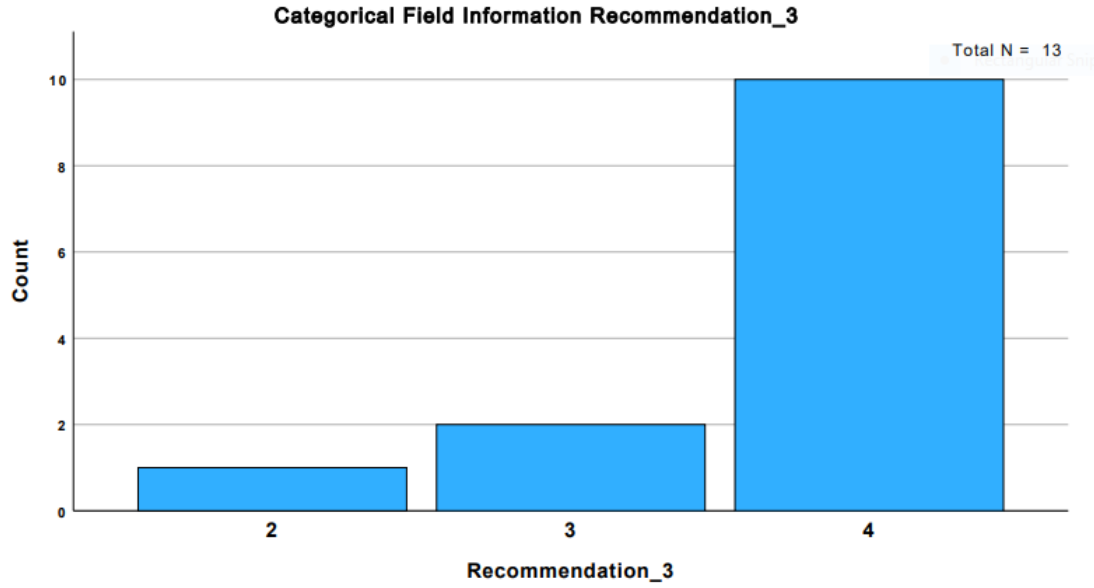
Interpretation: The result indicated that the differences among stakeholders rating the five recommendations were not significant. It documents that the stakeholders had similar responses to the recommendation.

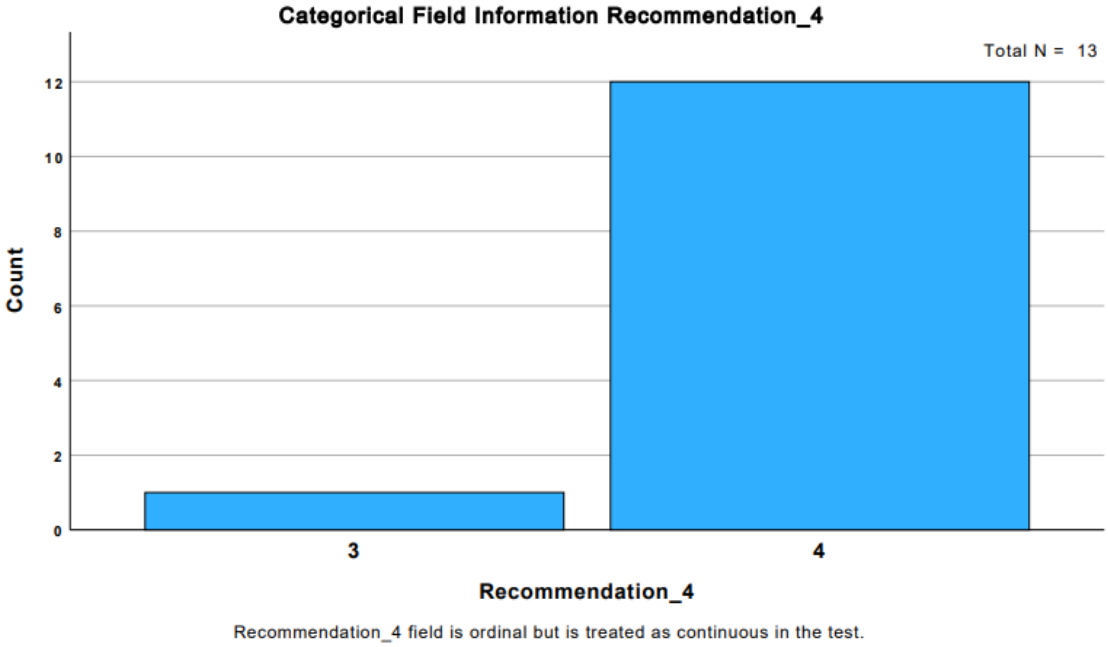
Figure 1

Stakeholder Responses Extrapolated From QuestionPro for Statistical Data

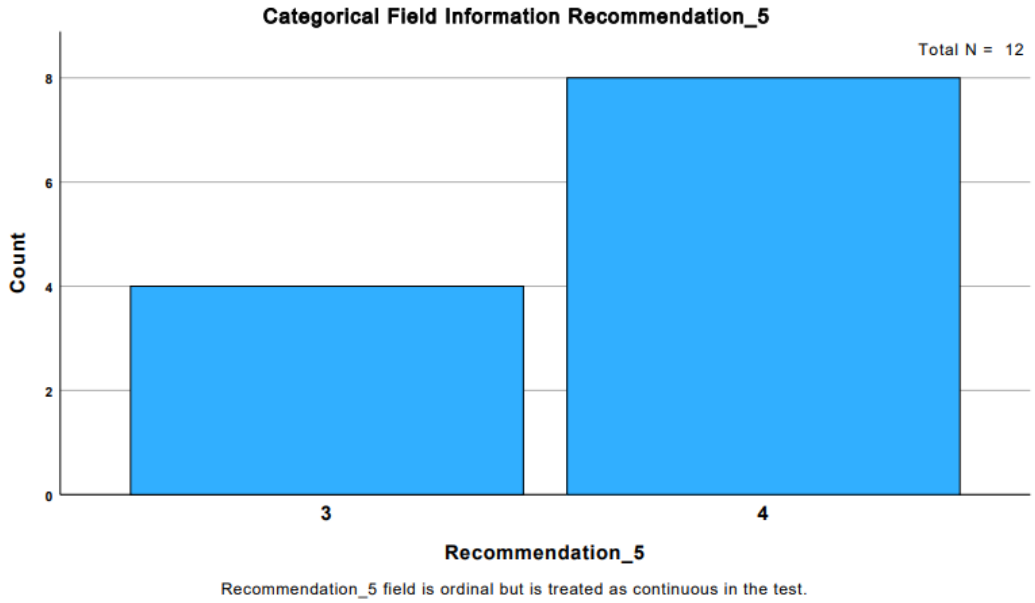








Recommendation_4 field is ordinal but is treated as continuous in the test.



Note: Total response rate per recommendation varied from 11 through 13.

Ranking =

1. Poor recommendation based upon evidence

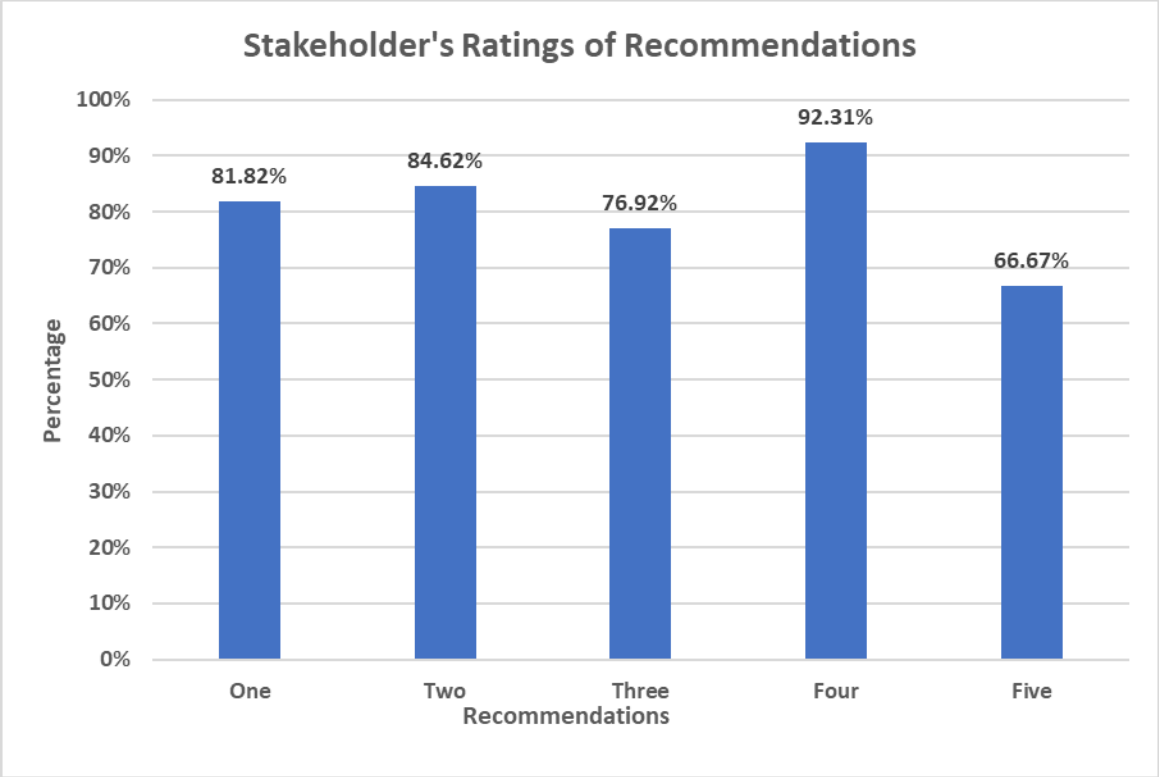
2. Fair or weak recommendation based upon evidence

3. Good or moderate recommendation based upon evidence

4. Excellent or high recommendation based upon evidence

Figure 2

Stakeholder Responses/Recommendations for Guidelines in Percentage



Note: This is a graphic representation of the percentage of acceptance rate per each of the five recommendations.

Appendix A

Guideline for Screening of *Trichomonas Vaginalis* Infection in the Correctional Setting

Project Question

Can a *Trichomonas vaginalis* screening guideline benefit healthcare providers in a correctional healthcare setting in screening incarcerated females entering the facility when recommendations are supported by critically appraised published literature, reviewed and graded by stakeholders in recommendations for implementation?

Appendix B

John Hopkins Nursing Evidence-Based Practices: Evidence Level and Quality Grade

Evidence Levels	Quality Guides
Level I Experimental study, randomized controlled trial (RCT) Systematic review of RCTs, with or without meta-analysis	**A High quality:** Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence **B Good quality:** Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence **C Low quality or major flaws:** Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn
Level II Quasi-experimental study Systematic review of a combination of RCTs and quasi-experimental, or quasi-experimental studies only, with or without meta-analysis	
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 with or without a meta-synthesis	
Level IV Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence Includes: • Clinical practice guidelines • Consensus panels	**A High quality:** Material officially sponsored by a professional, public, private organization, or government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **B Good quality:** Material officially sponsored by a professional, public, private organization, or government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **C Low quality or major flaws:** Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the last 5 years

Note. Adapted from Dang, D., Dearholt, S., Bissett, K., Ascenzi, J., & Whalen, M. (2022). *Johns Hopkins evidence-based practice for nurses and healthcare professionals: Model and guidelines* (4th ed). Sigma Theta Tau International.

Appendix C

Permission to use the tool John Hopkins Nursing Evidence-Based Practice Evidence level and Quality Guide

JOHNS HOPKINS EBP MODEL AND TOOLS- PERMISSION

Johns Hopkins Nursing
Center for Evidence-Based Practice

Thank you for your submission.
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EBP Boot Camp: We are offering a 5-day intensive Boot Camp where you will learn and master the entire EBP process from beginning to end. Take advantage of our retreat-type setting to focus on your project, collaborate with peers, and get expertise and assistance from our faculty. ***COMING in 2024!***

EBP Skill Build: This 3-day virtual workshop gives you a front-row seat to our EBP training and provides every participant with the guidance and support they need to get their EBP projects started.

Thank you for your interest in using the **Johns Hopkins Evidence-Based Practice Model and Tools**.

Appendix D

Evidence Table for Literature on Guidelines for Screening of Trichomonas

Citation Database Discipline	Aim/Method	Measurement	Setting/Sample	Results/ Recommendation	Strength & Limitations	Type of Study	Study Rating/ Quality	Category
Dang et al., 2021 PubMed Medicine	Aim: To implement and evaluate opt-out testing for *chlamydia/gonorrhea* testing paired with routine pregnancy tests for females entering that jail 50 years or younger. Methods: The results of all GC/CT urine tests in the Dallas County Jail were collected from October 2019 to February 2020. Medical records were reviewed to collect demographic factors and to determine the positivity of GC/CT infections, time to results, and time to treatment.	Measurement tool: *chlamydia/gonorrhea* testing rather than individuals Women 50 years or younger entering jail received opt-out testing for *chlamydia/gonorrhea* performed on urine specimens collected for routine pregnancy tests.	Population: Females 50 years or younger Setting: Dallas County Jail Sample: Before the intervention, 374 tests were performed among females, and 522 tests were performed in males. After intervention 1177 tests were performed in females within 1month	Pair testing of chlamydia/gonorrhea with a routine pregnancy test upon entry to the jail system resulted in a 4.7-fold increase in the number of STI tests and a comparable increase in the number of infections detected. Future efforts should focus on routine STI testing in jail practices, including treatment to improve outcomes.	Limitation: 1. Symptom information was unavailable, limiting the ability to determine what portion of the patient was symptomatic or asymptomatic. 2. Ethnicity was unavailable, limiting the opportunity to interpret differences by racial/ethnic group.	Retrospective Study	Level III Grade A	Pair Testing
Javanbakht et al., 2014 PubMed Biomedical and Life	Aim: Describe reports finding from STI screening program to identify STIs and HIV among inmates in Los Angeles County Jail.	One full-time staff person collected and maintained records. The chlamydia and gonorrhea screening were offered for	Setting: Los Angeles County Jail Sample: From 01/2002 to 12/2012, 76,207	Screening incarcerated women in Los Angeles County revealed a high prevalence of STIs and HIV. This sheds light on the	Strength: Unique description of STI and HIV prevalence among incarcerated females.	Cohort Study Quantitative Research	Level III Grade A	Universal screening

Citation Database Discipline	Aim/Method	Measurement	Setting/Sample	Results/ Recommendation	Strength & Limitations	Type of Study	Study Rating/ Quality	Category
Sciences Literature		females entering jail. Eligibility criteria included (1) 30 years or younger (2) Pregnant or possibly pregnant (3) Booked for prostitution or sex-related charges. HIV and syphilis testing were offered to all women between 2006 and 2009	females were screened for HIV, syphilis, gonorrhea, and chlamydia	opportunity for the identification of STIs and HIV. The surveillance data provide a useful and unique description of STI and HIV prevalence among women incarcerated in jail and suggest that jail-based testing can successfully reach an at-risk population, particularly one that may have limited access or be underserved by the health care system.	Limitations: Data did not include medical history or behavioral. Other limitations included staffing issues, making it difficult to test all that qualify based on inclusion criteria.			
Javanbakht et al., 2013 PubMed Biomedical and Life Sciences Literature	Aim: This study was to determine the prevalence and correlates of Trichomonas vaginalis using newly available and highly sensitive nucleic acid amplification tests (NAATs) in multiple populations of high-risk women. Methods: Remnant specimens collected from September-December 2010 from	Some of the data for this project were collected as part of a more extensive study, and details have been previously described.4 Our study includes additional data, including data from girls < 18 years of age and additional behavioral information from women tested in STD clinics. Differences between groups were evaluated using t-	Setting: 4 different venues 1. Public SID clinics 2. an internet-based home-testing program 3. An adult correctional facility 4. A juvenile detention facility. Sample: 1,215 remnant specimens.	The prevalence of *Trichomonas vaginalis* varied by venue type, with the highest prevalence noted among women testing through jail (22%), followed by STD clinics (17%), and lowest among women using home-test kits (7%). Regardless of venue, the prevalence was higher among women with a concurrent chlamydia or	Limitation: Women in the older age groups (>26 years in clinics and >30 years in jail) were likely tested because of symptoms, contact with a positive partner, etc., and were potentially at higher risk. This could result in an overestimation of the true prevalence of T.	Cohort Study Quantitative Research	Level III Grade A	EPI Screening Universal screening

Citation Database Discipline	Aim/Method	Measurement	Setting/Sample	Results/ Recommendation	Strength & Limitations	Type of Study	Study Rating/ Quality	Category
	women being screened for chlamydia/gonorrhea at four different venue types in Los Angeles County, CA, including (1) public STD clinics (n=12); (2) an internet-based home-testing program (www.dontthinkknow.org); (3) an adult correctional facility; and (4) a juvenile detention facility. The remnant specimens used for routine chlamydia/gonorrhea NAATs were tested using the APTIMA *Trichomonas vaginalis* assay (Hologic/Gen-Probe, San Diego, CA).	tests and chi-square methods, and associations between T. vaginalis and other factors were evaluated using logistic regression analysis. All analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC).		gonorrhea infection, though the pattern varied by venue. These findings highlight the need for targeted *Trichomonas vaginalis* screening recommendations and suggest that testing and/or presumptive *Trichomonas vaginalis* treatment should be considered in a subset of women, particularly in women treated for gonorrhea in jail or STD clinic settings and chlamydia in juvenile detention settings.	vaginalis in this group and may bias the association between T. vaginalis and gonorrhea co-infections.			
Krieger et al., 2019 CINAHL Nursing and Allied Health	Aim: To determine STI positivity for chlamydia, gonorrhea, syphilis, and hepatitis B virus during incarceration and in recently released patients living with HIV. Also, determine if the patient with STI were symptomatic. In addition, anticipate findings that will	Dallas County Jail Electronic medical record. Parkland Health and Hospital electronic medical record, and Prism Health North Texas electronic medical record.	Population: Incarcerated individuals are known to have HIV Setting: Dallas County Jail and Community HIV clinics. Sample: From 2,427 incarcerations,	During 2,472 incarcerations, 3% were positive for gonorrhea, 4% for chlamydia, 21% for syphilis, and 5% for Hep B virus antigen. Recommendation: Routine, opt-out screening for STIs, including rectal and oropharyngeal	Strength: Unique dataset integrates criminal justice and community with important implications for STI screening and secondary HIV prevention. Limitations:	Retrospective Study	Level III Grade A	Routine opt-out screening for STIs

Citation Database Discipline	Aim/Method	Measurement	Setting/Sample	Results/ Recommendation	Strength & Limitations	Type of Study	Study Rating/ Quality	Category
	guide screening strategies pre- and post-incarceration		1,696 unique patients known to have HIV meet the study criteria.	screening, conducted during or after release from jail, can potentially identify a high number of asymptomatic infections.	1. Data analysis is limited to pre-existing data. 2. Patient undergoing chlamydia/gonorrhea test was limited to urethral testing, leaving out extragenital testing. 3. Short incarceration, not all HIV-positive patients had medical visits during the study			
Masha et al., 2019 PubMed Biomedical and Life Sciences Literature	Aim: Assessment of the literature regarding the association of *trichomoniasis* and HIV-1 acquisition	An adapted tool to reduce the risk of bias based on the Newcastle-Ottawa scale was used as an appraisal tool. The systematic review was done in Sub-Saharan Africa.	Setting: Sub-Saharan Africa Sample: N – 11 out of 19 articles	The authors concluded that *Trichomonas* might be used as a biological marker for enhanced risk for HIV acquisition for both high-risk and moderate-risk women. Diagnosis and treatment of *Trichomonas* may be a potential tool to reduce new HIV infections.	Varying risks in selection attrition and reporting	Systematic review and meta-analysis	Level I Grade A	EPI Screening Opt-out testing Universal screening
Munson et al., 2016	Aim: Update laboratory diagnosis and epidemiology of	The arrival of novel commercial molecular essays specific to	Compared: Non-molecular modalities to	Recently commercialized, highly accurate diagnostic modalities,	Limitation: No information was provided on	Critically appraised topics	Level III Grade	Preferred diagnostic test

Citation Database Discipline	Aim/Method	Measurement	Setting/Sample	Results/ Recommendation	Strength & Limitations	Type of Study	Study Rating/ Quality	Category
Clinical Microbiology Newsletter	*Trichomonas vaginalis*.	*Trichomonas vaginalis* has offered a new outlook on trichomoniasis.	Molecular modalities.	particularly those based on transcription-mediated amplification (TMA), have facilitated an improved outlook on the epidemiology of trichomoniasis.	the cost of each testing modality.		A	
Muzny, 2018 PubMed Medicine	Aim: Review of the data presented by Patel et al., providing updated epidemiological data on the prevalence and correlates of *Trichomonas vaginalis* infections	Examination of the Survey from Nation Examination Survey (NHANES) cycle 2013-2014.	A nationally representative sample of the adult civilian, noninstitutionalized US population 18-59 years of age.	The data presented by Patel provides an opportunity to reevaluate our current efforts regarding control (or lack thereof) of *Trichomonas vaginalis*.	Not applicable	Editorial Commentary	Level III Grading B	EPI
Patel et al., 2018 PubMed Medicine	Aim: The epidemiology of *Trichomonas vaginalis* infection in the United States is poorly defined; in this study, the author described the prevalence and correlates of urinary *trichomonas* infection in a nationally representative sample of the adult civilian non-institutionalized US population.	The 2013-2014 National Health and Nutrition Examination Survey participants provided a urine specimen.	Males and females aged 18-59 years. Tested for *Trichomonas vaginalis* infection (n=4057)	There is a high and disproportionate burden of urinary *trichomonas* infection in the adult civilian, noninstitutionalized black population in the United States that warrants intervention.	Limitations 1. Varying risks in selection attrition and reporting. 2. NHANES is a cross-sectional design, so reported associations should not be interpreted causally.	Non-experimental study	Level III Grade A	EPI
Spaulding et al., 2022 PubMed	Aim: Review new recommendations from the CDC for the prevention of 2021	A comprehensive review was performed using published literature	This systematic review of recent literature (2012) on STIs in US jails,	1. Perform STI screening as early as possible. It is recommended to	Limitation: Using a restricted number of STIs in the search terms	Systematic Review	Level I Grade A	EPI Screening

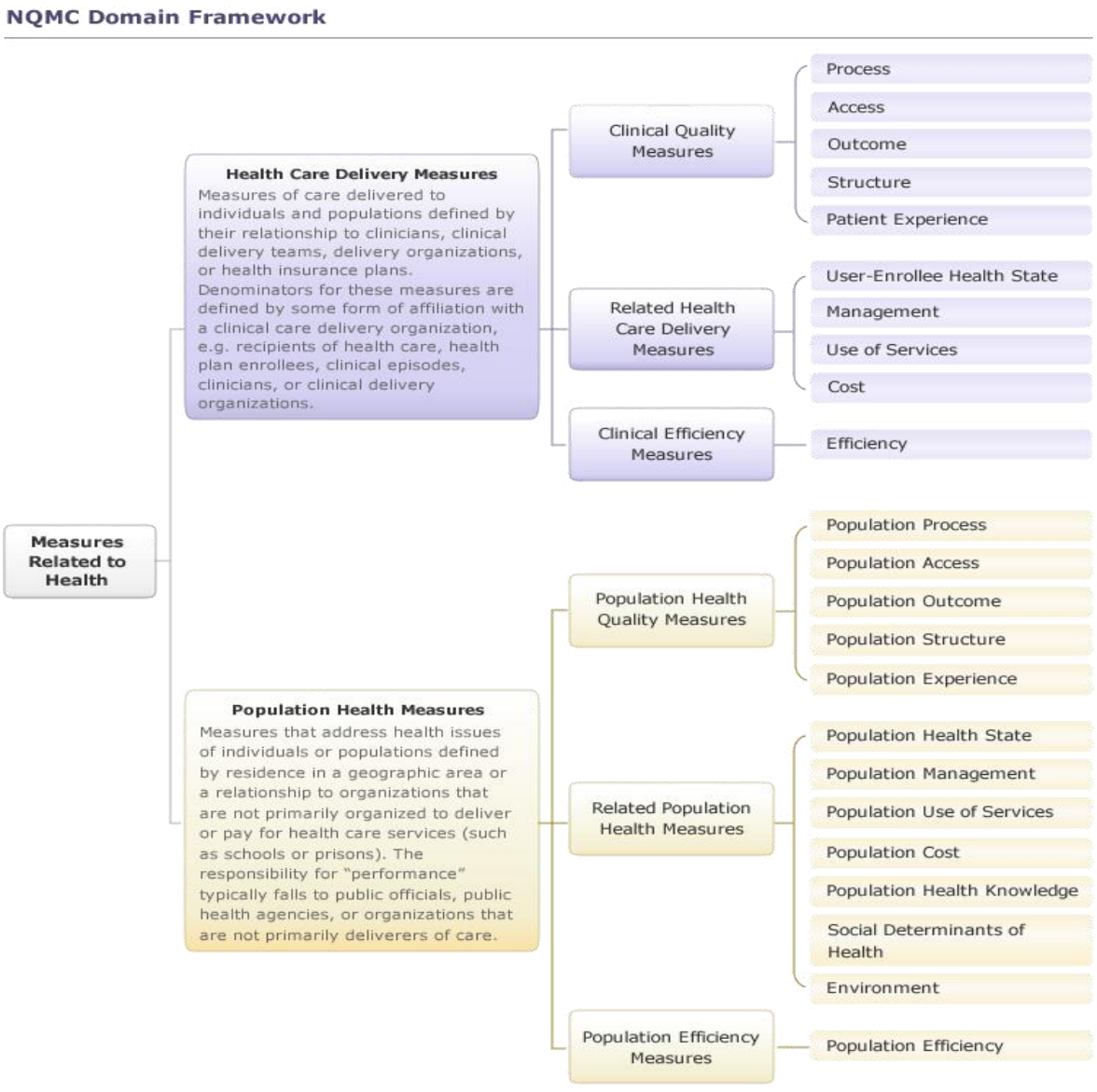
Citation Database Discipline	Aim/Method	Measurement	Setting/Sample	Results/ Recommendation	Strength & Limitations	Type of Study	Study Rating/ Quality	Category
Biomedical and Life Sciences Literature	treatment guidelines. It also synthesizes recommendations on screening: in particular, opt-out testing is superior to opt-in protocols.	from significant databases, Tables of evidence identified studies specific to the prevalence and prevention of STIs, respectively. A comprehensive review was performed. Based on several key topics of interest 1. Current prevalence of STI in juvenile and adult correctional settings 2. Diagnosis and treatment of STIs in a correctional setting. 3. Community involvement in STIs in the correctional setting. 4. Evidence of interventions.	prisons, immigration and customs, enforcement and detention centers, and juvenile facilities.	screen on arrival at the jail 2. Use short turnaround testing, preferably point-of-care tests. 3. opt-out rather than opt-in screening for STIs is preferred. Unless the patient is deemed incompetent. Providing information and offers is voluntary and not coercive. 4. When insufficient funds are allocated to the jail, prioritize testing.	limits the range of reported STIs.			Opt-out testing Universal screening
Van Der Pol, 2016 CINAHL Nursing and Allied Health	Aim: Educate about new testing options for *Trichomonas vaginalis*	The use of RNA-based transcription mediation amplification assay.		Single-test RNA options may be helpful in emergency departments where patients have extended waits. Furthermore, this can be combined with other testing, such as		Educational A non-experimental study	Level III Grade B	Pair testing Preferred diagnostic test

Citation Database Discipline	Aim/Method	Measurement	Setting/Sample	Results/ Recommendation	Strength & Limitations	Type of Study	Study Rating/ Quality	Category
				chlamydia/gonorrhea, on broad testing platforms.				

Note. CT = *Chlamydia trachomatis.* EPI = epidemiology of *Trichomonas vaginalis* infection; GC = *Neisseria gonorrhoeae.* NAAT = nucleic acid amplification test. HIV = Human immunodeficiency virus. PCR = polymerase chain reaction. STIs = sexually transmitted infections. *T. vaginalis = Trichomonas vaginalis*

Appendix E

NQMC Domain Framework



Note. From the Agency for Healthcare Research and Quality. (2018). *NQMC Measure Domain Framework.* https://www.ahrq.gov/gam/summaries/domainframework/index.html#fig

Appendix F

SWOT Analysis Table

Strengths	**Weaknesses**
1. Recommendations will be based on evidence-based literature. 2. Access to healthcare and medical examination on admission without delay upon arrival to jail. 3. Easy access to laboratory testing for TV 4. Equivalence of care stands for the same level of health care quality in jail as in the community. 5. Nurses and providers adapt fast to changes in workflow with minimal disruption.	1. Limited data on Trichomonas Vaginalis (TV) guidelines. 2. Limited statistical data on TV. 3. Custody shortages that will limit the movement of new inmates through the testing process.
Opportunities	**Threats**
1. Solid scientific evidence for adequate screening of TV in the correctional setting 2. Implementation of the TV screening guidelines. 3. Possibility for future research based on data collected during the guideline implementation. 4. Possibility for use of the TV screening guideline to be implemented in other settings.	1. Lack of motivation by stakeholders to review the recommendations and maintain engagement in the process. 2. Lack of motivation by nursing staff to implement changes. 3. Possible budget constraints. 4. Resistance from management to implement changes.

Appendix G

Risk Management Plan Table

Risk	**Probability**	**Impact**	**Mitigation of Risk**	**Contingency Plan**
Limited data on Trichomonas Vaginalis (TV) guidelines.	Likely	Critical	Seek help from the University of Texas Arlington (UTA) librarian to help with the literature search.	Utilize at least different search engines from other disciplines to broaden the search.
Limited statistical data on Trichomonas Vaginalis (TV).	Likely	Critical	Seek help from an expert on statistical data.	
Lack of motivation by stakeholders to review the recommendations and maintain engagement in the process.	Likely	Critical	Evaluate the commitment of stakeholders early in the process. Check-in with stakeholders throughout the process.	Provide ample opportunity for stakeholders to ask questions and provide clarification as needed.
Possible budget constraints.	Possible	Moderate	Have a plan early in the process on how to distribute the budget. Allow flexibility in the budget.	Consider secondary forms of funding the project.
Resistance from management/nursing or stakeholders to implement changes.	Possible	Moderate	Engage with management/nursing and stakeholders early in the process. Educate about the end goal of the guideline and how this will make a positive change in the community.	Positive reinforcement and collaboration between the disciplines to ensure easy transition. Allow questions and provide clarification as needed.

Appendix H

Organizational Change Readiness Assessment

This assessment is designed to reveal your organization's ability to change when change is needed. Read the following questions and indicate your level of agreement with each statement using the following scale.

5. We are excellent at this. I am confident we would succeed.
4. We are good at this. I believe we can manage
3. We are okay at this. I believe we can manage.
2. We need help with this. I don't think we would manage very well
1. We have problems with this. I don't think I can do this.

Sponsorship regularly comes from a senior level such as the President.	3
Leadership is provided from the highest senior levels that have direct responsibility for change.	5
There is a strong sense of urgency for change from the senior staff.	5
The organization has a culture that emphasizes continues improvement.	5
Any planned change initiative has clear objectives that are consistently communicated.	3
Management strongly believe the future should look different from the past.	5
Management has a clear vision of the future and can mobilize the necessary resources.	5
The change effort connects to other major initiatives underway or being planned within the organization.	4
Management is willing to change critical business processes.	3
All employees are supported when taking risks, being innovative and looking for new solutions.	3
The organization has successfully implemented major changes in the past 12 months.	5
Employees enjoy working in the organization and the level of individual responsibility and team spirit is high.	2
The organization is always experimenting and new ideas are easily implemented.	3
Organizational decisions use a participatory process, are made quickly and it's clear when the decision is made.	4
Employees have been extensively cross trained and have a good understanding of each others role in the organization	4
Employees view change as an opportunity	3
Employees work across boundaries with little trouble	3
Total Points	65

Note. From *Organizational Change Readiness Assessment* by the ABARIS Consulting Inc, 2001 (www.abarisconsulting.com). Copyright 2001 by ABARIS Consulting Inc.

Appendix I

Budget

Income	Notes	Hour rate per Stakeholder	Total budget for Organization
Expenses			
Direct Cost			
Snacks	Variety snack box and case of water	$41.79	$41.79
Printing	Variety of printing materials	$40.00	$40.00
Indirect Cost			
Registered Nurse	Estimating 3 hours to review recommendations and other project activities (e.g., literature review meeting and answering survey).	$57.41 X 3 Stakeholders	$516.69
Nurse Practitioner	Estimating 3 hours to review recommendations and other project activities (e.g., literature review meeting and answering survey).	$64.93 X 3 Stakeholders	$584.37
Physician Assistant	Estimating 3 hours to review recommendations and other project activities (e.g., literature review meeting and answering survey).	$ 59.05 X 1 Stakeholders	$177.15
Physician (MD, DO)	Estimating 3 hours to review recommendations and other project activities (e.g., literature review meeting and answering survey).	$ 105.05 X 3 Stakeholders	$945.45
	Total Project Expenses		$2,305.45
	Net		$0.00
Unused portion of expenses to be returned to HR budgets			

Appendix J

Review of Literature Evidence Table Recommendations for Guideline

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
Aaron et al., 2023	Meta-Analysis	N = 28 eligible articles	A systematic search of multiple databases from 1995 through 2021. Evidence from this analysis supports the CDC's recommendation that vaginal swabs are the optimal sample type for women being tested for chlamydia, gonorrhea, and/or trichomoniasis.	Grade - I
Alcaide et al., 2016	Randomized Controlled Trial	N = 1704	Prevalent and incident *T. vaginalis* is common among STD clinic attendees, and baseline *T. vaginalis* is the leading risk factor for incident *T. vaginalis*, suggesting high rates of reinfection or treatment failures. This supports the importance of rescreening women after treatment for *T. vaginalis* and evaluating current treatment regimens and programs to ensure the treatment of sexual partners.	Grade - I
Beyda et al., 2018	Prospective Cohort Study	N = 543	To evaluate TV prevalence and metronidazole efficacy among a sample of detained youth. Found the prevalence of *T. vaginalis* among detained young women was 10.8%. Half of our patients were asymptomatic, suggesting the need for routine screening among detained young women. However, given the low prevalence in young men, routine screening would not be warranted.	Grade - I
Bissessor et al., 2017	Randomized Controlled Trial	N = 12,488	Data was collected from August 2015 (micro broth culture and microscopy) and August 2016 (Aptima TV essay), including	Grade - I

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			referred, testing volumes, and test cost estimates. The change in current laboratory practice from culture to molecular platforms was associated with higher overall detection of *Trichomonas*. Additionally, there was a reduction in the numbers needed to test/cost for one *Trichomonas* diagnosis.	
Cheeks et al., 2021	Cohort Study	N = 593	Offered trichomonas screening to patients presenting for abortion. Trichomonas was highly prevalent, and universal testing and treatment was feasible in an urban abortion clinic.	Grade - III
Dang et al., 2021	Retrospective Study	N = 1,177	Pair testing of chlamydia/gonorrhea with a routine pregnancy test upon entry to the jail system resulted in a 4.7-fold increase in the number of STI tests and a comparable increase in the number of infections detected. Future efforts should focus on routine STI testing in jail practices, including treatment to improve outcomes.	Grade - III
European Center for Disease Prevention and Control [ECDC] & European Monitoring Center for Drugs and Drug Addiction, 2017	Systematic Review	N = 566	Systematically review the evidence on active case finding in prison settings, with a focus on the European Union (EU) and the European Economic Area (EEA) region. The communicable diseases targeted by this review were not selected a priori but were identified through the retrieved evidence. - Screen for HBV, HCV, chlamydia, gonorrhea, syphilis, trichomoniasis, active TB, and latent TB infection in the prison setting - Offering screening upon entry into prison - Use opt-out STI screening	Grade - I

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			- Screen for STI at routine blood draw - HCV testing targeting people who inject drugs	
Freeman et al., 2010	Randomized Controlled Trial	N = 1026	Using a highly sensitive TMA-based assay to assess the prevalence and correlates of *T. vaginalis* among incarcerated individuals in San Francisco. Given the availability of sensitive diagnostic tests, inexpensive and effective treatment, and the well-described adverse health outcomes associated with *T. vaginalis*, routine screening among incarcerated populations and other groups at high-risk merits serious further consideration.	Grade - I
Gannon-Loew & Holland-Hall, 2020	Systematic Review	Review of the epidemiology screening recommendations, diagnostic tests, and treatment guidelines for STIs most commonly encountered in adolescents and young adults	Compared current screening recommendations, diagnosis using preferred diagnostic methods, and appropriate treatment for STIs from US guidelines and European guidelines Adolescents and young adults are at increased risk for acquiring STIs due to behavioral, biological, and cultural factors. US Guidelines for screening *T. vaginalis* should be considered in high prevalence settings and at high risk for infection. No routine screening for man American Association of Pediatrics recommends against screening for *trichomoniasis* in asymptomatic women but considers screening women at high risk. A nucleic acid amplification test (NAAT) is preferred for diagnostic testing of *trichomoniasis d*ue to its high sensitivity and specificity (both 95-100%).	Grade - I

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
Getaneh et al., 2023	Retrospective Cohort Study	N = 8809	To examine adherence to the CDC's retesting guidelines in women with trichomoniasis, and to describe the characteristics of women who were not retested according to the guidelines. Additionally, to examine women who were pregnant when tested for *T vaginalis*, and identify characteristics associated with infection and adherence to CDC retesting guidelines. *T. vaginalis* infection was identified at a high frequency in a diverse, urban hospital-based obstetrics and gynecology clinic population. Opportunities exist to improve on equitable and guideline-concordant retesting of patients with trichomoniasis.	Grade - III
Gray et al., 2017	Randomized Controlled Trial	N = 101	To determine the prevalence of *T. vaginalis* in adolescents detained to evaluate whether routine screening is indicated. The prevalence of *T. vaginalis* in female detainees is similar to that of *N. gonorrhoeae* and *C. trachomatis*. Based on these findings, screening for *T. vaginalis* infection should be considered for female detainees. The continuing study will further examine demographic predictors of *T. vaginalis* infection in detained adolescent females.	Grade - I
Grodensky et al., 2016	Cross-sectional study	N = 871	Use knowledge of patient interpretation of the risk, fear of positive diagnosis, trust in healthcare workers, and the fidelity of the opt-out. To determine the patient's education needed to opt out of STIs screening. Results suggest that inmates were more susceptible to being tested without their knowledge	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			or receiving an unwanted test if they had less experience with and knowledge about testing in prison.	
Hathorn et al., 2015	Randomized Controlled Trial	N = 3,503	The rate of *T. vaginalis* positivity was higher in Black Caribbean. The overall prevalence of *T. vaginalis* infection in the UK population remains low, and routine screening in this setting is probably unjustified. *T. vaginalis* TMA may have a role in screening high-risk populations who have an increased prevalence of asymptomatic *Trichomonas* infection, in particular, black Caribbean women. In addition, *T. vaginalis* TMA testing of symptomatic women will detect over a third more infections than culture. *T. vaginalis* TMA is significantly more expensive than microscopy and culture, but its targeted use has the potential to identify a significant number of previously undiagnosed infections.	Grade - I
Hearn et al., 2015	Cross-sectional Study	N = 264	To examine the relationship between drug use, sexual-risk behaviors, and biologically confirmed *T. vaginalis* in a sample of mid-older and younger adults who reported recent drug use Age- and drug related immune decline is hypothesized to contribute to increase susceptibility to *T. vaginalis* in mid-older adults. Broad screening for trichomoniasis, particularly among older adults who are often not regarded as at risk for STIs, is needed to control this often-asymptomatic infection.	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
Herbst De Cortina et al., 2016	Systematic Review	N = 33 articles for the review	Highly sensitive and specific POC tests are available for *chlamydia*, *gonorrhea*, and *T. vaginalis*, but improvement is possible. Future research should focus on the acceptability, feasibility, and cost of POC testing. POC testing was acceptable to both providers and patients and was also demonstrated to be cost-effective.	Grade - I
Hobbs & Seña, 2013	Systematic Review	Compared: Direct Microscopy Culture Non-amplified molecular tests Nucleic acid amplification tests (NAATs)	Various diagnostic tests are now available to detect *T. vaginalis* infection in women. Rapid point-of-care with improved sensitivity compared with wet mount microscopy should facilitate the testing and treatment of women in clinical and non-clinical settings. *T. vaginalis* nucleic acid amplification tests enable the incorporation of testing for this infection in a setting where molecular diagnostic for *Neisseria gonorrhea* and *Chlamydia trachomatis* are already in place.	Grade - I
Holland-Hall et al., 2002	Quasi-experimental	N = 133	Comparison of a new protocol for sexually transmitted infections testing with the current standard of care, using the same subjects. Survey of attitudes regarding the self-collection technique. STI testing using self-collected specimens is highly acceptable to adolescent girls and can dramatically increase the detection rate of these three treatable infections when pelvic exams are not performed.	Grade - II
Huntington et al., 2018	Modeling Study	N = 965, 988	To quantify the costs, benefits, and cost-effectiveness of three multi-pathogen point-of-care	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			(POC) testing strategies for detecting common sexually transmitted infections (STIs) compared with standard laboratory testing. Many benefits can be achieved by using multi-pathogen POCTs to improve STI diagnosis and management.	
Javanbakht et al., 2014	Cohort Study Quantitative Research	N = 76,207	Describe reports finding from STI screening program to identify STIs and HIV among inmates in Los Angeles County Jail. -Screen female inmates aged 30 years or younger for STIs - Screen pregnant inmates for STIs - Screen inmates booked on sex-related charges for STIs - Ensure availability of treatment for those found positive	Grade - III
Javanbakht et al., 2013	Cohort Study Quantitative Research	N = 1,215	Remnant specimens collected from September-December 2010 from women being screened for *chlamydia/gonorrhea* at four different venue types in Los Angeles County, CA, including (1) public STD clinics (n=12); (2) an internet-based home-testing program; (3) an adult correctional facility; and (4) a juvenile detention facility. The remnant specimens used for routine chlamydia/gonorrhea NAATs were tested using the APTIMA *T. vaginalis* assay (Hologic/Gen-Probe, San Diego, CA). These findings highlight the need for targeted *T. vaginalis* screening recommendations and suggest that testing and/or presumptive *T. vaginalis* treatment should be considered in a subset of women, particularly in women treated for gonorrhea in jail or STD	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			clinic settings and chlamydia in juvenile detention settings.	
Jiwatram-Negron et al., 2020	Cross-sectional study	N = 337	Using baseline data from Project WORTH (Women on the Road to Health; N = 337), an RCT conducted between November 2009 and January 2012 in New York City to evaluate the efficacy of an HIV/STI prevention intervention for substance-involved women under community supervision, recruited from within probation and community supervision settings. Study findings underscore an urgent need for multipronged intervention efforts that simultaneously address multilevel risk exposures.	Grade - III
Kissinger et al., 2022	Systematic Review	Articles that were relevant but were published before 1 January 2013 (n = 80) or after 1 December 2019 (n = 4) were also included.	Newly available diagnostic methods, including point-of-care assays and multiple nucleic acid amplification tests, can be performed on various genital specimens in women and men, including urine, allowing more accurate and convenient testing and screening of those at risk for infection.	Grade - I
Lazenby et al., 2014	Decision tree analysis	N = 200 women	To determine if annual screening is cost-effective for the prevention of new HIV cases in susceptible male partners secondary to Trichomonas infection in HIV positive women. Trichomonas screening and treatment for the purpose of decreasing new HIV infections is not only cost-effective but also cost saving in HIV-positive women. If CDC treatment guidelines were followed in all HIV-positive women living in the United States, the lifetime cost of new HIV infections prevented would approximate US$159,264,000 and could potentially prevent new HIV	Grade - IV

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			cases secondary to female-to-male transmissions.	
Lederman et al., 2020	Cross-sectional study	N = 494	Of 494 detainees who were tested, 8.5% tested positive for at least 1 STI. The estimated cost to detect any STI ranged from $500 to $961; the estimated cost to identify one person infected with HIV ranged from $ 22,497 to $ 43,244. Forty of 42 persons who tested positive began treatment before release from custody. Opt-out STIS screening in the correctional setting to decrease transmission of STIs	Grade - III
Lewis et al., 2021	Retrospective analysis	Data was estimated using 3 data cycles (2013–2014, 2015–2016, and 2017–2018) of the National Health and Nutrition Examination Survey (NHANES)	The prevalence and incidence of *T. vaginalis* are substantial in the United States, particularly among those 25 years or older. Although the estimated prevalence is higher in women, the estimated incidence is similar in men and women.	Grade - III
Masha et al., 2019	Systematic review and meta-analysis	N = 11 out of 19 articles	Assessment of the literature regarding the association of *trichomoniasis* and HIV-1 acquisition. The authors concluded that *trichomonas* might be used as a biological marker for enhanced risk for HIV acquisition for both high-risk and moderate-risk women. Diagnosis and treatment of *Trichomonas* may be a potential tool to reduce new HIV infections.	Grade - I
Munson et al., 2016	Critically appraised topics	Compared non-molecular modalities to Molecular modalities.	Update laboratory diagnosis and epidemiology of *T. vaginalis*. Recently commercialized, highly accurate diagnostic modalities, particularly those	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			based on transcription-mediated amplification (TMA), have facilitated an improved outlook on the epidemiology of trichomoniasis.	
Muzny, 2018	Editorial Commentary	A nationally representative sample of the adult civilian, noninstitutionalized US population 18-59 years of age.	Review of the data presented by Patel et al., providing updated epidemiological data on the prevalence and correlates of *T. vaginalis* infections The data presented by Patel provides an opportunity to reevaluate our current efforts regarding control (or lack thereof) of *T. vaginalis*.	Grade - III
Muzny et al., 2014	Clinical Review of Data	N = 6,335	The overall prevalence was 20.2 %, 27.0 % in women, and 9.8% in men. This study demonstrates that routine implementation of *trichomonas* NAAT at that clinic could detect a significant proportion of infected male and female patients, significantly higher than those detected by wet mount alone in women. Additionally, the prevalence of *trichomonas* was high among men and women in this study, suggesting that both groups, including those aged >40, should be routinely screened. Improved detection of *Trichomonas* by the routine implementation of NAATs should result in better control of this common treatable STI.	Grade - II
Nicholls et al., 2018	Cross-sectional Study	N = 9,186	Samples from 9186 women undergoing *chlamydia* and *gonorrhea* testing in South West England between May 2013 and Jan 2015 were also tested for *T. vaginalis* by NAAT alongside existing tests. Aptima TV outperforms existing testing methods to identify *T. vaginalis* infection in	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			this population. A NAAT should be used when testing for *T. vaginalis* in women who present for testing with symptoms in primary care and GUM based on test performance and cost.	
Nijhawan, 2016	Interventional Trial	N = 529	Routine screening and treatment for STIs and HIV in the criminal justice system can identify many new infections and has the potential to both improve individual outcomes and reduce transmission to others. - Opt-out screening for HIV and tuberculosis to entering jail inmates. - use Blood test TB QuantiFERON Gold and HIV antibody test	Grade - I
Nijhawan et al., 2012	Randomized Controlled Trial	N = 423	Women older than 18 years entering the Department of Corrections between September 2009 and May 2011. All women submitted a self-collected vaginal swab for APTIMA transcription-mediated amplification testing. Each participant completed a survey addressing demographics, symptoms, sexual behavior, and substance use by audio computer-assisted self-interview. *Trichomonas* infection is common in incarcerated women, especially among black women, women with vaginal symptoms, and those not receiving routine gynecologic care. Screening for *Trichomonas* infection in high-risk populations, particularly if using highly sensitive methods such as transcription-mediated amplification, may lead to increased detection and treatment.	Grade - I

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
Nijhawan et al., 2011	Prospective Cohort Study	N = 1,310	The HIV Epidemiology Research Study (HERS) of HIV-seropositive and high-risk seronegative women in 4 urban centers. All participants enrolled between April 1993 and January 1995, with interviews and physical exams conducted at baseline and at follow-up visits every six months up to 7 years. A history of incarceration was independently associated with the detection of *trichomonas* infection in a cohort of high-risk women. These data have implications for increased STI prevention, screening, and treatment upon entry to jail, as well as in the communities most affected by incarceration.	Grade - I
Ogale et al., 2019	Systematic Review and Meta-analysis	11 studies N = 202,745	The literature suggests that self-collection of samples for STI testing increases the uptake of STI testing services, whether for testing any STI or a combination of multiple STIs.	Grade - I
Owusu-Edusei et al., 2016	Systematic Review	Population of sexually active women aged 15–24 years.	The proposed Opt-Out Testing strategy was cost-saving, improving health outcomes at a lower net cost than current testing. However, testing gaps would remain because many women might not have health insurance coverage or not utilize health care.	Grade - I
Parece et al., 1999	Interventional Trial	N = 3,086	The study assesses STD testing policies and practices in jail. Recommend rapid STI screening /testing be done at booking.	Grade - II
Patel et al., 2018	Non-experimental study	N = 4,057	There is a high and disproportionate burden of urinary *trichomonas* infection in the adult civilian, noninstitutionalized black population in the United States that warrants intervention.	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
Piwonka et al., 2016	Interventional Trial	N = 99	Although wet mount microscopy is commonly used in the laboratory for diagnosis since it is inexpensive and rapid, *Trichomonas* infections are likely to be underdiagnosed by relying on this methodology. Screening for *Trichomonas* using PCR- based assays should become the standard of care for symptomatic or asymptomatic patients.	Grade - I
Rogers et al., 2012	Randomized Control Trial	N = 2,936	Results suggest that public health interventions, such as STI screening and treatment in correctional settings, could substantially impact community health.	Grade - II
Roth et al., 2011	Comparative Study	N = 222 (First Study) N = 471 (Second Study)	A five-fold increase in the incidence of *T. vaginalis* infection was detected for both studies. Changing screening protocols to use improved diagnostic tools and universal screening resulted in increased case finding for *T. vaginalis* among high-risk women.	Grade - III
Rowley et al., 2019	Systematic Review and Meta-analysis	N = 130 studies	For *chlamydia*, *gonorrhea*, and *trichomoniasis*, a systematic search for studies reporting prevalence was conducted between 2009 and 2016. We also consulted regional experts. To generate estimates, we used Bayesian meta-analysis. Global estimates of the prevalence and incidence of these four curable sexually transmitted infections remain high. The study highlights the need to expand data collection efforts at a country level and provides an initial baseline for monitoring progress.	Grade - I

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
Schwebke et al., 2018	Cross-sectional	N = 1867 women and N = 4791 men tested	In women, the performance of the Xpert TV assay was compared to the patient infected status (PIS) derived from the results of InPouch TV broth culture and Aptima NAAT for *T. vaginalis*. Xpert TV assay can provide on-demand results in 63 minutes or less. This quicker turnaround time makes the GeneXpert platform ideal for use in high-risk settings where diagnosis and treatment could ideally take place in real-time for optimal public health control of this STD.	Grade - III
Schwebke et al., 2018	Cross-sectional	N = 77,740 female, and N = 12,60 male	Results suggest that both male and female individuals at high risk for STDs should also be screened for *T. vaginalis* using NAAT, especially in individuals older than 40 years. Such a screening program could be implemented as an adjunctive method to current screening efforts for *chlamydia* and *gonorrhea*.	Grade - III
Shaikh et al., 2015	Interventional Trial	N = 1,382	An opt-out testing approach was significantly more effective in finding cases of chlamydia than an opt-in approach. Having twice the likelihood of testing positive for *chlamydia* in the opt-out testing versus the opt-in approach was consistent with previous studies that found an added advantage of providing such testing routinely. These results demonstrate the potential public health benefit of implementing universal STI testing of jail inmates. Opt-out STI screening to rapidly identify STIs	Grade - II
Spaulding et al., 2022	Systematic Review	N = 66	1. Perform STI screening as early as possible. It is	Grade - I

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			recommended to screen on arrival at the jail 2. Use short turnaround testing, preferably point-of-care tests. 3. Opt-out rather than opt-in screening for STIs is preferred unless the patient is deemed incompetent. Providing information and offers is voluntary and not coercive. 4. When insufficient funds are allocated to the jail, prioritize testing.	
Sutcliffe et al., 2010	Quasi-Experimental	N = 988	Although not as high as in other studies of women entering US jails and state prisons, our observed *T. vaginalis* prevalence of 8.5 % was much higher than in the general US population. Therefore, screening for *T. vaginalis* infection may be warranted at federal prison entry, as well as sexual health education during prison stay.	Grade - II
Turpin et al., 2019	Prospective Study	N = 2,439 primarily African American cohort of women	Evaluated the association between perceived stress and incident sexually transmitted infections (STIs, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *T. vaginalis* genital infections) in women. This study advances understanding of the relationship between perceived stress and STIs and identifies high-risk sexual behaviors and development of BV—both known risk factors for STIs—as potential mechanisms underlying this association.	Grade - III
Van Der Pol, 2016	Educational A non-experimental study	N/A	Single-test RNA options may be helpful in emergency departments where patients have extended waits. Furthermore, this can be combined with other testing,	Grade - III

Author	Type of Design	Sample	Intervention/ Recommendations	Grade for Level of Evidence*
			such as *chlamydia*/*gonorrhea*, on broad testing platforms.	
Van Gerwen et al., 2021	Systematic Review and Meta-analysis	N = 770	Given the burden of *trichomoniasis* experienced by women of childbearing age, the impact of this infection in pregnancy, particularly on adverse birth outcomes (ABOs), is important to consider	Grade - I
Verwijs et al., 2019	Cross-sectional	N = 705	Point-of-care testing for urogenital infections might improve case-finding and infection management and is feasible in resource-poor settings. Point-of-care tests should be further developed, including those targeting multiple conditions. Additional studies in other populations, including populations with low prevalence of sexually transmitted and urogenital infections, are warranted.	Grade - III
Wynn et al., 2018	Prospective Study	N = 400 pregnant women	Among women with CT, NG, and/or *T. vaginalis* infection, those who received same-day results were more likely to be treated than those who received delayed results.	Grade - I

* **Grade for Level of Evidence: 1 (I) =** Experimental studies inclusive of systematic review (SR), meta-analysis (MA), Randomized control trials (RCTs); **2 (II) =** Quasi-experimental studies inclusive of RCTS and MA's; **3 (III) =** Non-experimental studies; 4 (IV) = National CPGs or Consensus; **5 (V) =** Expert opinions, case reports, quality improvement projects, or review of literature studies**.** Based upon the ©The John Hopkins Hospital/The Johns Hopkins University Appendix C: Evidence Level and Quality Guide.

Note. BV = bacterial vaginosis. *C. trachomatis = Chlamydia trachomatis.* CDC = Centers for Disease Control and Prevention. CPG= clinical practice guidelines. HIV = human immunodeficiency virus. MA = meta-analysis. *N. gonorrhoeae = Neisseria gonorrhoeae.* RCT = randomized control trial. SR = systematic review. STD = sexually transmitted disease. STI = sexually transmitted infections. *T. vaginalis = Trichomonas vaginalis*

Appendix K

Stakeholder Responses/Recommendations for Guideline

Stakeholder	Recommendation One: 1 = Poor recommendation based upon evidence 2 = Fair or Weak recommendation based upon evidence 3 = Good or Moderate recommendation based upon evidence 4 = excellent or high recommendation based upon evidence	Recommendation Two: 1 = Poor recommendation based upon evidence 2 = Fair or Weak recommendation based upon evidence 3 = Good or Moderate recommendation based upon evidence 4 = excellent or high recommendation based upon evidence	Recommendation Three: 1 = Poor recommendation based upon evidence 2 = Fair or Weak recommendation based upon evidence 3 = Good or Moderate recommendation based upon evidence 4 = excellent or high recommendation based upon evidence	Recommendation Four: 1 = Poor recommendation based upon evidence 2 = Fair or Weak recommendation based upon evidence 3 = Good or Moderate recommendation based upon evidence 4 = excellent or high recommendation based upon evidence	Recommendation Four: 1 = Poor recommendation based upon evidence 2 = Fair or Weak recommendation based upon evidence 3 = Good or Moderate recommendation based upon evidence 4 = excellent or high recommendation based upon evidence
Stakeholder 1					
Stakeholder 2					
Stakeholder 3					
Stakeholder 4					
Stakeholder 5					
Stakeholder 6					
Stakeholder 7					
Stakeholder 8					
Stakeholder 9					
Stakeholder 10					
Stakeholder 11					
Stakeholder 12					
Stakeholder 13					

Appendix L

Educational Outline (Meeting)

Meeting date: January 20, 2023

Meeting time: 1400 hours

Meeting place: Correctional Facility Meeting Room

1. **Personal Introduction**
    a. Name, Role, School
    b. Why?
2. **Introduction of the project**
    a. Gap in practice
3. **Identify Stakeholder role**
    a. Role of stakeholder
4. **Length of time for project**
    a. Importance of staying within the designated time frame
    b. Time management
5. **Accessing links**
    a. Review links included in the email
6. **Impact on population**
    a. How will this improve our practice
    b. How this will benefit our patient population
7. **Closing statement**
    a. Project lead information and closing statement

Appendix M

Email Template to Stakeholders

From: [redacted]

To: (Enter names of email recipients)

Subject: Guideline for Screening of *Trichomonas Vaginalis* Infections in the Correctional Setting (project).

Hello_____,

As mentioned before, I am currently working on a project for our organization. The project will help us screen our patients for *Trichomonas Vaginalis*. I am arranging a meeting where more information will be shared.

The meeting will discuss the project's specifics and how your help as experts in your area will shape the new guideline for screening patients for *Trichomonas Vaginalis.*

The meeting will take place:

Meeting date: January 20, 2024
Meeting time: 1400 hours
Meeting place: Correctional Facility Meeting Room

Please review the links below; more information will be provided during the meeting.

(Place survey link here)
(Place the share folder link here)

Thank you for your participation.

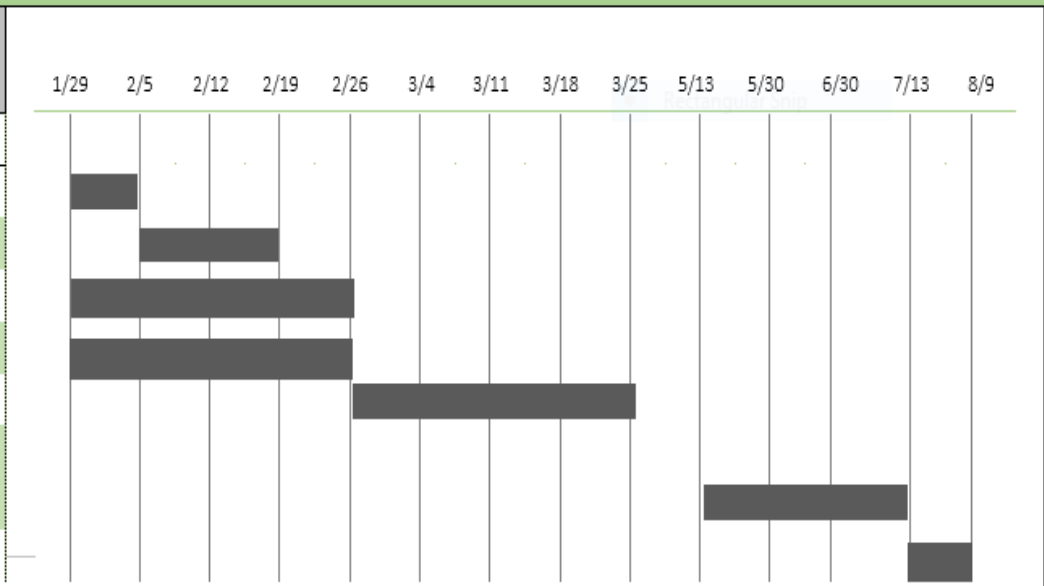
[redacted], FNP.
Correctional Facility, Primary Care

Appendix N

Guideline GANTT Chart

Guideline GANTT Chart

Construction Activities			DURATION (Days)
START DATE	END DATE	DESCRIPTION	
Practicum I			
1/29/24	2/5/24	Articles will be retrieved	7
2/5/24	2/19/24	Articles will be viewed, and recommendations started.	14
Milestone	2/26/24	Recommendations completed	30
1/29/24	2/26/24	Engage in conversation with stakeholders, education, meeting.	30
2/26/24	3/25/24	Data retrieval from stakeholder's review of the recommendations.	30
Practicum II			
5/13/24	7/13/24	Statistical analysis conducted on data retrieved.	60
7/13/24	8/9/24	Dissemination of findings.	30



Appendix O

Human Subject Certificate

UNIVERSITY OF TEXAS ARLINGTON

Human Subjects Protection Training (HSP): Training Completion Certificate

This document certifies that Nahirobi Madrid Antunez completed the training entitled "Human Subjects Protection Training (HSP)" on October 15th, 2023.

Training Start time: 10/14/2023 09:05 PM; Training End Time: 10/15/2023 12:04 AM

The Office of Regulatory Services
817-272-3723

regulatoryservices@uta.edu

Appendix P

Lead Recommendations for Screening of *Trichomonas Vaginalis* Infections in the Correctional Setting

Recommendation	**Grade** A=Systematics Review, Randomized Control Trial, meta-analysis B= Correlational/comparative Studies C=Descriptive and Expert Opinion The number represents the number of articles reviewed for that specific recommendation.	Recommended for practice based on the graded evidence-based literature and rating by the stakeholders Yes/No
Recommendation One: Screening of asymptomatic women for *Trichomonas vaginalis* is appropriate in settings such as sexual health services in geographical areas of high prevalence and women with associated risk factors. In all patients, *Trichomonas vaginalis* was significantly associated with older age, non-white ethnicity, particularly non-Hispanic black women, and current gonorrhea or chlamydia infection in women.	A: (2) Systemic Review (2) Systematic Review with meta-analysis (6) Randomized Control Trial. B: (2) Cross-sectional (2) Quasi Experimental (2) Retrospective (1) Cohort Quantitative Research (1) Cohort Study (1) Prospective Study C: (1) Non experimental (1) Decision Tree Analysis	Yes
Recommendation Two: Universal testing for *Trichomonas vaginalis* for all females upon arrival at Century Regional Detention Facility (CRDF) through the Inmate Reception Center (IRC). Due to the high morbidity level, correctional facilities are recognized as effective sites to improve public health through Sexually Transmitted Infections (STIs) control. Testing in correctional facilities may be critical to the success of *Trichomonas vaginalis* control in the community.	A: (2) Systemic Review (2) Systematic Review with meta-analysis (6) Randomized Control Trial. (1) Interventional Trial (2) Prospective Cohort B: (2) Cross-sectional (1) Quasi-Experimental (2) Cohort Quantitative Research (1) Cohort Study (1) Retrospective Cohort (1) Prospective Study	Yes

	C: (1) Decision Tree Analysis	
Recommendation Three: An opt-out testing strategy can decrease the prevalence of *Trichomonas vaginalis* by increasing overall testing while maintaining inmates' right to refuse the test. Opt-out testing is likely to be a more accurate estimate of the prevalence of *Trichomonas vaginalis* to ensure treatment of those testing positive. It may eventually reduce the potential spread of infections in the community upon release from incarceration.	A: (2) Systemic Review (2) Systematic Review with meta-analysis (1) Randomized Control Trial. (1) Interventional Trial B: (4) Cross-sectional	Yes
Recommendation Four: Pair testing for Trichomonas vaginalis is to be implemented as an adjunctive method to current screening efforts for Chlamydia/Gonorrhea/Pregnancy in urine.	A: (1) Systemic Review (2) Systematic Review with meta-analysis (1) Randomized Control Trial. (1) Prospective Study B: (3) Cross-sectional (1) Quasi-Experimental (1) Clinical review of data (1) Cohort Study C: (1) Modeling Study	Yes
Recommendation Five: Nucleic acid amplification tests (NATT) are the preferred screening method for *Trichomonas vaginalis.* Nucleic amplification tests offer the highest sensitivity for the detection of *Trichomonas vaginalis*. NATT has a sensitivity of 88%-110% from material in vaginal or endocervical swabs and in urine samples from women and also has a specificity of 95%-100% depending on the specimen and reference standard. Additionally, this platform can be used for pair testing. Already in place for chlamydia/gonorrhea/pregnancy testing in the correctional setting.	A: (3) Randomized Control Trial. (1) Meta-Analysis (1) Interventional Trial B: (3) Cross-sectional (1) Clinical review of data C: (1) Modeling Study	Yes