Use of Public Health Detailing to Improve Provider Practice in the Clinical Management of Syphilis

Tessa A. Robinson

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Use of Public Health Detailing to Improve Provider Practice in the Clinical Management of Syphilis

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Abstract

Background: Throughout history, syphilis has been a challenge to manage and control until the invention of penicillin in 1943 was available. Even with effective treatment, the diagnosis and clinical management of syphilis remains a challenge for providers. Purpose: The purpose of this project was to increase provider knowledge of evidence-based practice in the clinical management of syphilis, using public health detailing, to decrease inadequate and delayed identification and treatment of syphilis. Methods: Providers from a federally qualified health center (FQHC) participated in one public health detailing visit during March of 2021. Each provider completed a Provider Practice Assessment, which looked at their knowledge, practice, and attitudes in the clinical management of syphilis. Creation of an evidence-based Syphilis Pocket Guide was utilized to promote knowledge translation. Quantitative data was entered into Microsoft Excel and analyzed using descriptive statistics, such as frequency and percentages.

Results: A total of five providers participated in the public health detailing visit and completed the Provider Practice Assessment. The results are consistent with the claim that providers encounter challenges when managing patients with syphilis, with over 40% of providers self-rating their knowledge of syphilis staging as either fair or poor. Conclusion: Positive reception and feedback of the public health detailing visits suggests they are successful strategies to providing useful evidence-based practice education. Future recommendations include a more robust, edited Provider Practice Assessment, a larger provider participant population, and ongoing evaluation.

Keywords: syphilis, clinical management, provider practice, public health detailing
Use of Public Health Detailing to Improve Provider Practice
in the Clinical Management of Syphilis

Introduction

Syphilis is an infection caused by the bacterium *Treponema pallidum* (Center for Disease Control and Prevention [CDC], 2017). It is transmitted sexually, and from mother to child, and can invade any organ in the body (Nyatsanza & Tipple, 2016). Syphilis infection progresses through different stages, which have unique clinical manifestations that can last weeks to years (CDC, 2017; Forrestel et al., 2019). According to CDC (2018, p. ), “primary and secondary syphilis are the earliest stages of infection, reflect symptomatic disease, and are indicators of incident infection.” Dubbed “The Great Pretender”, signs and symptoms of early infection may be overlooked or misdiagnosed by patients and providers, which can lead to increased morbidity and transmission (CDC, 2017; Petrosky et al., 2016; Soreng, 2018).

After the invention of penicillin in 1943, the United States experienced a decline in the number of cases for several decades, reaching a historic low of 5,979 cases (2.1 per 100,000) in 2000 (Clement et al., 2014; Forrestel et al., 2019). However, according to CDC sexually transmitted disease (STD) surveillance data, the number of cases increased every year since, with 30,644 cases (9.5 per 100,000) reported in 2017 (CDC, 2018). Syphilis has reemerged as a serious public health threat. In response to this growing epidemic and to prevent further transmission, early detection and treatment is vital (Petrosky et al., 2016; Soreng, 2018).

Background

Diagnosis and management of patients with syphilis requires a thorough sexual history, assessment of clinical presentation, and interpretation of serologic test results. The CDC (2005) recommends providers assess their patient’s sexual history at their initial visit, when signs or
symptoms of sexually transmitted infections (STI) are reported and during annual preventive exams. Information obtained from a thorough sexual history identifies patient risk factors, guides appropriate STI screening and frequency and creates an opportunity to discuss evidence-based preventions, such as pre-exposure prophylaxis (PrEP). Despite the overwhelming benefits, provider implementation and adherence remain a challenge, with many barriers reported (Barbee et al., 2015; Chavez et al., 2018; Lanier et al., 2014).

Staging of syphilis is categorized according to clinical presentation and time since initial infection, with stages often overlapping during the progression of the disease (Clement et al., 2014). Early syphilis (primary, secondary, and non-primary non-secondary) is defined as syphilis acquisition within the past 12 months, which is based upon the observation that infectivity declines after the first year (Clement et al., 2014; Cohen et al., 2013). The first (primary) stage of syphilis is marked by the appearance of chancre, typically indurated with raised borders, at the site of inoculation, one week to three months (median=21 days) after exposure (CDC, 2018; Cohen et al., 2014; Forrestel et al., 2019). Most often the chancre is painless, located on the genitalia and will and heal in 3 to 6 weeks, regardless of treatment (Cohen et al., 2014; Forrestel et al., 2019).

If primary syphilis is left untreated, the infection will progress to the secondary stage. Secondary infection is associated with an onset of a rash on one or more areas of the body or mucous membrane lesions (condyloma lata) in the anogenital region, two to eight weeks after the disappearance of the chancre (CDC, 2018). According to Forrestel et al. (2019) systemic signs and symptoms, such as fever, lymphadenopathy, and headache are often present; less frequently, patients may have oral lesions or patchy “moth-eaten” hair loss. Early non-primary non-secondary staging applies to individuals who are asymptomatic, with earliest date of exposure or
infection determined to have occurred within the past year (Forrestel et al., 2019). According to Clement et al. (2014), diagnosis of this stage is made when in the previous year an individual has had one of the following: documented seroconversion or a ≥4-fold increase of a nontreponemal titer, documented seroconversion of a treponemal test, or sexual exposure to a person with early syphilis.

Unknown duration or late syphilis refers to infection (or reinfection) that lacks clinical signs or symptoms, is accompanied with reactive serology and infection or exposure occurred more than a year ago or is unknown (Clement et al., 2014; Forrestel et al., 2019)

The United States is currently experiencing a dramatic increase in syphilis incidence, with the highest rates of reported primary and secondary cases in 2017 occurring in the West (13.2 cases per 100,000) (CDC, 2018). In accordance with this trend, syphilis in Oregon has reached epidemic levels (14 cases per 100,000), increasing over 1000% from 2008-2017 (Oregon Health Authority [OHA], 2018). Consistent with previous years, early syphilis cases reported in both Oregon and the rest of the U.S in 2017 occurred predominately among men who have sex with men (MSM) (CDC, 2018; OHA, 2018). Parallel to increased rates of primary and secondary syphilis among all women and women of reproductive age, rates of congenital syphilis have steadily increased every year since 2012, with a 325% increase between 2013-2017 in the West. (CDC, 2018). Oregon Health Authority (OHA) (OHA, 2019, p. 1) reported in their Communicable Disease CD Summary “prior to 2014, Oregon averaged one congenital syphilis every three years; since 2014 the numbers have been rising, with 10 cases reported in 2018.”

The CDC (2018) reports that 57.9% of all primary and secondary cases occurred among men who have sex with men (MSM), with 52.1 % among men who have sex with men only and 5.8% among men who have sex with both men and women. Moreover, syphilis has also been
associated with increased risk of HIV transmission and acquisition, with a high rate of HIV co-infection among primary and secondary cases (CDC, 2018; Holman et al., 2012; OHA, 2018; Petrosky et al., 2016). In Oregon, OHA (2018) states that people living with HIV (PLWH) account for half of all recent syphilis infections. Finally, CDC (2018) reported that among early syphilis cases with known HIV status, 45.5% of cases among MSM were HIV-positive.

Syphilis is primarily acquired during sexual activities (anogenital, orogenital, and vaginal) when an infectious lesion (chancre, condyloma lata, or mucous patch) is in contact with an uninfected person’s mucous membrane or skin (Cohen et al., 2013; Forrestel et al., 2019). According to Forrestel et al. (2019), risk of transmission after sexual exposure is estimated at 33%. In the context of increasing rates, now more than ever, it is important that providers promptly and accurately diagnose and manage patients with syphilis.

**Problem Statement**

Diagnosis and clinical management of syphilis remains a challenge for providers. The navigation of ambiguous staging, interpretation of serologic tests, obtaining a thorough sexual history, treatment and follow-up contribute to these challenges. The purpose of this project was to increase provider knowledge of evidence-based practice in the clinical management of syphilis through public health detailing to decrease inadequate and delayed identification and treatment of syphilis.

**Organizational “Gap” Analysis of Project Site**

In 2015, Washington County eliminated all clinic services, which included family planning and STI clinics. Patients who received services at these clinics, especially those considered high-risk, had to receive care elsewhere. Community providers, namely federally qualified health centers (FQHCs), urgent care and emergency departments, were tasked with
absorbing these clients. One of the driving factors associated with this shift was adoption of Public Health Modernization, which focused on population rather than individual health. Instead of providing services directly, focus on collaboration with community providers to ensure access and care according to CDC recommendations was adopted.

Washington County Public Health has expanded in the past few years, with the onboarding of an additional STI public health nurse and community health worker to meet the growing need for case investigations. One of the primary goals of case investigations is to ensure that patients (cases) and their contacts are treated appropriately and in a timely manner. This provides an opportunity for provider education during case follow-up; however, an official public health detailing program with an evidence-based action kit does not currently exist.

**Review of the Literature**

A comprehensive search of the literature for syphilis and clinical management, clinical management and public health detailing was conducted on the following databases: PubMed of the National Library of Medicine, Cumulative Index of Nursing and Allied Health Literature (CINHAL) and Discovery Search. The Medical Subject Headings (MeSH) terms used were syphilis for the PubMed search, in addition to terms clinical management, randomized and meta-analysis. For the search of CINHAL and Discovery Search, the following terms were used: syphilis, clinical management, clinical practice, randomized controlled trial (RCT), meta-analysis, and public health detailing.

The search from the databases lists above yielded 68 articles, mostly reviews. Inclusion criteria included full-text articles and articles that were published in the past five years. This left six articles to review, in addition to six supplemental review articles to obtain the most recent, evidence-based practice guidelines. The six articles that were reviewed for this project consisted of one retrospective case study, one retrospective case-control study, one retrospective cohort
One of the main challenges that providers face when managing syphilis is the interpretation of serologic results upon diagnosis and post-treatment. Treponema pallidum cannot be cultured in a lab and providers must rely on indirect tests, which include treponemal and nontreponemal tests (Tuddenham & Ghanem, 2015). In addition, two separate algorithms are in used in the United States, the traditional and reverse screening algorithm (RSA). Recently, more laboratories are implementing the use of the RSA, in which a treponemal test is used initially, and if reactive is followed by a nontreponemal test. With these results a second treponemal test is needed. If positive, this represents discordant results. According to Tuddenham and Ghanem (2015), there are a few settings in which this could occur: early primary syphilis, history of past treatment, a false positive result, the prozone phenomenon and syphilis that has been untreated for a long time. Providers must then rely on their assessment and chart review to determine the cause of the discordant results.

A review by Clement et al. (2017) evaluated the implementation of the RSA at a Veteran’s facility and found that out of 160 patients who had discordant test results, only 26 (16.3%) had provider documentation of no previous treatment and an additional 60 (37.5%) had unclear treatment histories. Moreover, of the 83 veterans who had no previous treatment, 37 (44.6%) received treatment and 46 (55.4%) did not have treatment documented after the test results (Clement et al., 2017).

Another study that analyzed data from a prospective, randomized syphilis trial found an association between stage of infection and baseline RPR titer was apparent in predicting treatment response (Sena et al., 2011). “Serological cure was independently associated with
young age, fewer sex partners in the past 6 months, earlier stage of infection, higher baseline RPR titers, and a J-H reaction after treatment” (Sena et al., 2011, p. 1095).

One important piece to the clinical management of syphilis is a thorough sexual history of the patient, especially when determining the stage and associated treatment regimen. In an experimental cohort study, Lanier et al. (2014), which trained 26 physicians on sexual history taking and then examined their integration into their practice, found four major themes. These included the need for more training on how to take a sexual history, the significance of providing a gender-neutral tool, numerous barriers exist for routine sexual history taking and HIV/STD testing and inadvertent outcomes occurred for providers conducting sexual histories (Lanier et al., 2014). Interventions recommended from this study included the need for improved, routine provider-based sexual history trainings and the creation of clinical performance indicators to track routine sexual history documentation and HIV/STD measures that could remind and facilitate a dialogue between providers and their patients (Lanier et al., 2014).

A retrospective case study completed by Petrosky et al. (2016), examined possible gaps in clinical management of early syphilis among men who have sex with men (MSM) in Multnomah County, Oregon, found differences in treatment time of positive patients among providers who worked at STD versus private clinics. Most patients who were diagnosed at the STD clinic received same day treatment compared to a median time of three days for those who were seen in a private practice. Additionally, almost a quarter of MSM with secondary syphilis saw more than one provider with the same symptoms before being diagnosed. Finally, according to Petrosky et al. (2016), providers in private practice may be less likely to take a sexual history or recognize signs and symptoms of syphilis.
Another intervention that has been reviewed and could be implemented in the clinical management of syphilis is built-in reminders and systematic STI screenings in electronic health record systems. Since patients with early syphilis may be asymptomatic, patients who are considered at high risk should be screened more frequently. The CDC (2017) recommends that providers perform a syphilis test on all sexually active MSM, including those who are HIV positive annually and more frequently, such as every three to six months, if there are multiple partners or substance abuse. With the implementation of an electronic patient record (EPR) annual checklist for HIV-infected patients, Brook, et al. (2013) found routine screening identified sex of 13 patients (46%) who were asymptomatic with syphilis infection. In addition, they found that their systematic screening also increased the rate of STI diagnoses not only for MSM, but also heterosexual patients.

Another study conducted by Bissessor et al. (2011) also found that a computer alert increased the frequency of syphilis testing significantly among higher-risk MSM. As stated by Bissessor et al. (2011, p.58), “The proportion of higher-risk men who received a diagnosis of early syphilis and who were asymptomatic for syphilis increased from 16% (5 of 31 patients) to 53% (31 of 58).” Both studies represent an increase in both screening and detection of syphilis when an alert or prompt is built into the patient’s electronic medical records and provide evidence to support this intervention.

Public health detailing emerged from pharmaceutical detailing, where representatives from pharmaceutical companies would visit provider offices to promote using their medications over their competitors. According to Larson et al. (2006, p. 229), “utilizing the behavior change strategies of pharmaceutical detailing, has proven effective in improving provider practices in areas from diabetes and asthma to otitis media and acute bronchitis.” Specifically, for public
Public health detailing and the utilization of toolkits can support knowledge translation (KT), connecting research to practice. A range of evidence-based KT strategies have been employed and include printed educational materials, educational meetings, educational outreach, audit and feedback, and reminders (Barac et al., 2014; Yamada et al., 2015). According to Yamada et al. (2015), “these strategies have been used alone as single KT intervention or as multifaceted KT interventions, which consist of two or more strategies or variations of the same strategies (e.g., educational materials) delivered in combination to change practice.” A toolkit, which can be defined as multiple resources or tools that codify explicit knowledge (templates, pocket card guidelines, algorithms) and are applied to share knowledge and educate and/or facilitate behavior change (Barac et al., 2014; Yamada et al., 2015).

**Evidence Based Practice Intervention**

The planned intervention used public health detailing to implement provider education, to those who have seen syphilis cases in the community, on evidence-based practice in the clinic management of syphilis.
Theoretical Framework

The theoretical framework used to guide this DNP project is Kurt Lewin’s Theory of Planned Change (TPC). According to Galli (2018), Lewin identified three assumptions for effective change: a change motivator must be present, employees are at the center of the changes within an organization, and individuals who are affected by the change need to adapt and include the new changes into their routine, thus discontinuing their past practices. Prior to initiating the three phases of change, which include unfreezing, movement and refreezing, Lewin developed force field analysis (FFA). Force field analysis is the framework that provides the foundation for TPC. “An FFA specifies forces as either driving (helping forces) or restraining (hindering forces) movement toward a goal” (Shirley, 2013, p. 69). A diagram of this framework is included in the appendix (see Appendix A).

The first phase of TPC is unfreezing, which entails identifying a problem, recognizing the need for change and then mobilizing others to also see the need for change. Providers are encountering difficulties with the clinic management of syphilis. In the context of increasing rates of syphilis, there is a need for increased provider education and adoption of evidence-based practices. Acknowledgement of the need to incorporate best practices when managing patients with syphilis is critical. Additionally, a sense of urgency to change is also part of this phase. For example, delayed identification and treatment of patients who present with early syphilis, not only can lead to long-term individual sequelae, but also impact the health of the community in which they practice. Identifying helping and hindering forces is essential. For this project, surveying providers on their current practice and barriers they encounter to providing evidence-based care helps identify solutions and needed behavior changes.
Movement is the second phase of TPC. This phase consists of trial and error around new practices and norms. As Shirley (2013, p. 70) states, “this stage necessitates creating a detailed plan of action and engaging people to try out the proposed change.” This project used public health detailing to operationalize the behavior change (e.g., taking a thorough sexual history, staging appropriately, etc.) that providers must make.

The last phase is known as refreezing, in which change is stabilized and becomes rooted into systems such as culture, practice and policies. As providers use evidence-based practice to clinically manage patients with syphilis, it becomes more routine to take a sex history, or a new policy on using the reverse testing algorithm might be incorporated. For these practice changes to be sustainable, these changes must be embedded in both the individual provider practice and clinic levels.

Methods

Goals and Objectives

The goal of this DNP project was to increase provider awareness and implementation of evidence-based practice in the clinical management of syphilis through public health detailing visits and distribution of action kits. Additional goals of this project included provider appreciation of local epidemiological data, evaluation of the provider pocket guide, and improved collaboration between Washington County Disease Control and Prevention and community providers.

Objectives

- Completion of at least two visits to each provider over the course of a 12-week period
- Distribution of action kits to 30 providers by the end of the 12-week period
- Completion of a pre- and post-provider assessment by 30 providers
Outcomes

- Adoption of at least one evidence-based practice change by each provider by the end of the 12-week period
- Increase in provider self-reported knowledge of syphilis staging and treatment or syphilis labs and interpretation by one point on the Likert scale by the end of the 12-week period.

Project Site and Population

This project took place in Washington County, Oregon, part of the Portland Metro region, which also includes Multnomah and Clackamas counties in Oregon and Clark County in Washington. In 2015, Washington County eliminated all clinic services, which included family planning and STI clinics. Sites of public health detailing were chosen based upon current epidemiological data collected from the Orpheus, the Oregon Public Health Epi User System. This system is used by local health departments (LHDs) when completing investigations of reportable communicable disease. Criteria for selection included sites that have diagnosed a syphilis case or have requested assistance from the LHD in the clinical management of a case, including treatment, in the past year.

Public Health Detailing Visits

According to Kattan et al. (2016, p. 1430), “public health detailing campaigns are focused on specific clinical topics, emphasize a limited number of key messages, and offer practice tools, provider information, and patient education resources at the one-on-one visits.” The first visit included the following: action kit was be dispersed, assessment of current practice, syphilis overview with epidemiological data, review of key messages/strategies, commitment to one action item. The second visit included reinforcement of key messages, and during the last visit, the assessment will be re-administered to assess for practice change.
An evidence-based provider pocket guide was developed as part of the action kit. Barac et al. (2014) reviewed the use of toolkits in health and healthcare and found that the type of evidence underlying the development was wide-ranging. The type of evidence that was found included literature reviews, evidence-based guidelines, expert panels, qualitative data (interviews or stakeholder surveys), and less frequently, best-practice approaches and observations of existing practices (Barac et al., 2014).

The provider pocket guide that was developed and used for this project incorporated evidence from a literature review, evidence-based guidelines and algorithms, best-practice approaches, and review with feedback from local and state subject matter expert colleagues. Additionally, observed trends of knowledge gaps in existing provider practice was also considered in the toolkit development. The flow of the provider pocket guide was meant to align with a best-practice STI clinical visit, starting with a thorough sexual health history. According to the CDC’s Guide to Taking a Sexual History, “a sexual history should be taken as part of routine health care, as well as when there are symptoms or physical exam findings of STIs” (CDC, 2022, p.). Questions such as does the patient have a history of any STIs, what symptoms are reported by the patient, what is found on their physical exam, and are they a recent contact to someone who was recently diagnosed with an STI will help guide their assessment/plan.

Knowing what syphilis tests to order and how to interpret them is the next part of the provider pocket guide. Incorporating the two syphilis algorithms into the pocket guide was to help providers walk through the ordering and syphilis testing cascade, regardless of which algorithm their lab used. Additionally, a syphilis titer chart displayed the difference between a two-fold and four-fold increase/decrease lab result. This is critical when determining if a new
infection is present in a patient who has had a previous syphilis infection, and when evaluating response to treatment.

Syphilis staging is the evaluation of clinical presentation, sexual history, and lab results. This is important because the syphilis stage will determine the treatment plan. Patients who are staged as having early syphilis (primary, secondary, or non-primary/non-secondary) should receive one dose of benzathine penicillin G, compared to those with late syphilis, who need three doses of benzathine penicillin G. A staging algorithm was added to the pocket guide to help the provider appropriately stage and treat the patient accordingly. Follow-up testing and evaluation relies on interpretation of the patient’s syphilis titer.

When developing the provider pocket guide, additional information on extra genital chlamydia/gonorrhea screening and treatment were included for a comprehensive tool (see Appendix B).

Action kits were handed out to the providers at the first detailing visit and included the following: a provider pocket guide, posters (visual for self-collected swabs), and patient education materials (see Appendix C).

**Measurement Instruments**

To measure the outcomes of this DNP project, the following instruments were used: a Detailing Log (see Appendix D) and Provider Practice Assessment (see Appendix E) for each provider. A numerical code was assigned for each type of provider and practice to protect their identity. The detailing log included information on provider training, years in practice, practice setting, time spend with each provider and site location. In addition, one Likert scale item was used to assess how well the detailing visit was received. A provider practice assessment, a 15-item survey, collected information on current practice at the first and practice changes at the last visit. Clinical practice information included sexual history taking, lab ordering and interpretation,
Data Collection Procedures

Quantitative and qualitative data were collected at the first and last visit (see Appendix C and D). During the first visit, information was collected on the detailing log and entered on an Excel spreadsheet. Provider assessments were administered during the initial visit and last visit. The data collected from the provider assessments were entered in Microsoft Excel for analysis. Informal, unstructured face-to-face conversations with providers, direct observations, field notes and written quotes were also collected.

Data Analysis

Quantitative data was analyzed using descriptive statistics, such as frequency and percentages. Qualitative information obtained during the project was compiled and summarized to identify common themes.

Ethical Considerations/Protection of Human Subjects

The University of Massachusetts, Amherst (UMass) Internal Review Board (IRB) approval was obtained prior to initiating the DNP Project (see Appendix F). Information collected did not include any patient health information (PHI), thus eliminating any direct risk to human subjects. Provider identity was protected by assigning codes and files were stored on a password protected computer.
Results

This project was implemented during the month of March 2021 and was entirely online due to the COVID pandemic. A total of five providers, from a locally qualified health center (FQHC) in Washington County, participated via a Microsoft Teams meeting. Demographic characteristics of the providers are described below in Table 1.

Table 1

Provider Characteristics

<table>
<thead>
<tr>
<th>Type of provider</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse Practitioner</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Physician Assistant</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years in practice</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3-6</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>7-9</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>More than 10</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

Over half, 60% (n=3), were nurse practitioners, and all providers had at least 3 years of experience. A provider practice assessment was used to evaluate the provider’s self-reported knowledge, practice, and attitudes. First, providers were asked when they take a sexual health history, and how they would rate their sexual history taking skills. See Table 2. Eighty percent (80%, n=4) of providers reported taking a sexual health history as part of an annual or wellness visit and if warranted during a problem focused visit. However, when asked how they would rate
their sexual history taking skills, the answers varied. Over half, 60% (n=3), rated themselves as either excellent or good.

Table 2

Sexual Health History

<table>
<thead>
<tr>
<th>When do you take a sexual health history?</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have never taken a sexual health history</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>I only take a sexual health history during problem-focused visits</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>I take a sexual history as part of an annual or wellness visit</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>I take a sexual history as part of an annual or wellness visit and if warranted during a problem-focused visit</td>
<td>4</td>
<td>80</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

How would you rate your sexual history taking skills?

<table>
<thead>
<tr>
<th>How would you rate your sexual history taking skills?</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Good</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>Neutral</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Fair</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Poor</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

Providers were then asked about their practice regarding syphilis lab ordering and interpretation (See Table 3).

Table 3

Syphilis Lab Ordering and Interpretation

<table>
<thead>
<tr>
<th>Do you know which syphilis screening algorithm your lab uses?</th>
<th>Count</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
When you screen for syphilis, which test(s) do you order?

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPR</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Treponemal EIA/CIA</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Both</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>Depends on patient’s history</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

How would you rate your knowledge of syphilis labs and interpretation?

<table>
<thead>
<tr>
<th>Rating</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>Good</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neutral</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fair</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>Poor</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

Over half, 60% (n=3), of the providers did not know which syphilis screening algorithm their labs use. When asked which test(s) they order for syphilis, 60% (n=3) reported ordering both RPR and Treponemal EIA/CIA tests, with only one provider stating it depends on the patient’s history. Regarding self-reported knowledge of syphilis labs and interpretation, it was divided, with 40% (n=2) of providers answering good versus 60% (n=3) answering fair.

Next, they were asked to rate their knowledge of syphilis staging and treatment. Another question assessed if they presumptively treat patients who have clinical signs/or symptoms of syphilis or if they wait for test results. See Table 4 below.
Table 4

Syphilis Staging and Treatment

<table>
<thead>
<tr>
<th>How would you rate your knowledge of syphilis staging and treatment?</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Good</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neutral</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>Fair</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Poor</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How would you best describe your treatment practice for syphilis?</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>I presumptively treat for syphilis if my patient has clinical signs/or symptoms of early syphilis</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>I wait for serologic test results before I treat my patient, regardless of clinical signs/or symptoms</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
</table>

Interestingly, self-reported knowledge of syphilis staging, and treatment was low, with 40% (n=2) of providers stating they were either fair or poor. However, over half, 60% (n=3), reported that they presumptively treat patients who present with clinical signs/or symptoms. Last, the providers were asked what their biggest challenge is when managing patients with syphilis. Two providers reported syphilis staging, one reported clinical presentation, one reported follow-up testing, and the last provider reported other: distinguishing between old versus new infections. All providers stated that their practice carried benzathine penicillin G for syphilis treatment, and that they do not refer patients out for treatment.
After reviewing the provider pocket guide, providers were asked to provide any feedback. All providers stated that the pocket guide was helpful, with the information being clear, concise, and useful. Only one provider stated that they “just need to know what test to order and to take out the algorithm.”

**Discussion**

This project focused on improving provider awareness and practice in the clinical management of syphilis using public health detailing and the development of an evidence-based action kit. A total of five providers participated in one public health detailing visit and completed the Provider Practice Assessment. The results are consistent with the claim that providers encounter challenges when managing patients with syphilis. According to Clement et al. (2014), syphilis serology is used in both the diagnosis and assessment of treatment response. Considering the significance, when asked to rate their self-reported knowledge of syphilis labs and interpretation, only 40% answered good versus 60% answering fair. Moreover, 40% of providers rated their knowledge of syphilis staging and treatment as either fair or poor.

Positive reception and feedback of the public health detailing visits suggests they are successful strategies to providing useful evidence-based practice education. Finally, this project strengthened the collaboration between public health and the providers who participated. By meeting “face to face”, this allowed for formal introductions, discussions regarding resources that public health can offer to providers, and a commitment to ongoing partnership.

There are several future recommendations based on the project findings, engaging a larger provider population from a variety of clinic settings, verifying the providers’ perceptions, and revising the Provider Practice Assessment. This project included five providers from one
Although the project was successful, it is imperative to expand and evaluate the effectiveness among a larger provider population.

Moreover, after implementing the Provider Practice Assessment, it could be further refined. For example, in addition to asking the provider when and how they would self-rate their sexual history taking skills, asking them what specific questions, or set of questions are used, and how it is administered (patient filling out a sexual history assessment on paper or electronically, an MA reviewing it with the patient, etc.) is suggested. Two questions which asked the providers to self-rate their knowledge of syphilis labs and interpretation, and syphilis staging, and treatment should be separated into four questions, assessing syphilis lab ordering, lab interpretation, staging, and treatment individually. This would allow for a more comprehensive assessment and highlight gaps in knowledge and areas for improvement in finer detail. Finally, the addition of questions that assess the following: what resources (Apps, guidelines, provider consultations, health department, etc.) are used when challenges or questions in clinical management arise; when pregnancy status is evaluated, are providers assessing for neurosyphilis signs and symptoms (if so, how and when; what referral process(s) are in practice for patients who may have neurosyphilis, including additional diagnostics, specialty consultations, and treatment.

Facilitators of this project included an already established relationship between the FQHC and Washington County Public Health. All providers who participated were enthusiastic to participate and eager to learn. Additional facilitators of this project include ongoing leadership support at Washington County Public Health and assistance of the Washington County graphic designer on the Syphilis Pocket Guide.
Due to the COVID pandemic, the scale of the project had to be scaled down. Instead of implementing the project at multiple sites, only one site was selected. In addition, due to the limited availability of the providers, one visit was completed per provider via a Microsoft Teams meeting. The development of the provider pocket guide took much longer than expected. The content was reviewed by internal and external colleagues for feedback prior to implementation and underwent a few edits. Because the project was done entirely online, action kits were not distributed during the project implementation. Rather, they will be distributed after incorporating the feedback from the providers who participated in this project.

Results of this project and the final provider pocket guide will be presented this summer at our Quad County Meeting, which gathers public health nurses, disease intervention specialists (DIS), and management of four local health departments in the Portland Metro area. Additionally, further action includes the continuation of provider education using public health detailing and the action kits, expanding to other providers and clinics in Washington County.

**Conclusion**

In the context of increasing syphilis rates in the United States, now more than ever, it is important that providers are adequately screening, diagnosing, and managing syphilis patients. The literature supports assessment of challenges providers encounter and implementation of interventions that promote evidence-based practice, such as lab ordering and interpretation, syphilis staging, treatment, and follow-up monitoring. This project concentrated on these challenges using public health detailing and the creation of a Syphilis Pocket Guide to improve provider practice in the clinical management of syphilis.
Future recommendations include a more robust, edited Provider Practice Assessment that can be entered into a software program, such as Qualtrics, which includes skip logic and data analysis features. Additionally, a larger population size would allow for more complex data analysis and evaluation, with the potential for generalizable data and interventions. Another way of providing greater accessibility to the Syphilis Pocket Guide would be to create a smart App, in which a provider may enter clinical information (labs, clinical presentation, etc.) that would walk them through the algorithms and provide tailored guidance for a specific patient.

Evidence-based practice in the clinical management of syphilis is imperative. As the number of cases continue to rise each year, interventions that provide education and guidance will continue to be a valuable tool. Use of public health detailing, with the distribution of action kits and a Syphilis Pocket Guide can be utilized as a tool to support knowledge translation.
References


Los Angeles County Public Health, Division of HIV and STD Programs.

http://www.publichealth.lacounty.gov/dhsp/Syphilis.htm


US Preventative Services Task Force (USPSTF). (2016). Screening for syphilis infection in


Retrieved from https://www.co.washington.or.us/HHS/News/upload/waco-cha-2016-summary-of-findings-for-web_fixed20170203c.pdf
Appendix A

Lewin’s (1951) Change Model

*Please let your patients know the Health Department will be following up with them*
Your patients’ sexual history is an important part of their overall health and wellness. Taking a sexual history will help guide the physical exam, screening of all exposed sites for sexually transmitted infections (STI) and establish your patients’ STI/HIV risk. Take a sexual history from all patients.

**THE 5P’S OF SEXUAL HEALTH**

1. **PARTNERS**: Number and gender of partners over a given time.
2. **PRACTICES**: Types of sexual practices – oral, vaginal, anal.
3. **PROTECTION FROM STIS**: Use of condoms and other methods.
4. **PAST HISTORY OF STIS**: Establish risk of repeat infections, HIV status and hepatitis risk.
5. **PREVENTION OF PREGNANCY**: Desire of pregnancy and use of prevention methods.

**BEST PRACTICES FOR OBTAINING A SEXUAL HISTORY**

- Ensure a safe patient environment
- Assure confidentiality
- Be non-judgmental
- Be sensitive and matter-of-fact
- Avoid assumptions
- Take a sexual history from all patients
WHAT
- Testing for GC/CT at any site other than the urethra, vagina, or cervix
- Includes testing in the rectum and throat, based on patient-reported exposure
- In May 2019, the FDA cleared two NAATs for extragenital testing
  - Aptima Combo 2 Assay
  - Xpert CT/NG

WHY
- Among men who have sex with men (MSM)
  - Nearly 90% of rectal GC and CT infections are asymptomatic
  - Urine only screening would miss 77% of rectal CT and 95% of GC infections
  - Rectal infection is linked to an increased risk of HIV infection
- Among women, 30% of GC and 14% of CT infections would have been missed with urogenital testing only

WHO
- Rectal
  - The patient (any gender) has had receptive anal intercourse with a male in the past year, regardless of condom use
- Throat
  - The patient (any gender) had oral intercourse within the past year

HOW
- Specimens can be clinician or self-collected
- Self-collection, especially for rectal specimens, increases the uptake of testing
GONORRHEA AND CHLAMYDIA TREATMENT

CHLAMYDIA

Uncomplicated urogenital/oral infections
- Azithromycin 1 gram PO in a single dose

Uncomplicated rectal infections
- Doxycycline 100 mg PO BID x 7 days* or
- Azithromycin 1 gram PO in a single dose

* Recent research suggests that doxycycline may be more effective than azithromycin for rectal CT and can be considered first-line therapy for this infection

GONORRHEA

Uncomplicated cervix/urethra/oral/rectal infections
- Dual therapy is no longer recommended
  - Ceftriaxone 500 mg IM x 1
  - For people weighing > 150 kg (300 lb) ceftriaxone 1 gram IM x 1
- If chlamydia cannot be ruled out: ceftriaxone (based on weight) PLUS doxycycline 100 mg po BID x 7 days
  - During pregnancy, azithromycin 1 gram po should be used
- For those allergic to ceftriaxone: gentamicin 240 mg IM x 1 PLUS azithromycin 2 grams po x 1

EXPEDITED PARTNER THERAPY (EPT)

Expedited partner therapy (EPT)
- Cefixime 800 mg PO x 1 only
- If chlamydia cannot be ruled out in the partner: cefixime 800 mg PO x 1 PLUS doxycycline 100
TREATING PARTNERS

- Recent sex partners (i.e., persons having sexual contact with the infected patient within the 60 days preceding onset of symptoms or gonorrhea diagnosis) should be referred for evaluation, testing, and presumptive treatment.

- If you are unable to locate or treat partner(s), please call the Washington County Disease Control and Prevention Program 503-846-3594

ADDITIONAL RECOMMENDATIONS

- For people with pharyngeal gonorrhea: test-of-cure is recommended 7-14 days after treatment regardless of treatment regimen

- Repeat testing is recommended 3 months after treatment of gonorrhea infection (any site)
REVERSE SEQUENCE SCREENING

EIA/ CIA (treponemal)

EIA/CIA +

EIA/CIA –
(no lab evidence of syphilis infection)

RPR (nontreponemal test)

RPR +

RPR –

TP-PA /FTA

TP-PA/FTA +
(New or Old Injection)

TP-PA/FTA –
(Syphilis unlikely)
TRADITIONAL SCREENING

RPR \textit{(nontreponemal test)}

- RPR+
  - TPPA/FTA \textit{(treponemal)}
    - TP-PA/FTA+ \textit{(New or Old Infection)}
    - TPPA/FTA- \textit{(Syphilis Unlikely)}
  - TPPA/FTA- \textit{(no lab evidence of syphilis infection)}
DILUTIONS OF NON-SPECIFIC TESTS

(RPR/VDRL)

1:1024
1:512
1:256
1:128
1:64
1:32
1:16
1:8
1:4
1:2
1:1

2 dilution or "4 fold"
1 dilution or "2 fold"
Clinical and Serologic Evaluation After Treatment

- Treponemal antibody will remain positive throughout lifetime
- Serologic response is monitored by nontreponemal (RPR) titer

**HIV Negative:** Serology (RPR titer) intervals
- Primary and secondary disease: 6 and 12 months
- Latent disease: 6, 12 and 24 months

**HIV Positive:** Serology (RPR titer) intervals
- More frequent follow-up is recommended: 3, 6, 9, 12 & 24 mo.

Appropriate Response to Treatment

- A fourfold change (decrease) in titer, usually within 6-12, is an appropriate response to treatment
- Might be longer for latent disease, patients with low titers or history of previous infection

Serofast State

- Patients with previous history of treated syphilis may have a persistent low-positive titer for years to lifelong

Treatment Failure

- Failure of titers to decline fourfold within 6-12 months after treatment for primary and secondary disease may be indicative of treatment failure
- Consideration should also be given for cerebrospinal fluid evaluation and HIV infection
**SYPHILIS TREATMENT RECOMMENDATIONS**

<table>
<thead>
<tr>
<th>EARLY SYPHILIS</th>
<th>LATE SYPHILIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STAGE</strong></td>
<td><strong>STAGE</strong></td>
</tr>
<tr>
<td>Primary, Secondary, and Early Latent</td>
<td>Late or Unknown Duration Greater than 12 months</td>
</tr>
<tr>
<td><strong>Less than 12 months</strong></td>
<td><strong>RECOMMENDED REGIMENS</strong></td>
</tr>
<tr>
<td></td>
<td>Benzathine penicillin G</td>
</tr>
<tr>
<td><strong>RECOMMENDED REGIMENS</strong></td>
<td><strong>DOSE/ROUTE</strong></td>
</tr>
<tr>
<td>Benzathine penicillin G</td>
<td>3 doses of 2.4 million units IM each, at 1-week intervals</td>
</tr>
<tr>
<td><strong>DOSE/ROUTE</strong></td>
<td><em>Alternative for PCN Allergy</em></td>
</tr>
<tr>
<td>2.4 million units IM in a single dose</td>
<td>Doxycycline 100 mg BID x 14 days</td>
</tr>
<tr>
<td><em>Alternative for PCN Allergy</em></td>
<td><em>Alternative for PCN Allergy</em></td>
</tr>
<tr>
<td>Doxycycline 100 mg BID x 28 days</td>
<td></td>
</tr>
</tbody>
</table>

*For Neurosyphilis and Ocular Syphilis see 2015 CDC STD Treatment Guidelines*

**MANAGEMENT OF SEX PARTNERS**

**Early syphilis**
- Contacts - sex in 90 days preceding onset of case’s symptoms
  - Test and treat with 1st dose of Benzathine PCN without waiting for test results
- Contacts - >90 days since last sex
  - Test-Treatment based on results and staging
  - Treat if testing not available or follow-up uncertain

**Late syphilis**
- Test partner(s)
ADDITIONAL TREATMENT INFORMATION

- On the day of treatment, order an RPR test for a “day of treatment titer.” This will serve as a benchmark to determine whether patient has adequate treatment response.

- Pregnancy should always be ruled out in all patients treated for syphilis who could be pregnant.

- Educate patients they might experience a Jarisch-Herxheimer reaction
  > Fever, malaise, nausea, vomiting, chills
  > Within 24 hours after treatment, resolves in 24 hours
  > Self-limiting. Supportive care.

ASSISTANCE
For help interpreting test results and guidance on appropriate staging and treatment, call the Washington County Disease Control and Prevention Program 503-846-3594
SYPHILIS IN PREGNANCY

SCREENING

- **ALL** pregnant women should be screened:
  > First prenatal visit
  > Beginning of third trimester (28 weeks)
  > Delivery

- All women who deliver a stillborn infant (after 20 weeks) should be tested for syphilis.

STAGING

- Transmission can occur during any trimester and any stage of syphilis, but the risk is higher when a pregnant woman is in the primary or secondary stage.

- Pregnant women should be treated with the penicillin regimen appropriate for their stage of infection.

TREATMENT

- Pregnant women diagnosed with syphilis should be treated with penicillin **immediately**.

- **Intramuscular Benzathine penicillin G is the only therapy with documented efficacy for syphilis during pregnancy.**

- Pregnant women with syphilis in any stage who report penicillin allergy should be desensitized and treated with penicillin.

- Pregnant women diagnosed with late syphilis must be treated with exactly 3 doses **7 days** apart. Pregnant women who miss any doses must repeat full course of therapy.

- **Treatment ≥30 days prior to delivery is likely to prevent most cases of congenital syphilis.**

- **Test and treat her sex partner(s) as well to avoid reinfection.**
REFERENCES


A Guide to Taking a Sexual History (cdc.gov)

Los Angeles County Public Health, Division of HIV and STD Programs.  
http://www.public-health.lacounty.gov/dhp/Syphilis.htm
Appendix C

Action Kit Outline

Provider pocket guide

- How to take a sexual health history
- Syphilis serologic screening algorithms
  - Reverse and traditional
- Dilutions of non-treponemal (RPR/VDRL) tests
- Congenital syphilis screening and treatment
- Syphilis staging algorithm
- Syphilis treatment recommendations
  - Treating partners
  - Follow-up and monitoring
- Extragenital testing recommendations for chlamydia and gonorrhea

Posters

- Oregon Public Health Division Reporting for Clinicians
- Poster with visualization of correct swabs to use
- The Visual Guide for a Self-collected Swab
  - Rectal Swab-English
  - Rectal Swab-Spanish
  - Pharyngeal Swab-English
  - Pharyngeal Swab-Spanish
  - Vaginal Swab-English
  - Vaginal Swab-Spanish

Additional Materials

- Pens
- Handout on penicillin allergies
- Washington County Disease Control and Prevention (DCAP) reporting forms
  - Chlamydia and gonorrhea
  - Syphilis
Appendix D

Detailing Log

1). Encounter Date______________________________________________

2). Type of Provider (MD, DO, NP, PA, ND) _____________________________

3). Time spent with provider/clinic staff_______________________________________________________

4). Practice Setting
   o Private Practice
   o Hospital Based Primary Care Clinic
   o Urgent Care
   o FQHC
   o Other

5). Clinic Name______________________________________________________________

6). Clinic Address_____________________________________________________________

7). Number of years in practice________________________________________________________

8). Where does the provider appear to be on the enthusiasm spectrum?

Not Interested

1 □  2 □  3 □  4 □  5 □

Very Interested
Appendix E

Provider Practice Assessment

1). When do you take a sexual history?
   - I have never taken a sexual history
   - I only take a sexual history during problem-focused visit (i.e. when there is concern about risk or a sexually transmitted infection)
   - I take a sexual history as part of an annual or wellness visit
   - I take a sexual history as part of an annual/wellness visits and if warranted during a problem-focused visit

2). What are the reasons why you have never taken a sexual history? (Check all that apply)
   - Time
   - Not reimbursable by insurance
   - Staff are not supportive
   - Patients don’t want to talk about sex
   - Comfort or training in asking sexual health questions
   - Other__________________________

3). What are the reasons why you only take a sexual history as part of a problem-focused visit? (Check all that apply)
   - Time
   - Not reimbursable by insurance
   - Staff are not supportive
   - Patients don’t want to talk about sex
   - Comfort or training in asking sexual health questions
   - Other__________________________

4). What are the reasons why you only take a sexual history as part of an annual/wellness visit? (Check all that apply)
   - Time
   - Not reimbursable by insurance
   - Staff are not supportive
   - Patients don’t want to talk about sex
   - Comfort or training in asking sexual health questions
   - Other__________________________
5). How would you rate your sexual history taking skills?
   - Excellent
   - Good
   - Neutral
   - Fair
   - Poor

4). When do you order a STI test? (Check all that apply)
   - I do not test for STI’s
   - When patients are symptomatic
   - When patients request screening
   - As part of a routine annual/wellness visit
   - Other ________________________________

5). Which STI tests do you routinely order?
   - CT/GC (genital)
   - CT/GC (extra-genital)
   - Syphilis
   - HIV
   - Other ________________________________

6). What are the reasons why you do not order extra-genital CT/GC tests? (Check all that apply)
   - I was am not aware or familiar with extra-genital CT/GC testing
   - Time
   - My staff are not trained
   - My practice does not support it
   - Not reimbursable by insurance
   - My practice does not carry the correct swabs for collection
   - Other ________________________________

7). Do you know which syphilis screening algorithm your lab uses?
   - Reverse
   - Traditional
   - Unknown

8). When you screen for syphilis, which test(s) do you order?
   - RPR
   - Treponemal EIA/CIA
   - Both
   - Depends on patient’s history
9). How would you rate your knowledge of syphilis labs and interpretation?
   - Excellent
   - Good
   - Neutral
   - Fair
   - Poor

9). How many patients have you seen with syphilis in the last 12 months?
   - 0
   - 1
   - 2-3
   - 3+

10). How would you rate your knowledge of syphilis staging and treatment?
   - Excellent
   - Good
   - Neutral
   - Fair
   - Poor

11). How would you best describe your treatment practice for syphilis?
   - I presumptively treat for syphilis if my patient has clinical signs/or symptoms of early syphilis
   - I wait for serologic test results before I treat my patient, regardless of clinical sign/or symptoms

11). Does your practice carry benzathine penicillin G?
   - Yes
   - No

12). If no, where do you refer patients for treatment of syphilis?
   - Patient’s PCP
   - Urgent Care/ED
   - Safety net provider/FQHC
   - Washington County Public Health
   - Other__________________________

13). Have you encountered any barriers to treating syphilis in your practice?
   - No
   - Yes
14). If yes, what barriers?
   ○ I have never treated a patient with syphilis
   ○ Time
   ○ Not reimbursable by insurance
   ○ Recommended treatment not available at my practice
   ○ Unsure how to best treat complicated cases
   ○ Other______________________________

15). What is the biggest challenge for you when managing patients with syphilis?
   ○ Clinical presentation
   ○ Lab ordering/interpretation
   ○ Syphilis staging
   ○ Syphilis treatment
   ○ Follow-up testing
   ○ Other______________________________
Appendix F

Human Subjects Research Determination

Memorandum – Not Human Subjects Research Determination

Date: October 2, 2019

To: Tessa Robinson, College of Nursing

Project Title: Use of Public Health Detailing to Improve Provider Practice in the Clinical Management of Syphilis

IRB Determination Number: 19-178

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination based on the information provided to our office:

☐ The proposed project does not involve research that obtains information about living individuals [45 CFR 46.102(f)].

☐ The proposed project does not involve intervention or interaction with individuals OR does not use identifiable private information [45 CFR 46.102(f)(1), (2)].

☒ The proposed project does not meet the definition of human subject research under federal regulations [45 CFR 46.102(d)].

Submission of an Application to UMass Amherst IRB is not required.

Note: This determination applies only to the activities described in the submission. If there are changes to the activities described in this submission, please submit a new determination form to the HRPO prior to initiating any changes.

A project determined as “Not Human Subjects Research” must still be conducted in accordance with the ethical principles outlined in the Belmont Report: respect for persons, beneficence, and justice. Researchers must also comply with all applicable federal, state and local regulations as well as UMass Amherst Policies and procedures which may include obtaining approval of your activities from other institutions or entities.

Please do not hesitate to call us at 413-545-3428 or email humansubjects@ora.umass.edu if you have any questions.

Iris L. Jenkins, Assistant Director
Human Research Protection Office