

Master of Public Health Field Experience Report

EARLY DETECTION OF ALZHEIMER'S DISEASE IN THE MILITARY POPULATION & PUBLIC HEALTH FIELD EXPERIENCE: HIV PREVENTION USING PRE-EXPOSURE PROPHYLAXIS

by

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submitted in partial fulfillment of the requirements for the degree

MASTER OF PUBLIC HEALTH

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Abstract

Globally there has been approximately 35 million deaths because of the human immunodeficiency virus (HIV) since the start of this epidemic and it is still an ongoing battle (WHO). Research continues in the hopes to stop this epidemic and the development of pre-exposure prophylaxis might be the key to this problem. Pre-exposure prophylaxis--PrEP--is an HIV prevention tool that was approved by the U.S. Food and Drug Administration in 2012. It is an intervention tool developed for those who are at high risk of acquiring HIV. In my field experience, at the Kansas Department of Health and Environment, I was able to create a PrEP toolkit which consisted of educational materials for providers and consumers on PrEP. The overall goal of this field experience is for Kansans to have the opportunity to use PrEP as a prevention tool which may lead to a decrease of HIV cases per year in the state of Kansas.

Furthermore, my capstone project focused on Alzheimer's disease (AD) within the military population. Alzheimer's disease is a neurodegenerative disease that is currently affecting more than five million Americans. The aging military veterans are one of the populations most affected with Alzheimer's disease. Evidence suggest that this aging military population has potentially been subjected to additional risk factors compared to the general population. Consequently, it is believed that this population represents an elevated risk for AD and other dementias. Therefore, the goal of our study was to use existing statistical classification methods to be able to detect AD at an early stage and determine important biomarkers for the military population.

Subject Keywords: human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), pre-exposure prophylaxis (PrEP), HIV prevention, Alzheimer's disease (AD), veterans, traumatic brain injury (TBI), post-traumatic stress disorder (PTSD)

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Chapter 1 - Kansas Department of Health & Environment: STI/HIV Section

Introduction

At the end of 2013, there were approximately 1.2 million people in the United States living with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) from the age of thirteen and older (Hiv/aids.2016). Furthermore, globally, there are approximately 36.7 million people who are currently living with HIV/AIDS (Global statistics.2016). HIV/AIDS is not something from the past, but it is an ongoing battle. There are many global and U.S. government agencies interested in decreasing the AIDs burden. AIDS.gov is one of the U.S. government agencies that focuses on increasing HIV testing, awareness, and access to Federal HIV information. Additionally, there are many state health departments that work with HIV prevention and with those individuals who are HIV-positive (HIV/AIDS: U.S. government agencies.2016).

The Kansas Department of Health & Environment (KDHE) is one of those state health departments that possesses an STI/HIV sector. KDHE is comprised of the following three divisions: Public Health, Environment, and Health Care Finance (About KDHE.2016). I had the opportunity to work for the Bureau of Disease Control and Prevention under the division of Public Health. The Bureau of Disease Control and Prevention is composed of the following sectors: immunization, influenza information, STI/HIV, and tuberculosis. My preceptor, Stephanie Green, is the STI/HIV Section Chief for KDHE in Topeka, Kansas. My project focused on the prevention of HIV by the use of pre-exposure prophylaxis (PrEP). Chapter two will focus on my project involving PrEP.

HIV Pathogenesis

HIV gradually destroys the immune system by attacking CD4 +T cells, otherwise known as T-helper cells. These white blood cells are destroyed by HIV replication, thus not allowing CD4 cells to participate in protecting the body from infection (The HIV life cycle | understanding HIV/AIDS.2016). Dendritic cells bind to the HIV envelope glycoprotein gp120 with high affinity. This plays a crucial role in the initiation of HIV infection since this allows the virus to be presented to susceptible cells. HIV begins its

replication cycle when the virus binds to a CD4 molecule on the surface of a T cell (Fauci, 2007).

The virus utilizes CD4 T cells to proliferate and spread to other parts of the body. Viral spread takes place in different stages, and begins with binding of the viral gp120 to the CD4 co-receptor. The glycoprotein undergoes conformational change to facilitate this binding and for fusion to occur. Fusion between the HIV envelope and the CD4 cell membrane then occurs, which allows for the establishment of the infection (Fauci, 2007).

Next, the virus converts viral RNA into DNA by using the HIV specific enzyme, reverse transcriptase. This gives the virus the ability to enter the host cell nucleus and insert its viral DNA into the DNA of the CD4 cells. Integration occurs with the release of an HIV specific enzyme, integrase. This integration into the host DNA allows the virus to make long proteins chains by using the machinery of the CD4 cells. Then, these proteins translocate to the surface of the host cell along with HIV-RNA leading to the assembly of immature HIV virions, which are noninfectious. The immature HIV virions then bud out of the host cell. When virions bud out of the cell, the HIV enzyme protease is released. This enzyme breaks up the long protein chains that make up the immature virions into individual proteins. These individual proteins are recombined and they form a mature HIV, which is now infectious (The HIV life cycle | understanding HIV/AIDS.2016). Establishment of persistent and chronic infection occurs with spreading of virus to the gut-associated lymphoid tissues and other lymphoid tissues and organs. There are multiple vital cellular and humoral responses during the initiation and the establishment of an HIV infection. HIV can escape the immune-mediated responses; therefore, this creates a persistent infection that cannot be eliminated completely (Fauci, 2007).

HIV cannot be eliminated completely, but it can be controlled by focusing on preventive measures that help reduce the detectable viral load. The viral load refers to the amount of HIV present in a milliliter of blood. The CD4 cell count decreases as the viral load increases. Consequently, antiretroviral therapy (ART) is now used for many who are HIV-positive. Antiretroviral treatment is used to decrease the viral load to almost undetectable levels in the blood. Studies have shown that reducing viral load can

also reduce the transmission rate (Prevention of mother-to-child transmission (PMTCT) of HIV | AVERT.2017; Fauci, 2007).

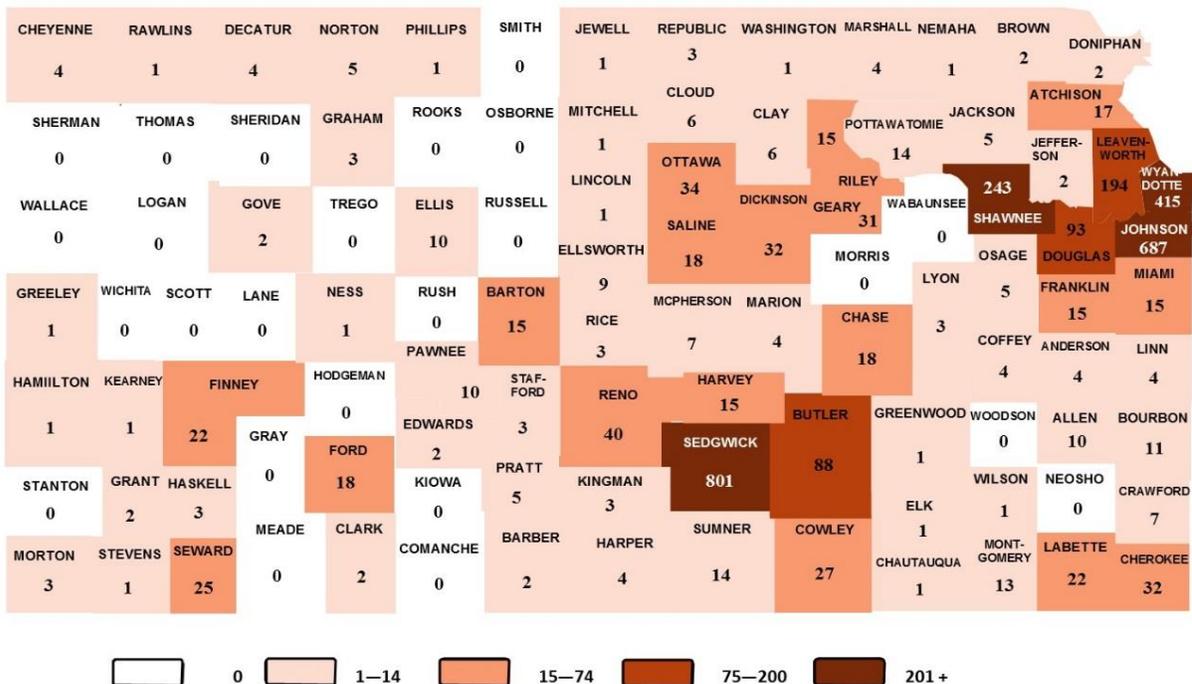
Epidemiology of HIV in Kansas

The Kansas Department of Health and Environment in the Disease Control and Prevention Bureau emphasizes prevention. Their mission is: “To improve the quality and longevity of life for the citizens of Kansas by reducing the incidence of death and disability from infectious disease.” According to KDHE, there are approximately 150 people in Kansas being diagnosed with HIV each year (Kansas department of health and environment: STI/HIV section.2016). The spread of HIV is mostly found in the areas of Kansas City and Wichita, but there are several other cities in Kansas affected by this virus, such as Topeka in Shawnee County. Figure 1.1 is an image from KDHE HIV



02/22/2017

Number of People Living with HIV by County for the State of Kansas as of December 31, 2016



This map reflects the number of persons living in Kansas who have been diagnosed with HIV. Last reported address was utilized to determine residency. If the last reported county variable was unknown, that individual will not be reflected in this map.

report. It displays the number of people living with HIV by County in Kansas as of December 2016 (Kansas department of health and environment: STI/HIV section.2016).

Figure 1.1 Number of People Living with HIV in the State of Kansas by County (2016)

Men who have sex with men (MSM) is the population most affected by HIV. Black/African American MSM continue to experience a disproportionate increase of HIV diagnoses compared to Non-Hispanic White MSM (Pre-exposure prophylaxis (PrEP).2016). Figure 1.2 categorizes the routes of exposure for those who were newly diagnosed with HIV in Kansas from 2010-2014.

In the state of Kansas, there were 139 new cases of HIV diagnosed in 2014; 2,827 HIV-positive people were known to live in the state of Kansas as of 2014 (Kansas department of health and environment: STI/HIV section.2016). Figure 1.3 is adapted from KDHE HIV report and it shows the incidence (those newly diagnosed with HIV in Kansas during that year) and prevalence (the total of all those living with HIV in Kansas) of HIV from 2010-2014.

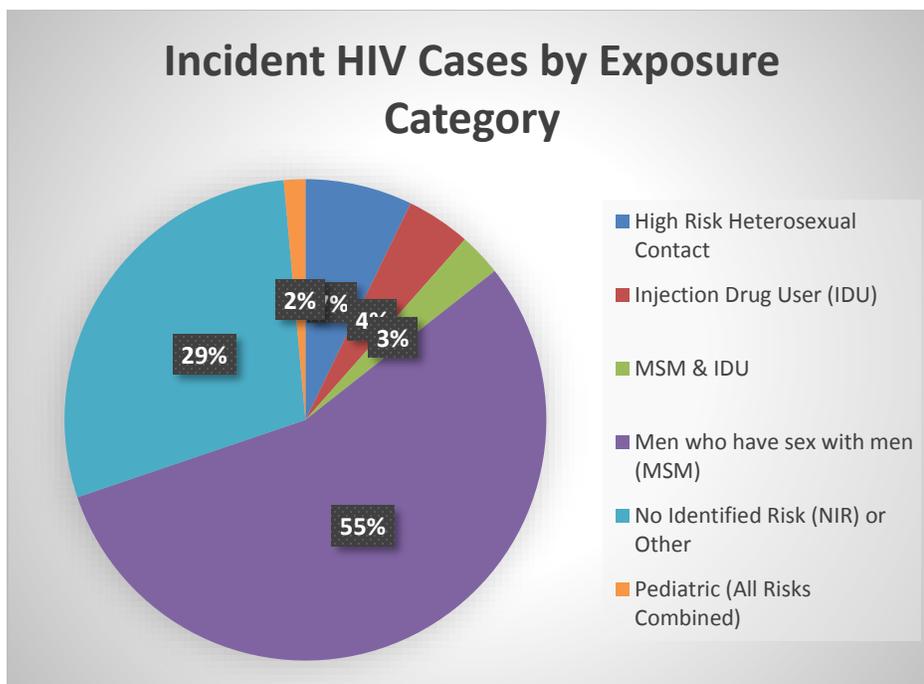


Figure 1.2 Incident HIV Cases by Exposure Category (2010-2014)

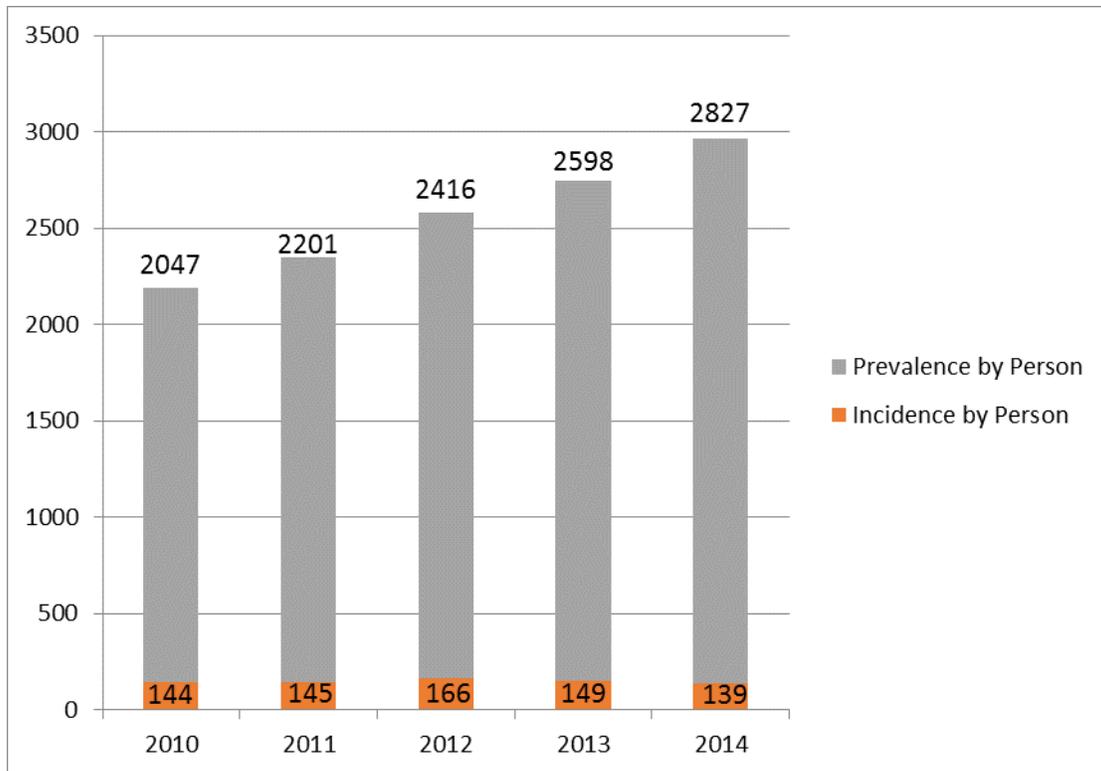


Figure 1.3 Incidence & Prevalence in Kansas (2010-2014)

In Figure 1.3, there is a steady increase of prevalence each year. There are many factors that can play into this stable increase such as longer life expectancy. An aspect to consider is the development of antiretroviral therapy (ART). The prognosis of HIV-positive individuals has improved drastically with the introduction of ART. ART has allowed for viral suppression making HIV a disease that can be controlled and no longer considered to be fatal. Studies show that early diagnosis of HIV and good adherence to antiretroviral drugs triggers higher life expectancies (Nakagawa et al., 2012).

Furthermore, the incidence each year is stable and not significantly increasing or decreasing. This allows for more opportunities of infection since there is no significant decrease in incidence and there is a higher life expectancies leading to a higher prevalence. Therefore, Kansans should focus on preventive strategies such as pre-exposure prophylaxis to significantly decrease the incidence each year.

Chapter 2 - Field Experience: Pre-Exposure Prophylaxis for HIV

Overview

In 2012, Truvada® (a fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate), an oral antiretroviral medication was approved by the U.S. Food and Drug Administration (FDA) as pre-exposure prophylaxis (Katz, 2013). Pre-exposure prophylaxis—PrEP—is used as an HIV prevention tool for those who are HIV uninfected, but are at a high risk of HIV acquisition (Hiv/aids.2016). The approval of PrEP was based on strong evidence from randomized clinical trials. In these clinical trials, all participants were given counseling on safer-sex behaviors and were given a regular supply of condoms. These participants were either given PrEP or a placebo and were regularly tested for STIs (Pre-exposure prophylaxis (PrEP).2016).

The iPrEX (Pre-exposure Prophylaxis Initiative) trial was the first trial to produce valuable results and expose the idea that PrEP works. In this trial, 2,499 seronegative MSM and transgender women were given a combination of emtricitabine and tenofovir disoproxil fumarate (FTC-TDF) or a placebo and were asked to be taken daily. There were 10 participants who were found to be HIV-positive at enrollment and 100 participants tested HIV-antibody positive during follow-up. Among these 100 participants, 64 occurred in the placebo group and 36 occurred in the FTC-TDF group; providing an efficacy of 44% (Grant et al., 2010).

For the iPrEX trial, adherence was based upon self-report and the number of pills left in the bottles. This resulted to not be a reliable indicator of adherence. Drug levels were tested in those individuals that became infected with HIV and only drug levels were detected in 9% of those individuals. Since many of the subjects were not taking the drug as prescribed and the indicator of adherence was not reliable, researchers were able to calculate that the efficacy would have been at least 92% if participants would have taken the drug as prescribed (Grant et al., 2010). Altogether, in these clinical trials, higher adherence demonstrated lower HIV transmission for those individuals who took PrEP consistently. Present day, according to the CDC, PrEP is

known to help reduce the risk of getting HIV by 92% when used as prescribed (Pre-exposure prophylaxis (PrEP).2016).

PrEP is a prevention tool that should be taken every day to obtain high adherence. It is an effective prevention tool when combined with other preventive methods, such as condoms, and should not be a substitute for other safe sex practices. It is only recommended for those individuals that are uninfected since Truvada® is only one of the three medications prescribed for HIV-positive individuals (What is TRUVADA for PrEP.2017). If recently been exposed to the virus, post-exposure prophylaxis is to be used. Post-exposure prophylaxis—PEP—is used for those individuals who believe have been exposed to HIV within the past 72 hours and it involves taking the complete treatment of antiretroviral medications (Hiv/aids.2016). Therefore, PrEP requires regular testing to confirm that the individual is HIV-negative. Otherwise, the individual should be started on antiretroviral medications. The following are tests and evaluations necessary when starting on PrEP (What is TRUVADA for PrEP.2017):

- Confirmed negative HIV-1 test
- Creatinine test for creatinine clearance
- HBV screening test
- Confirm that the patient is not taking other HIV-1 or HBV medications
- Pregnancy test- evaluate risk & benefits for a women who may be pregnant or may want to become pregnant
- Ask about symptoms of acute HIV infection (flu-like symptoms)

When starting PrEP the individual should be tested for STIs and HIV at least every three months.

Field Experience Objective

The main objective of this field experience was to create a PrEP toolkit for providers that will eventually lead for Kansans to easily access PrEP as an HIV preventive intervention. This toolkit consists of educational information for providers in Kansas, but also for the current and future consumers. To fulfill this objective, I had to demonstrate an understanding of the following: the HIV virus and how it affects the body; HIV laboratory testing technology; PrEP and what it means for an individual to be

on PrEP; the CDC defined high-risk individuals and who are good candidates for PrEP; the STI/HIV Prevention Program at KDHE.

Activities Performed

My field experience at KDHE consisted of completing multiple courses, conducting research, and producing resources for the implementation of PrEP in the state of Kansas. Figure 2.1 consists of an overview of all the activities performed at KDHE. The following information provides a more detailed overview of my field experience.

During my field experience at KDHE, I completed the HIV 101 Course online via KS-Train to ensure a fundamental understanding of HIV. Additionally, via the National LGBT Health Education Center, I completed the following webinars: “Current Topics in HIV Pre-Exposure Prophylaxis (PrEP)” and “Preventing HIV with PrEP: A clinical update.” These webinars were led by a current physician that provides PrEP. The webinars provide a basic overview of PrEP, a clinical approach to common quandaries in PrEP management, and how to apply PrEP into clinical cases (Kevin L. Ard, 2016a; Kevin L. Ard, 2016b). These webinars will be accentuated to providers interested in prescribing PrEP. Providers will also receive an AAFP Prescribed credit for every webinar completed. This credit is accepted by many associations such as the American Medical Association and it equivalent to AMA PRA Category 1 Credit. These types of credits go towards the AMA Physician Recognition Rewards.

Furthermore, my field experience consisted of developing educational materials for providers and consumers. To achieve this, I researched and reviewed the following: clinical trials conducted for PrEP, basic information about PrEP offered by the CDC and other well-recognized organizations, payment methods for PrEP (Truvada®), and current reviews on PrEP. I also had the opportunity to work and interact with the Disease Intervention Specialists (DIS). The DIS assisted in gaining further understanding of the individuals at high-risk of STIs/HIV and implement this information when creating educational materials for potential consumers of PrEP.

As a final point, we got approval for a PrEP tab to be added to the KDHE website under the Bureau of Disease Control and Prevention. Within this website, I added basic PrEP information and PrEP website links for providers and consumers. The educational

materials can be found on the website, and an order form can also be found for providers to order any more supplies needed from the toolkit provided. Likewise, I created a provider directory of all family medicine and infectious disease specialists practicing in Kansas by using Access. The directory provides general contact information of the providers and the addresses to send the toolkits. The anticipating goal is to add a provider resource directory to the website which outlines all the providers in Kansas that offer PrEP.

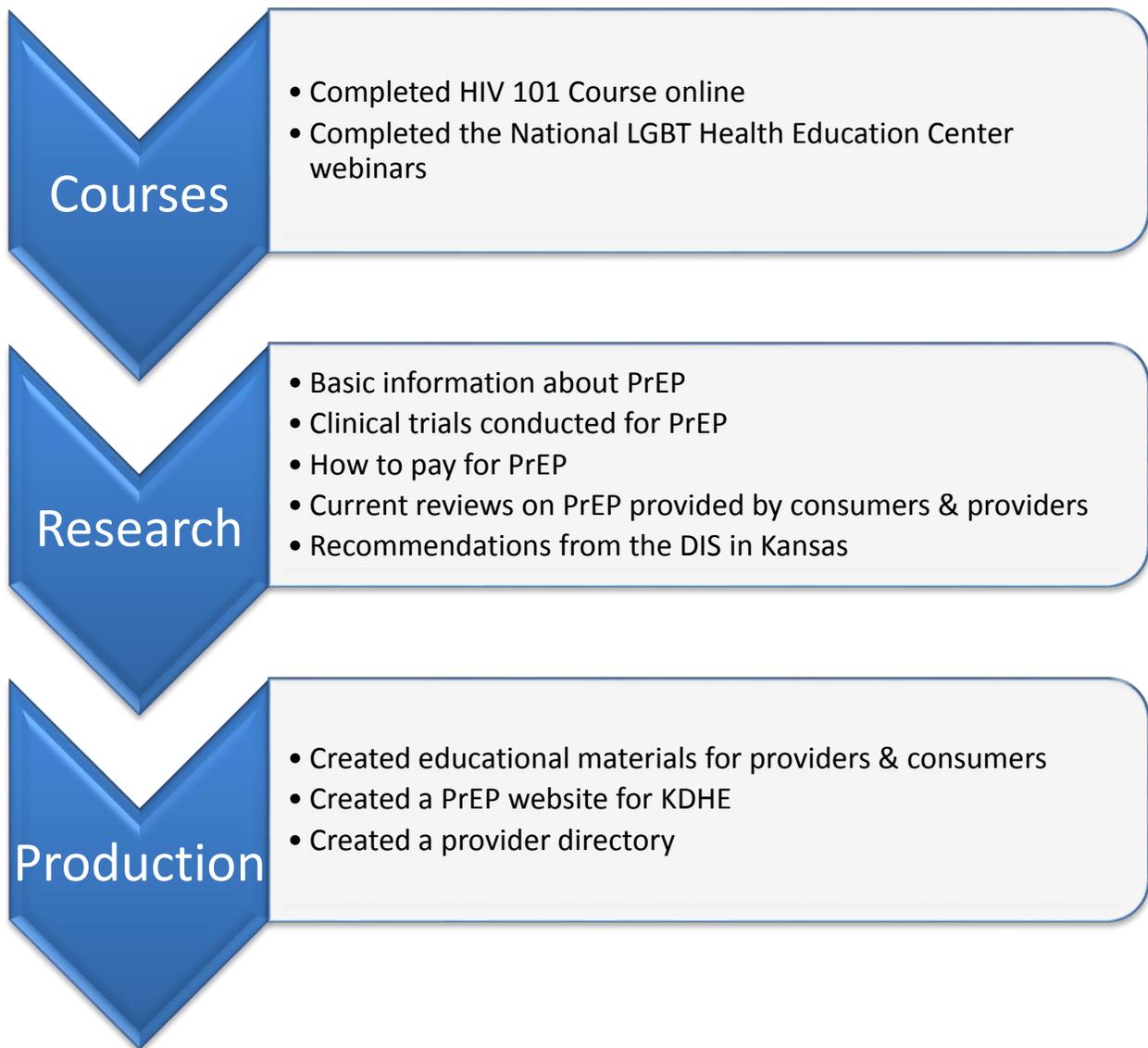


Figure 2.1 Activities Performed at KDHE for the STI/HIV Section

Implementing PrEP to at High-Risk Individuals

HIV is a lifelong disease and just one unsafe sexual behavior or action can lead to exposure to this virus. For this reason, it is important to recognize those individuals at high-risk of acquiring HIV and allowing them to access preventive care, such as PrEP. According to the CDC, there are roughly 1.2 million adults in the United States that could benefit from PrEP (Silapaswan, Krakower, & Mayer, 2017). The following are those individuals considered to be at high-risk (Pre-exposure prophylaxis (PrEP). 2016):

- Gay or bisexual men who have had anal sex without condoms
- Those who use injection drugs
- Those who have had an STI within the past 6 months
- Those with an HIV-positive partner
- Those with a partner whose HIV status is unknown
- Those who are not in a mutually monogamous relationship
- Those who exchange sex for commodities

PrEP is a preventive intervention; therefore, primary care providers should be prescribers of PrEP (Silapaswan et al., 2017). Primary care providers can play a vital role in identifying these individuals when conducting sexual histories in their practices. Conducting sexual histories gives providers access to their patients' risk for STIs and HIV. This opens a window for risk-reduction counseling and potentially recognizing good candidates for PrEP. Unfortunately, studies have shown that less than 40% of providers conduct sexual histories in their practice (Lanier et al., 2014). Many of these providers state to not have received any formal type of training regarding sexual histories in school. For this reason, my project consisted of creating an educational sexual history brochure for providers in Kansas, which can be found in the appendix.

Many providers may avoid sexual histories since it may be uncomfortable for the provider and/or the patient. As stated in *The Hidden Epidemic*, "Ironically, it may require greater intimacy to discuss sex than to engage in it" (Thomas R. Eng, William T Butler, 1997). Conducting a sexual history can be a challenge, but it is essential for being able to provide high-quality care. Figure 2.1 is an image of a sexual history form I was able to create for providers in the state of Kansas to have access to. The questions can easily be answered at any time. As a result, the patient can answer the questions before or during his or her appointment.

Additionally, it is important to not make any assumptions when conducting a sexual history. For example, I made question number 3 and 4 separate questions (3. “When was the last time you had sex with a male?” and 4. “When was the last time you had sex with a female?”) instead of combining the questions. Having them be separate questions gives the patient two opportunities to be sincere if he/she is sexually active with both males and females. Also, it gives the physician a better opportunity to catch these types of sexual behaviors.

Sexual History Form

Patient Name: _____ DOB: _____

Please take a few minutes to fill this form regarding your sexual health. Sexual health is an important part of your general health. Your information is strictly confidential.

1. When was the last time you had sex (genital, anal, or oral)?
 Date: _____ Never
2. How many sex partners have you had in the past 12 months?
 No partners One partner More than one partner: _____
3. When was the last time you had sex with a male? Date: _____
4. When was the last time you had sex with a female? Date: _____
5. When was the last time you had any of the following:
 Genital sex (penis in vagina)/Date: _____ Anal sex (penis in anus)/Date: _____ Oral sex (mouth on penis, vagina, anus)/Date: _____
6. When was the last time you received/given money for drugs or sex?
 Date: _____ Never
7. How often do you use condoms?
 Always Most of the time Sometimes Never
8. Have you ever been diagnosed with HIV or other sexually transmitted infections (STIs)?
 Yes No
9. If yes, which one (chlamydia, gonorrhea, syphilis, herpes, or HIV) and when:
 Type: _____ When: _____
 Type: _____ When: _____
10. Have any of your sexual partners had an STI in the past 12 months?
 Yes: Specify _____ No I do not know
11. When was the last time you were tested for HIV or other STI(s)?
 Date: _____ Never tested Never, but would like to be tested
12. When was the last time you injected drugs?
 Date: _____ Never
13. Have you ever been educated on prevention, such as PrEP?
 Yes No No, but would like more information
14. Any Contraception (birth control) use? If yes, what method? If no, reason.
 Yes _____ No _____
15. Questions/Comments:



Figure 2.2 Sexual History Form

Lastly, KDHE has a Disease Intervention Program which focuses on intervening in the spread of STIs and HIV. Disease Intervention Specialists (DIS) work within the program in offering assistances with treatment to the infected individuals. The DIS is also in charge of contacting the patient that has been infected for further questioning (Kansas department of health and environment: STI/HIV section.2016). This helps

identify those individuals that need testing and notify the partners of the infected individual.

The DIS is constantly working with individuals at high-risk of getting HIV since it has been shown that people with an STI have a higher chance of acquiring HIV, when compared to people who do not have an STI (Hiv/aids.2016). Within the field experience, I was able to create labels for the DIS to hang in a custom-made lanyard. Figure 2.2 is an image of the labels made for the DIS. These labels consist of five different PrEP points, such as the possible side effects. The back of the label consists of different indicators that show if PrEP is right for his or her client.

PrEP Points	Is PrEP right for your client?
Studies have shown that PrEP reduces the risk of getting HIV from sex by up to 92% when used consistently.	<p>Ask and Explore:</p> <ul style="list-style-type: none"> • How would taking a pill everyday fit or not fit in your life right now? <p>Summarize Strengths and Challenges:</p> <ul style="list-style-type: none"> • Some strengths are: <ul style="list-style-type: none"> ○ takes a med daily, easy link to daily event, positive attitude • Some challenges you have with daily pill taking are: <ul style="list-style-type: none"> ○ away from home, busy schedule, substance use, toxicity concerns <p>Identify and Strategize:</p> <ul style="list-style-type: none"> • Given what we just talked about, what kinds of things need to happen for you to take PrEP every day? • Generate menu of options. <p>Moving Forward:</p> <ul style="list-style-type: none"> • You said you'll use this strategy. Let's find a provider nearest to you who will prescribe PrEP for you. <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Menu of Strategies:</p> <ul style="list-style-type: none"> -Link PrEP to daily routine -Identify what to do if missed -Pillbox -Understand side effects -Disclose PrEP use to significant other -Plan for intentional discontinuation -Link dose to event (like brushing teeth) -Alarms/texts </div>
1pill/day, every day . Skipping doses reduces effectiveness.	
Some possible side effects: upset stomach, nausea, loss of appetite, vomiting, fatigue and dizziness. Most side effects are mild and usually go away within the first month.	
Client will need repeat STI/HIV tests every 3 months.	
PrEP does NOT protect against STI's or pregnancy, so condoms should still be used for additional protection.	

Figure 2.3 PrEP Labels for the Disease Intervention Specialist (DIS)

Correspondingly, figure 2.3 is an image of a patient referral card that folds into the size of a business card that I created for the DIS to handout to their clients. The labels that the DIS will carry will help in introducing PrEP to their clients, but the referral cards will offer continuation. The referral cards are meant for the clients to keep; this

way they can refer to the card at any time. The client may not feel like he or she currently is not at high-risk of acquiring HIV, but that does not guarantee that it will change with time. For this reason, the information folds into a business card allowing for easy repository and access. The idea of the labels and referral cards was made with the contribution of the Tennessee Department of Health.

PrEP Yourself

What is PrEP?

PrEP is an HIV prevention pill that should be taken every day. It only works for those individuals that are HIV-negative and are at high risk of getting HIV.

Reduces the risk of getting HIV from sex by up to 92%

Where Can I Get PrEP?

Name of Physician: _____

Phone: _____

More PrEP info:

- whatisprep.org
- cdc.gov/hiv/basics/

Is PrEP Right For Me?

- Is your partner HIV-Positive or HIV status unknown?
- Not in a mutually monogamous relationship?
- Do not consistently use condoms?
- A gay or bisexual man who have had anal sex without a condom?
- Been recently diagnosed with an STI?

If you answered YES to any of these questions, you should discuss PrEP with your doctor.

How Do I Pay for PrEP?

If you have insurance – You may be able to save on co-pay, deductibles, or co-insurance for TRUVADA prescription with the following:

- Gilead Advancing Access Co-pay Card- gileadcopay.com- 877-505-6986
- Patient Access Network Foundation/ panfoundation.org/hivtreatment-and-prevention—866-316-7263

If you do not have insurance – The following provide assistance for people who cannot afford to pay for TRUVADA:

- Gilead U.S. Advancing Access Program— GileadAdvancingAccess.com—800-266-2056
- Partnership for Prescription Access (PPA) Program— PPARX.org

Figure 2.4 Referral Card

PrEP Toolkit

Family medicine providers and infectious disease specialist will be given the opportunity to receive a PrEP toolkit. The materials provided in the toolkit can be found in the appendix. The following is the content found in the PrEP toolkit:

- PrEP Brochure for Patients

This brochure explains the basics of PrEP. It explains what PrEP is and who should take PrEP. It also offers information on programs that may help pay for PrEP.
- PrEP Brochure for Providers

This brochure explains the basics of PrEP and how Truvada® is currently the medication used for PrEP. It also explains some of the possible side effects and who are good candidates for PrEP.
- PrEP Patient Referral Card (see figure 2.4)

The card provides an explanation of what is PrEP. It also includes information on how to pay for PrEP

- **Why a Sexual History is Important Brochure**

This brochure consist of information on why it is important to conduct a sexual history and when a sexual history should be taken. It offers tips on how to conduct a sexual history.

- **Sexual History Patient Form (see figure 2.2)**

A sexual history form may use by providers to use for sexual histories.

- **Paying for PrEP Brochure**

This is a brochure provided by the CDC that shows different routes when it comes for covering the cost of PrEP.

- **CDC PrEP Posters**

These are 3 different PrEP posters offered by the CDC to promote and educated people on PrEP.

- **Truvada® Medication Information Sheet (English & Spanish)**

This is an information for the patient for when he or she gets started on Truvada®. Gives an explanation on how to use the medication and some of the possible side effects.

- **Initiation of Truvada®:Checklist for Prescribers**

This is a checklist provided by Gilead Sciences, Inc. It is a checklist for providers to complete when prescribing Truvada®. It consist information on the labs and evaluations needed before prescribing Truvada®.

- **Taking a Pill Everyday Brochure**

This is brochure for providers to give to their patients when prescribing PrEP. It discusses the importance of taking PrEP every day.

- **Kansas Notifiable Disease Form**

This form should be used to report STI and HIV cases to the state of Kansas. When completed this forms need to be faxed to 785-559-4225.

- **Linkage to Care (LTC) Coverage Map**

The LTC programs was established to navigate newly diagnosed HIV-positive individuals into medical care. The map shows the different regions of the LTC program and their prospective coordinators.

- **Disease Intervention Specialists (DIS) Assignment Areas**

The DIS offers support services to providers, patients, and the public throughout the state of Kansas.

Family medicine and infectious disease specialists will be contacted individually using the provider directory I created during my field experience. This directory is composed of over 400 providers in the state of Kansas. Contacting the provider will

permit us to know which providers are interested in receiving the toolkit and keeping them in our system. With time, we will arrange follow-ups with those providers that opt to receive the toolkit. These follow-ups are to indicate if the provider is prescribing PrEP or interested in receiving more information. The overall objective is to educate providers on PrEP and recruit them to offer and prescribe PrEP.

Chapter 3 - Early Detection of Alzheimer's Disease in the Military Population

Introduction

Alzheimer's disease is the most common form of dementia. It is an irreversible and neurodegenerative disease. There are more than five million Americans living with Alzheimer's disease and by 2050 it is estimated that this number will rise to 16 million (Alzheimer's disease facts and figures.2017). According to the Alzheimer's Association, by the end of 2017, AD and other dementias will cost Americans 259 million dollars; it is estimated that these costs could rise as high as 1.1 trillion dollars by 2050. This makes it the most expensive disease in America and it cost more than heart disease and cancer (Alzheimer's disease facts and figures.2017).

From this rapidly increasing number of people being affected with AD, the aging military veterans are one of the populations most affected by it (Sibener et al., 2014). This is an important public health challenge and has become a priority for the military because of this the rapidly growing number of veterans be affected with AD and other dementias. The aging military population have been subjected to the same risk factors as the general population for AD and other dementias; but, evidence suggest that this population has potentially been subjected to additional risk factors compared to the general population. Therefore, it is believed that this population represents an elevated risk for AD and other dementias. Evidence suggest that some of the potential military risk factors include exposure to: a traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), chemicals, such as pesticides, and lifestyle, such as depression that all eventually trigger the development of neurodegenerative diseases such as AD. Therefore, understanding this potential association has become a priority for the military since evidence show that these are common military risk factors for AD and other neurogenerative diseases (Khachaturian & Khachaturian, 2014).

The goal of our study was to use existing statistical classifications methods to be able to detect AD at an early stage. In order to detect AD at an early stage, we needed to identify the most important biomarkers for the military population. The statistical methods used for this study were Su and Liu's combination methods based on AUC

(area under the curve) and the stepwise method proposed by Kang et al (Kang, Liu, & Tian, 2016). The overall goal was to improve the classification rate of these biomarkers.

The biomarkers considered for this study were the following: Mini-Mental State Exam (MMSE), the volume of hippocampus, the apolipoprotein gene (APOE ϵ 4), TBI, and PTSD. Evidence indicate that these biomarkers are strong indicators of early stages of AD. The MMSE consist of a 30-point questionnaire and it is recommended for primary care physicians to use when evaluating older patients for cognitive impairments. It is used to estimate the progression of a cognitive impairment but it can have a low sensitivity when distinguishing between normal and mild cognitive impairment (MCI) (Trzepacz, Hochstetler, Wang, Walker, & Saykin, 2015). Additionally, loss of tissue throughout the brain and decreasing hippocampal volumes are characteristics associated with AD. Studies have shown that short-term memory loss results from the shrinkage of the hippocampus (Mu & Gage, 2011). Correspondingly, APOE ϵ 4 is known to be a risk-factor gene since evidence show that it increases a person's risk of developing AD (Alzheimer's disease facts and figures.2017; Petersen et al., 2010). Furthermore, an association of TBI with dementia has be found in studies involving the veteran and nonveteran populations. TBI consist of any injuring to the head from any external force. Also, the National Patient Care Database found that those individuals diagnosed with PTSD are twice more likely to develop dementia. Unlike TBI, PTSD is a psychological condition developed from the failure to recover from a distressing event (Weiner et al., 2013).

DOD ADNI Description

For this project, data were obtained from the Department of Defense (DOD) Alzheimer's Disease Neuroimaging Initiative (ADNI). ADNI was launched in 2003 and it is a longitudinal study that evaluates a range of biomarkers that could be used to measure the progression of AD (Jedynak et al., 2012). Some of these biomarkers include brain metrics derived from magnetic resonance imaging (MRI) and positron emission tomography (PET) scans, and blood, cerebrospinal fluid, and other biological markers (Braskie & Thompson, 2014). The ADNI study consists of three phases: ADNI1, ADNI GO and ADNI2. New participants were added with each phase, but some were carried on from the previous phase to the new phase.

For our classification analysis, this project consisted of four biomarker profiles and each profile included the following three biomarkers: MMSE based on a scale of 24-30; APOE ϵ 4 based on the number of genes; hippocampal volumes measured with MRI. The second profile consisted of the three biomarkers in combination with TBI which was based on the number of TBI's encountered during service. The third profile included the three biomarkers in combination with PTSD which was based on the Current Clinician Administered PTSD scale score. The final profile consisted of all five biomarkers combined. When the biomarkers were combined some of the data was lost. Table 3.1 consists of a more detailed statistical description of the data.

<i>Biomarkers</i>	<i>Sample size</i>	<i>Mean</i>	<i>Standard Deviation</i>	<i>Missing Data Rates</i>
<i>MMSE (scale 24-30)</i>	441	28.84	1.38	7.03%
<i>Hippocampal Volumes (MRI scans)</i>	411	7251.08	987.29	0.24%
<i>APOE ϵ4 (number of genes)</i>	440	0.35	0.55	6.79%
<i>TBI (numbers encountered during service)</i>	69	1.64	1.64	83.25%
<i>PTSD (scale)</i>	32	47.34	36.98	92.22%

Table 3.1 Statistical Description of Biomarkers at Baseline

Statistical Analysis

In classification studies, the area under the ROC curve (AUC) is the classification analysis typically used for biomarker selection and evaluation. A greater AUC indicates a stronger classifier, so the AUC for a strong classifier is closer to the value one than to zero. The AUC is the most prevalent diagnostic accuracy index used by many researchers when combining multiple biomarkers into a single score (Yin & Tian, 2014). In our project, the AUC was calculated for all five biomarkers (MMSE, hippocampus, APOE ϵ 4, TBI, and PTSD) using two different methods. The combination of these biomarkers was performed to obtain sufficient information for more accurate disease diagnosis. The biomarkers MMSE, APOE ϵ 4, and the hippocampal volumes were the three biomarkers used for every profile. The methods were performed by using real data from the DOD ADNI for all those individuals that were classified as normal at baseline. Then these individuals were either classified as healthy (N_h) or diseased (N_d) if during

any follow-ups they were diagnosed with AD. The following were the two methods used to calculate the AUC for each profile:

- Method 1: Su and Liu’s combination based on AUC (Kang et al., 2016)
 - This approach consists of a linear combination under the multivariate normality assumption. Under the assumption of normality, a large sample size is required for optimal results.
- Method 2: Stepwise method proposed by Kang et al (Kang et al., 2016)
 - This is a nonparametric approach that maximizes the AUC by linearly combining markers by using a ‘distribution-free’ stepwise approach.

We considered four biomarker profiles for the classification analyses. All the analyses were performed using R packages.

Results

All biomarker profiles consisted of a high AUC using both methods. Comparing both methods (Su and Lui’s combination methods based on AUC and the stepwise method), the AUC were similar for all four biomarker profiles. The three biomarkers (MMSE, APOE ε4, and hippocampal volumes), TBI, and PTSD combined consisted of the highest AUC results compared to all the other profiles. The profile with the three biomarkers combined with the PTSD biomarker had the lowest AUC compared to all the other biomarkers. The three biomarkers combined with TBI had similar results compared to the profile with the three biomarkers alone.

	3 Biomarkers	3 Biomarkers + TBI	3 Biomarkers + PTSD	3 Biomarkers+ TBI + PTSD
	N _h = 375	N _h = 57	N _h = 26	N _h = 12
	N _d = 37	N _d = 6	N _d = 5	N _d = 2
	AUC			
Method-1	0.8888	0.8567	0.8000	0.9583
Method-2	0.8509	0.8567	0.8000	1.0000

Table 3.2 The AUC of Various Biomarker Profiles using Two Classification Methods

Discussion

The results reveal that TBI is a stronger biomarker compared to PTSD. When PTSD was included in combination with MMSE, APOE ϵ 4, and hippocampal volumes the AUC values decreased compared to when PTSD was not included. When TBI was included with the other three biomarkers the AUC was high using both methods. This is an indicator that TBI is a stronger biomarker compared to PTSD. The three biomarkers, TBI and PTSD, combined with MMSE, APOE ϵ 4 and the hippocampal volumes had an exceptionally high AUC. This indicates that the combination of all biomarkers are strong indicators of AD. In this combination, the AUC reached up to 1 using method-2.

However, the sample size in this study was a crucial limitation encountered, since a large portion of the data was missing, specifically data for TBI and PTSD. This could have potential affected the AUC since one of the methods used is approached under the assumptions of normality.

Furthermore, the three biomarkers (MMSE, APOE ϵ 4, and hippocampal volumes) alone were also strong biomarkers for AD. This shows consistency with numerous literature reviews since these three biomarkers are frequently being used for the detection of AD in the general population (Alzheimer's disease genetics fact sheet.2017; Mu & Gage, 2011; Trzepacz et al., 2015).In addition to these biomarkers, covariates such as age and history of TBI could have enhanced the performance of these statistical methods. In conclusion, having had a larger sample may improve the performance of these statistical methods. A possible way to overcome this limitation is by adapting existing imputations methods which can be used to input the missing values in our data. In a future study, this may allow us to re-evaluate the biomarkers of TBI and PTSD.

Chapter 4 - Master of Public Health Core Competencies

The following core competencies were obtained and practiced for the completion of this report.

Epidemiology- Introduction to epidemiology course clarified the terminology used at KDHE. For example, understanding incidence and prevalence of HIV in Kansas. This was useful since the overall goal for the implementation of PrEP is to reduce the incidence of HIV in Kansas.

Environmental Health- This core competency introduced me to how social economics and poverty can play a role in the health of a community. Working with the DIS and creating educational materials for consumers evolved in having knowledge on the importance of these factors. For example, when creating educational materials for consumers, we had to determine those at high-risk and how to reach them.

Fundamental Methods of Biostatistics- Fundamental understanding of biostatistics was essential for the completion of the capstone project. The project consisted of knowing how to interpret the AD data and being able to discuss interpretations with my major professor. It also consisted of cleaning the data using SAS and having data management skills.

Administration of Health Care Organizations- This course involved apprehending the general policies of health insurances in America. Knowing how to pay for PrEP and educating consumers on how to pay for PrEP was needed for the implementation of PrEP. This consisted of finding resources for those individuals who have health insurance and those without health insurance.

Social and Behavioral Bases of Public Health- This competency was practiced in the implementation of PrEP. We looked at patterns of transmission in Kansas and risk factors for HIV. We will be implementing PrEP in Wichita, Topeka, Lawrence, Manhattan, and Junction City since these are the areas with higher numbers of reported HIV cases.

Chapter 5 - Conclusion

My field experience at KDHE and my capstone project granted me the opportunity to adapt my education to real world experiences. For my capstone project, I had the opportunity to work with real data. This consisted of having permission granted to use the data from the ADNI committee of researchers. Furthermore, this project consisted of implementing data management knowledge, such as modifying and cleaning the data using SAS. This also included implementing statistical knowledge to analyze the data. The final step consisted of interpreting the results and identify the connotation of these results.

Additionally, my field experience at KDHE helped me develop professional skills and activities practiced in state agencies. For example, I had to understand legal issues when asking for approval to add PrEP to the KDHE website. The website had to be approved by the director of the bureau, the IT department, and from the Secretary of State. At KDHE, I also had the opportunity to develop professional relationships with others at the Bureau. For example, the information for the educational materials for consumers enhanced after interacting with the DIS and asking for their opinions, since they are constantly working with individuals at high-risk of HIV. Overall, this interaction assisted in understanding certain health behaviors and what factors might influence those behaviors.

Furthermore, as a public health professional, I encountered the significance of understanding health care insurances, such as Medicare. Having encountered this information during the Administration of Health Care Organizations course allowed me fully understand the assistance programs offered for patients with or without health insurance on how to pay for PrEP. Finally, within this field experience I learned to appreciate the significance of applying epidemiological principles to this project. Reviewing the epidemiology of HIV in Kansas granted me the opportunity to view the potential impact PrEP can have in decreasing the incidence for HIV in Kansas.

In conclusion, my field experience and capstone project consisted of understanding the importance of applying knowledge gained within the program and applying it to the real-world experiences and work. Having this hands-on experience

helped me reassure that I chose the right career and I look forward to contributing in improving the health of others.

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Appendix

Appendix A: PrEP Brochure for Patients

**HAVE CONTROL
AND INFORM
YOURSELF!**

**WHERE TO FIND
MORE
INFORMATION**

<https://www.cdc.gov/hiv/risk/prep/>
<http://www.projectinform.org/prep/>

FAQs

How often will I be tested for HIV?

You will be tested at least every 3 months when taking PrEP.

Does PrEP protect me against all STIs?

No, PrEP is only an anti-HIV medication.

Is there a difference between PEP (Post-exposure prophylaxis) and PrEP (Pre-exposure prophylaxis)?

Yes, PEP is used for when you have been exposed to HIV. This antiretroviral therapy should be started within 72 hours of being exposed to the virus.

**IS PREP
RIGHT FOR
YOU?**

Worried that you may become HIV-Positive?

It is time to take control!





WHAT IS PREP?

PrEP stands for pre-exposure prophylaxis. It is an HIV prevention tool that helps reduce the risk of getting HIV. PrEP is recommended for those who are HIV-negative and are at high risk of acquiring HIV. PrEP needs to be taken daily in order to reduce the risk of becoming infected with the virus. It can protect against HIV by retaining and stopping the spread of the virus throughout the body. It is most effective when consistently taken. For this reason, it is important to take the pill daily.

"WHEN TAKEN CONSISTENTLY, PREP HAS BEEN SHOWN TO REDUCE THE RISK OF HIV INFECTION IN PEOPLE WHO ARE AT HIGH RISK BY UP TO 92%"

-CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

PrEP is even more effective when combined with other preventive tools, such as condoms. PrEP is not a vaccine, but a pill that needs to be taken daily. For full effectiveness, it needs to be taken every day.



WHO SHOULD CONSIDER PREP?

PrEP is considered a good option if you are HIV-negative and:

- Those with an HIV-positive partner
- Partners HIV status is unknown
- Not in a mutually monogamous relationship
- Those who do not consistently use condoms
- Gay or bisexual man who have had anal sex without a condom
- Use injection drugs
- Those who have had an STI within the past 6 months

IS IT SAFE?

PrEP is known to be safe and no severe side effects have been detected. Most side effects are mild and usually go away within the first month. The following are some of the common side effects:

- Upset stomach
- Mild nausea
- Mild headaches
- Loss of appetite

HOW DO I GET STARTED?

Mention PrEP to your healthcare provider. Have an honest discussion about your sexual activities with your provider and he/she will determine if PrEP is the right decision for you. If so, an HIV test will be required before starting PrEP. Your provider may suggest a general physical and may test for other STIs. It is also important to routinely follow-up with your provider for HIV testing.



HOW DO I PAY FOR PREP?

Talk to your medical provider on how to pay for PrEP. Many health insurance programs cover PrEP. The following are medication assistance programs that may help pay for PrEP:

- MAP for TRUVADA
- Gilead Co-pay Program
- Patient Access Network Foundation
- Patient Advocacy Foundation

Appendix B: PrEP Brochure for Providers

Do Health Insurance Programs Cover PrEP?

Yes, many health insurance programs cover PrEP. The following are medication assistance programs that may help pay for PrEP:

- MAP for Truvada
- Gilead Co-pay Program
- Patient Access Network Foundation
- Patient Advocacy Foundation

As A Provider, What Are Some Of My Duties When Prescribing PrEP?

It is necessary to educate the patient about the medication and how to conduct safe sexual practices. Also, monitor the patient to detect if any infection is present. It is recommended to have them tested for HIV every 3 months when he/she is on PrEP. Finally, clarify that it is a prevention tool that has 92% effectiveness when taken properly and combined with condoms, but there are still some risks.

What Lab Tests/Evaluation Is Needed?

- Confirmed negative HIV-1 test
- HBV screening test
- Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or HBV medications
- Evaluated risk/benefit for women who may be pregnant or may want to become pregnant

CONTACT US

STI/HIV Prevention Program
Phone: (785)296-6174
Website: PrEP Link



Information adapted from:
US Public Health Service
PREEXPOSURE PROPHYLAXIS
FOR THE PREVENTION OF HIV
INFECTION IN THE UNITED
STATES - 2014
A CLINICAL PRACTICE GUIDELINE

PrEP

Information for
healthcare
providers



What is PrEP?

Pre-exposure Prophylaxis (PrEP) is an HIV prevention tool for those who are at high risk of HIV acquisition. Truvada is an oral antiretroviral medication for PrEP that helps reduce the risk of getting HIV by 92% when used as prescribed. It is a fixed-dose combination of 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate which is used to treat HIV-1 infection. In 2012, the U.S. Food and Drug Administration (FDA) approved the use of Truvada for PrEP with the combination of safer sex practices as an HIV prevention strategy. PrEP should only be used as a prevention tool since Truvada alone is not a complete treatment for those who are HIV-positive.



"Approximately 50,000 people in the United States are infected with HIV each year."

-Centers for Disease Control and Prevention (CDC)

Who Is A Good Candidate For PrEP?

PrEP is a good option for those who are HIV-negative and are people at high risk of acquiring HIV. The following are people considered to be at high risk:

- Those with an HIV-positive partner
- Partners HIV status is unknown
- Not in a mutually monogamous relationship
- Those who do not consistently use condoms
- Gay or bisexual man who have had anal sex without a condom
- Use injection drugs
- Those who have had an STI within the past 6 months

Side Effects

PrEP is known to be safe and no severe side effects have been detected. Most side effects are mild and usually go away within the first month. The following are some of the common side effects:

- Upset stomach
- Mild nausea
- Mild headaches
- Loss of appetite



Where Do I Start As A Medical Provider?



As part of primary care, start by taking a sexual history of all your patients who are sexually active or have been sexually active. Be open and do not allow the lack of sexual health discussions with your patients cause a life-time virus that could have possibly been prevented. Initiate the conversation before it is too late. Discomfort from both the provider and the patient are reasons why many times sexual history may be deferred. Stigma can be a big barrier when having sexual health discussions. The following are some tips:

- Start out with assuring confidentiality
- Make no assumptions about his or her sexual history
- State how you ask every patient the same questions



Appendix C: Sexual History Brochure for Providers

Five P's

The Five P's were developed by the Centers for Disease Control Prevention (CDC) to simply categorize sexual history questions.

- **Partners**
Never make assumptions about your patient's sexual orientation. Determine the number and gender of your patient's sex partners
- **Practices**
Ask about sexual practices and condom use to determine risk-reduction strategies if needed
- **Past History of STIs**
Ask about past STIs
- **Protection from STIs**
Suggest getting tested if the patient is at high risk
- **Pregnancy Plans**
Determine if pregnancy is desired or not

Resources for Providers

Webinars:

- **National LGBT Health Education Center**- "Taking a History of Sexual Health: Opening the Door to Effective HIV and STI prevention."
(AAFP Prescribed credit accepted by American Medical Association (AMA), American of Physician Assistants (AAPA), and National Commission on Certification of Physician Assistants (NCCPA))
- **National Medical Association**- "Sexual History Tool"
-by Dr. Madeline Sutton



Why A Sexual History?

"Less than 40% of providers conduct sexual histories with patients and many do not receive formal sexual history training in school."

Information adapted from: LGBT Health Education Center
"Taking Routine Histories of Sexual Health: A System-Wide Approach for Health Centers" -2014

Why a Sexual History?

Sexual histories are conducted in order to learn about your patients' sexual health and behaviors. It should not be avoided, but should be necessary for the following reasons:

- Important part of patients overall health
- Greatly impacts their quality of life
- Essential for being able to provide high-quality and efficient care
- Your patients have entrusted you with their health



Conducting sexual histories grants you the opportunity to assess patients risk for STIs and HIV

When Should a Sexual History Be Taken?

- At patient's initial visit
- At routine preventive exams
- Any signs or symptoms of STIs



Benefits of a Sexual History

- Identify those who are at risk for STIs and HIV
 - Recognize good candidates for Pre-Exposure Prophylaxis (PrEP) or other preventive services
- Allows for risk-reduction counseling
 - Discuss behaviors that may lead to the risk of contracting an STI

Tips For Conducting a Sexual History

- Ensure confidentiality
- Don't assume your patient's sexual orientation or gender identity
- Ask open-ended questions
- Don't show any type of judgmental reaction
- Respect patient's pronoun preference
- Explain that you ask these questions to all your patients



"Ironically, it may require greater intimacy to discuss sex than to engage in it."

The Hidden Epidemic
Institute of Medicine, 1997



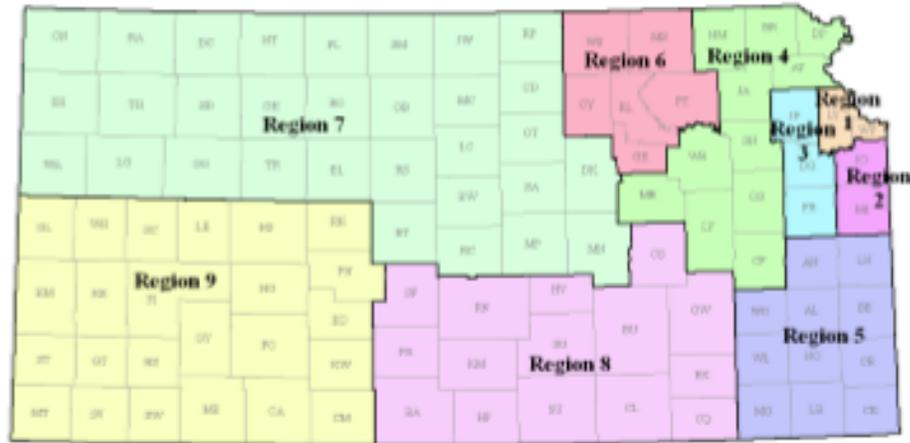
Provider Barriers

- High levels of discomfort when introducing the subject
- Time constraints or concerns about reimbursement
- Lack of sexual health training
- Lack of professional resources
- Personal factors (gender and age)
- Limited communication skills
- Lack of counseling or misconceptions

Patient Barriers

- Reluctance due to embarrassment
- Age or gender of provider
- Cultural or religious differences

HIV/AIDS Community Planning Regions



Published by:
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Data Source:
Kansas Geographic Dataset
Kansas HIV/AIDS Surveillance Program

Disclaimer: The purpose of this publication is to illustrate the status of the HIV/AIDS systems under a state of Kansas. This may present a general overview of information as implied or expressed, accuracy of accuracy for use may be beyond these purposes. The organization assumes no responsibility for publication or use of the product for purposes other than those expressed. This product may be corrected or updated as necessary without prior notification.

Linkage to Care Coordinator (LTC) Positions State Coverage

Vacant
1000 SW Jackson, Suite 210
Topeka, Kansas 66612-1274

Regions 3, 4, 5, 6, and 7

Kelly Jobe
130 S Market Suite 6050
Wichita, KS 67202
316-213-2309
Kelly.Jobe@ks.gov

Regions 8 and 9

Kansas City Free Health Clinic
3515 Broadway
Kansas City, Mo 64111
816-990-2411

Regions 1 and 2 *

* This is informational only as these regions are independent of KDHE/BEDP/HIV/AIDS/ policies and procedures.

Appendix E: Paying for PrEP Brochure

Resources

To apply for health insurance on the federal exchange: www.healthcare.gov

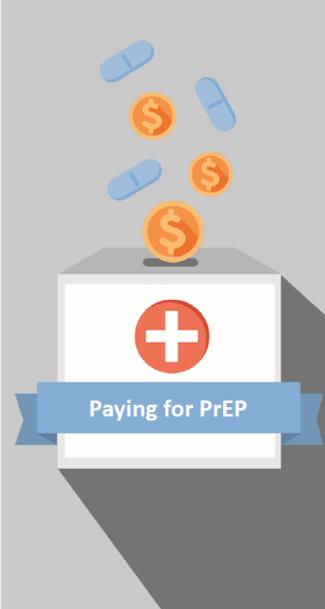
Community Health Center Locator: <http://findahealthcenter.hrsa.gov/>

Washington state (residents):
PrEP drug assistance program (PrEP-DAP)
<http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP>

New York state (residents):
PrEP assistance program (PrEP-AP)
 Call 1-800-542-2437

Gilead Sciences:
Medication Assistance Program and Co-Pay Assistance
<https://start.truvada.com/individual/truvadaprep-copay>

Patient Advocate (PAF) Foundation:
Co-Pay Relief Program
<https://www.copays.org/diseases/hiv-aids-and-prevention>



**Division of HIV/AIDS Prevention,
 National Center for HIV/AIDS,
 Viral Hepatitis, STD, and TB Prevention**

Centers for Disease Control and Prevention
 1600 Clifton Road
 Atlanta, GA 30329-4027 USA
 Phone: 800-232-4636

December 2015



Centers for Disease Control and Prevention
 National Center for HIV/AIDS,
 Viral Hepatitis, STD, and TB Prevention

Covering the Cost of PrEP Care

Insured

Not insured
But may be eligible for
Medicaid or ACA Plans

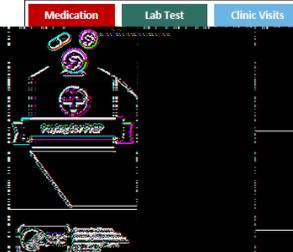
Not eligible for Medicaid
or ACA plans
OR
Insurance denies claim

Medication

Lab Test

Clinic Visits

Apply



Category	Details
Applying for coverage	Apply for coverage through Medicaid or ACA
ACA - Affordable Care Act	ACA - Affordable Care Act ACA - Affordable Care Act ACA - Affordable Care Act
Eligibility	Eligible to be covered by Medicaid or ACA
Co-payment	Partial percentage of costs may not be paid by Medicaid or ACA
Deductible	Amount of health care cost (including prescription) that must be paid by the insured person before insurance begins to cover costs

PrEP Medication Assistance Program (Gilead Sciences)

People eligible for this program must:

- Be 18 years of age or older
- Be without insurance or have payment of such denied
- Be a resident in the US (either currently or in the last 12 months)
- Have family income at or below the federal poverty level

Once enrolled in this program:

- Medication will be sent to the provider at patient's home
- Patients can get their medication at no cost when on pharmacy for as long as they are eligible
- Eligibility must be confirmed every 6 months

Appendix F: CDC PrEP Posters

THIS LITTLE PILL IS
**CHANGING THE
HIV CONVERSATION**

PrEP (Pre-Exposure Prophylaxis) is an HIV prevention pill. When taken daily, it can greatly reduce your risk of getting HIV.

There are more HIV prevention options than ever before. Talk to your doctor about which options are right for you.

**Start Talking.
Stop HIV.**

cdc.gov/StartTalking
/ActAgainstAIDS
/StartTalkingHIV
@TalkHIV

CDC ACT AGAINST AIDS

TALK PrEP

PrEP is an HIV prevention option. When taken daily it can greatly reduce your risk of getting HIV. You can protect yourself even more if you use condoms and other prevention tools.

**Start Talking.
Stop HIV.**

There are more HIV prevention options than ever before. Learn more about PrEP to decide if it is right for you.

cdc.gov/StartTalking
/ActAgainstAIDS
/StartTalkingHIV
@TalkHIV

CDC ACT AGAINST AIDS

TALK PrEP

PrEP is an HIV prevention option. When taken daily it can greatly reduce your risk of getting HIV. You can protect yourself even more if you use condoms and other prevention tools.

**Start Talking.
Stop HIV.**

There are more HIV prevention options than ever before. Learn more about PrEP to decide if it is right for you.

cdc.gov/StartTalking
/ActAgainstAIDS
/StartTalkingHIV
@TalkHIV

CDC ACT AGAINST AIDS

Truvada Medication Information Sheet

Truvada Medication Information Sheet for Patients

Brand name: Truvada (tru va duh)

Generic name: tenofovir disoproxil fumarate and emtricitabine

Why is this medication prescribed?

- Truvada is one of several medications that are currently used to treat human immunodeficiency virus (HIV) and hepatitis B virus infection.
- Truvada is now being used to *prevent* HIV infection.
- Truvada is sometimes prescribed to some people who do not have HIV infection (for example, those who do not always use condoms or who have a sex partner that has HIV infection) to help reduce their chances of getting HIV infection
- When you take Truvada to prevent HIV infection, doctors refer to this use as “pre-exposure prophylaxis” or “PrEP”.

How does Truvada (PrEP) help prevent HIV infection?

- HIV is a virus that attacks your body’s immune cells (the cells that work to fight infections).
- The 2 medications that make up Truvada (tenofovir and emtricitabine) block important pathways that viruses use to set up infection.
- If you take Truvada as PrEP daily, the presence of the medication in your bloodstream can sometimes stop the virus from establishing itself and slow the spread of HIV in your body.
- By itself, PrEP with Truvada does not work all the time so you should also use condoms during sex for the most protection from HIV infection.

How should this medicine be used?

- You must take one tablet of Truvada by mouth every day .
- Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand.
- Do not stop taking Truvada without talking to your doctor. When your supply of Truvada starts to run low, contact your doctor or pharmacist to get more.
- You may be at higher risk of becoming infected with HIV if you miss doses or stop taking Truvada than if you take it every day.

What special precautions should I follow?

Before taking Truvada (tenofovir and emtricitabine) you must do the following:

- Tell your doctor and pharmacist if you are allergic to tenofovir, emtricitabine, or any other medications.
- Tell your doctor and pharmacist about all prescription and nonprescription medications, (vitamins, nutritional supplements, and herbal products) you are taking. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your doctor if you have or have ever had kidney or liver disease.
- Tell your doctor if you become pregnant or if you are breastfeeding

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Division of HIV/AIDS Prevention



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What special dietary instructions should I follow?

- Continue your normal diet unless your doctor tells you otherwise.

What should I do if I forget a dose?

- Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

You may experience the following side effects while taking Truvada:

- upset stomach
- headache
- vomiting
- loss of appetite

These side effects usually fade during the first month of taking Truvada for PrEP. Tell your doctor if any of these symptoms are severe or do not go away.

Truvada may cause other side effects. Some side effects can be serious. Call your doctor immediately if you have any unusual problems while taking this medication or if you have any of the following:

- fever or chills especially with
- sore throat, cough, rash or other signs of infection

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (at <http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

How should I store Truvada in my home?

- You should keep Truvada in the container it came in, tightly closed, and out of reach of children.
- You must store it at room temperature and away from excessive heat and moisture.
- Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

What should I do in case of emergency/overdose?

- In case of overdose, call your local poison control center at 1-800-222-1222. If the person has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

- Do not let anyone else take your medication.
- Ask your pharmacist if you have any questions about refilling your prescription.
- Write a list of all of your prescription and over-the-counter medicines, as well as any vitamins, minerals, or other dietary supplements that you take.
- Bring your medication list with you each time you visit a doctor or if you are admitted to a hospital. Keep it with you always in case of emergencies.

Hoja informativa sobre el medicamento Truvada

Hoja informativa para pacientes sobre el medicamento Truvada

Marca comercial: Truvada

Nombre genérico: fumarato de disoproxilo de tenofovir y emtricitabina

¿Por qué se receta este medicamento?

- Truvada es uno de varios medicamentos que se utilizan actualmente para tratar la infección por el virus de la inmunodeficiencia humana (VIH) y la infección viral de hepatitis B.
- Truvada también se está utilizando ahora para prevenir la infección por el VIH.
- A veces se les receta a algunas personas que no tienen la infección por el VIH (por ejemplo, a quienes no siempre usan condones o que tienen una pareja sexual infectada con ese virus) para ayudar a reducir sus probabilidades de contraerla.
- Cuando usted toma Truvada para prevenir la infección por el VIH, los médicos se refieren a este tratamiento como "profilaxis preposición" o "PrEP", por sus siglas en inglés.

¿De qué manera Truvada (PrEP) ayuda a prevenir la infección por el VIH?

- El VIH es un virus que ataca las células inmunitarias de su cuerpo (las células que luchan contra las infecciones).
- Los dos medicamentos que componen Truvada (tenofovir y emtricitabina) bloquean vías importantes que usan los virus para comenzar la infección.
- Si usted toma Truvada diariamente como PrEP, la presencia de los medicamentos en su torrente sanguíneo a veces puede impedir que el virus se establezca y hacer más lenta la propagación del VIH en su organismo.
- Por sí sola, la PrEP con Truvada no funciona todo el tiempo; por lo tanto, usted también debe utilizar condones cuando tenga relaciones sexuales para lograr una mayor protección contra la infección por el VIH.

¿Cómo se debe usar este medicamento?

- Usted debe tomar una pastilla de Truvada todos los días.
- Siga cuidadosamente las instrucciones de la etiqueta del medicamento y pídale a su médico o farmacéutico que le explique cualquier parte que no entienda.
- No deje de tomar Truvada sin consultar a su médico. Cuando su provisión de Truvada comience a acabarse, comuníquese con su médico o farmacéutico para obtener más.
- Si se salta dosis o deja de tomar Truvada, usted puede tener un riesgo más alto de infectarse con el VIH que si la toma todos los días.

¿Qué precauciones especiales debo tomar?

Antes de tomar Truvada (tenofovir y emtricitabina), usted debe hacer lo siguiente:

- Decirle a su médico y al farmacéutico si usted es alérgico al tenofovir, la emtricitabina o cualquier otro medicamento.
- Informar al médico y al farmacéutico acerca de todos los medicamentos recetados y no recetados, vitaminas, suplementos nutricionales y productos herbarios que esté tomando. Puede ser que su médico tenga que cambiar las dosis de sus medicamentos o hacerle un seguimiento cuidadoso sobre los efectos secundarios.
- Decirle a su médico si tiene o ha tenido alguna vez enfermedad de los riñones o del hígado.
- Avisarle al médico si queda embarazada o si está amamantando.

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Division of HIV/AIDS Prevention



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¿Qué directrices alimentarias especiales debo seguir?

- Continúe con su alimentación normal a menos que su médico le indique lo contrario.

¿Qué debo hacer si se me olvida tomar una dosis?

- Tómela tan pronto como se acuerde. Sin embargo, si ya casi es la hora de la dosis siguiente, no tome la dosis que olvidó y siga con el horario normal.
- No tome dos dosis para reponer la que olvidó tomar.

¿Qué efectos secundarios puede causar este medicamento?

Usted puede presentar los siguientes efectos secundarios mientras toma Truvada:

- Malestar estomacal
- Dolor de cabeza
- Vómitos
- Pérdida del apetito

Por lo general, estos efectos secundarios desaparecen durante el primer mes en que se toma Truvada para la PrEP. Dígale a su médico si alguno de estos síntomas es intenso o no se va.

Truvada puede causar otros efectos secundarios y algunos pueden ser graves. Llame a su médico inmediatamente si tiene cualquier problema inusual mientras toma este medicamento o si presenta lo siguiente:

- fiebre o escalofríos especialmente con
- dolor de garganta, tos, sarpullido u otros signos de infección.

Si presenta un efecto secundario grave, usted o su médico puede enviar un informe al programa de Notificación de Reacciones Adversas MedWatch de la Administración de Alimentos y Medicamentos (FDA) a través de la Internet (en <http://www.fda.gov/Safety/MedWatch>) o por teléfono (1-800-332-1088).

¿Cómo debo guardar Truvada en mi casa?

- Usted debe mantener Truvada en el envase original, cerrado herméticamente y lejos del alcance de los niños.
- Debe guardarlo a temperatura ambiente y donde no haya calor ni humedad excesivos.
- Deseche todo medicamento que esté vencido o que ya no sea necesario. Hable con su farmacéutico sobre la manera adecuada de desechar sus medicamentos.

¿Qué debo hacer en caso de una emergencia o sobredosis?

- En caso de una sobredosis, llame a su centro de control de intoxicaciones local al 1-800-222-1222. Si la persona se ha desmayado o no está respirando, llame al servicio de emergencias local al 911.

¿Qué otra información debo saber?

- No deje que nadie más tome su medicamento.
- Hágale a su farmacéutico cualquier pregunta que tenga acerca del surtido de su receta.
- Escriba una lista de todos los medicamentos —los recetados y los que se venden sin receta—, así como de todas las vitaminas, minerales u otros suplementos nutricionales que esté tomando.
- Lleve su lista de medicamentos cada vez que vaya al médico o si es hospitalizado. Manténgala con usted siempre en caso de emergencia.

Checklist for Prescribers:

Initiation of TRUVADA® for Pre-exposure Prophylaxis (PrEP)

Individual Label

Instructions: Complete checklist at each visit and file in individual's medical record.

I have completed the following prior to prescribing TRUVADA for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to start or is taking TRUVADA for a PrEP indication:

Lab Tests/Evaluation

- Completed high risk evaluation of uninfected individual
- Confirmed a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication
 - If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposure is suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. (Note: TRUVADA for a PrEP indication is contraindicated in individuals with unknown HIV-1 status or who are HIV-1 positive)
- Performed HBV screening test
- Confirmed estimated creatinine clearance (CrCl) >60 mL/min prior to initiation and periodically during treatment. In patients at risk for renal dysfunction, assess estimated CrCl, serum phosphorus, urine glucose, and urine protein before initiation of TRUVADA and periodically while TRUVADA is being used. If a decrease in estimated CrCl is observed in uninfected individuals while using TRUVADA for a PrEP indication, evaluate potential causes and reassess potential risks and benefits of continued use
- Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or HBV medications
- Evaluated risk/benefit for women who may be pregnant or may want to become pregnant

Counseling/Follow-up

- Discussed known safety risks with use of TRUVADA for a PrEP indication
- Counseled on the importance of scheduled follow-up every 2 to 3 months, including regular HIV-1 screening tests (at least every 3 months), while taking TRUVADA for a PrEP indication to reconfirm HIV-1–negative status
- Discussed the importance of discontinuing TRUVADA for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants
- Counseled on the importance of adherence to daily dosing schedule
- Counseled that TRUVADA for a PrEP indication should be used only as part of a comprehensive prevention strategy
- Educated on practicing safer sex consistently and using condoms correctly
- Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)
- Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission
- Offered HBV vaccination as appropriate
- Provided education on where information about TRUVADA for a PrEP indication can be accessed
- Discussed potential adverse reactions
- Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk

Truvada
emtricitabine-tenofovir disoproxil fumarate

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Safety Information Fact Sheet for Prescribers About TRUVADA® for a Pre-exposure Prophylaxis (PrEP) Indication

TRUVADA (emtricitabine/tenofovir disoproxil fumarate) is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples.

BOXED WARNING SPECIFIC FOR USING TRUVADA FOR A PrEP INDICATION:

TRUVADA used for a PrEP indication must only be prescribed to individuals confirmed to be HIV-1 negative immediately prior to initiating and periodically (at least every 3 months) during use. Drug-resistant HIV-1 variants have been identified with the use of TRUVADA for a PrEP indication following undetected acute HIV-1 infection. Do not initiate TRUVADA for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed.

Key Safety Information to Communicate Regarding the Use of TRUVADA for a PrEP Indication:

1. Risk of Development of Drug-Resistant HIV-1 Variants in Undiagnosed HIV-1–Infected Individuals

- HIV-1 variants with resistance have emerged in individuals taking TRUVADA for a PrEP indication with undetected acute HIV-1 infection
- You must confirm a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication. If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting TRUVADA for a PrEP indication for at least 1 month and reconfirm HIV-1 status or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection
- Screen for HIV-1 infection at least once every 3 months while taking TRUVADA for a PrEP indication. If symptoms consistent with acute HIV-1 infection develop following a potential exposure event, PrEP should be discontinued until negative infection status is confirmed using a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection
- TRUVADA for a PrEP indication is contraindicated in individuals with unknown or HIV-1–positive status
- Do not prescribe TRUVADA for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed

– HIV-1–infected patients must take TRUVADA in combination with other antiretroviral agents to fully suppress virus replication and avoid the development of resistance

2. Only Use TRUVADA for a PrEP Indication as Part of a Comprehensive Prevention Strategy

- TRUVADA for a PrEP indication does not replace other HIV-1 infection prevention measures, including safer sex practices and correct and consistent condom use
- Clinical trials included comprehensive prevention counseling, screening for and treatment of other sexually transmitted infections, and strong emphasis regarding consistent use of condoms and other safer sex practices

3. The Importance of Strict Adherence to the Recommended Dosing Regimen

- The effectiveness of TRUVADA for a PrEP indication in reducing the risk of acquiring HIV-1 infection is strongly correlated with adherence and measurable drug levels
- All uninfected individuals at high risk taking TRUVADA for a PrEP indication must be counseled to strictly adhere to the recommended daily dosing schedule to reduce the risk of acquiring HIV-1 infection

For more information about TRUVADA and its indication for PrEP, please see the Prescribing Information, including the BOXED WARNING, and the Medication Guide. For more information about the REMS program for TRUVADA for a PrEP indication, please log on to www.TRUVADAprEP.com. You may also obtain additional information and educational materials about the use of TRUVADA for a PrEP indication at 1-800-445-3235.



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Truvada

emtricitabine-tenofovir disoproxil fumarate

Appendix J: Taking a Pill Everyday Brochure

Still Unsure?

If you have a concern or don't understand something, speak up. Ask your health care provider.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Division of HIV/AIDS Prevention,
National Center for HIV/AIDS,
Viral Hepatitis, STD and
TB Prevention

Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027 USA
Phone: 800-232-4636

Are you taking PrEP medication to stay HIV negative?

A Pill A Day Keeps HIV Away

Taking Daily Medication

Take Charge of Your Health

Taking your PrEP medicine is critical to keep from getting HIV. For PrEP to work, you need to have enough medicine in your body. When you miss doses, you make it harder for the medicine to protect you.

MON	TUE	WED	THURS	FRI	SAT	SUN
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X

Taking PrEP every day gives you the most protection.

MON	TUE	WED	THURS	FRI	SAT	SUN
				X	X	
				X	X	
				X	X	
				X	X	
				X	X	

Not taking PrEP every day greatly lowers your protection against HIV.

Is PrEP All You Need?

PrEP is one important tool for protecting yourself from HIV. No method offers 100% protection. While taking your PrEP medicine, you should also reduce your exposure to HIV by using:

- Condoms during sex
- Clean injection equipment if you inject drugs

Together, these methods offer more protection.

Is Taking a Pill Daily Tough? You Can Do It

- Do you forget to take your pills?
 - ⊗ Add an app to your phone that reminds you when it's time to take your pill
 - ⊗ Make it a part of your daily routine
 - * Take the pills at the same time each day
 - * Take your pill at the same time as another daily activity like brushing your teeth
 - ⊗ Plan to take pills with you when you won't be at home or are traveling
- Are you worried about possible side effects?
 - ⊗ Side effects are not common, if they happen:
 - * They are mild and do not last long
 - * Ask your doctor how to manage them
- Do you want help in taking your medicine?
 - ⊗ Talk to another PrEP user about what works for them
 - ⊗ Find a PrEP user support group or online forum
 - ⊗ Ask friends to remind & support you
 - ⊗ Find a community program that can assist you
 - ⊗ Use other services
 - * Pharmacists
 - * Social workers
- Are you worried about paying for your medicine?
 - ⊗ Ask your doctor to explain drug assistance programs that might help with payment
- Are problems with alcohol or other substances getting in the way?
 - ⊗ Talk to your doctor about treatment
 - ⊗ Use support groups and programs to stay on track
 - ⊗ Seek counseling to support your mental health

Medicines for Prevention

PrEP is the newest of many uses of medicine to prevent unwanted health outcomes

Birth control pills to prevent pregnancy

Flu shots before winter season each year

Using an inhaler before exercising to prevent asthma

PrEP to prevent HIV

Resources

My PrEP Experience Blog
<http://myprepexperience.blogspot.com>

CDC PrEP Patient Brochures
http://www.cdc.gov/hiv/pdf/risk_preep_TalkingtoDr.pdf

Appendix K: Kansas Notifiable Disease Form

KANSAS NOTIFIABLE DISEASE FORM

Today's Date: ___/___/___

Patient's Name: _____ <div style="display: flex; justify-content: space-around; font-size: small;"> Last First Middle </div>		
Day Phone: _____		Evening Phone: _____
Residential Address: _____		
City: _____	Zip: _____	County: _____
Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown		
Race: <i>(Check all that apply)</i>		
<input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American		
<input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown		
Sex: <input type="checkbox"/> M <input type="checkbox"/> F	Date of Birth: ___/___/___	Age if DOB unknown: _____
Is Patient Pregnant? (Females Only) <input type="checkbox"/> Yes <input type="checkbox"/> No		
Disease Name: _____		
Symptoms: Onset: ___/___/___ List the 3 most prominent symptoms:		
Symptom 1: _____ Symptom 2: _____ Symptom 3: _____		
Outbreak associated? <input type="checkbox"/> Y <input type="checkbox"/> N Died? <input type="checkbox"/> Y <input type="checkbox"/> N Hospitalized? <input type="checkbox"/> Y <input type="checkbox"/> N		
Institutional Residence? <input type="checkbox"/> None <input type="checkbox"/> Nursing Home <input type="checkbox"/> Correctional <input type="checkbox"/> Residential <input type="checkbox"/> Hospital <input type="checkbox"/> Psych		
Physician Name: _____		Physician Phone: _____
Laboratory Information:		
Specimen Collection Date: ___/___/___		Date Reported To You: ___/___/___
Name of Test Performed: _____		Results of Test: _____
Name of Laboratory: _____		Laboratory Results Attached? <input type="checkbox"/> Y <input type="checkbox"/> N
Treatment Information:		
Date of Treatment: ___/___/___		Treatment Type and Dosage: _____
Treatment Status: <input type="checkbox"/> Complete <input type="checkbox"/> On-going <input type="checkbox"/> Discontinued		

Name of person reporting: _____ **Phone:** _____

Comments: _____

Mail or fax reports to your local health department and/or to:
 KDHE Bureau of Epidemiology and Public Health Informatics, 1000 SW Jackson, Suite 210, Topeka, KS 66612-1274
Fax: 877-427-7318 (toll-free) Epidemiology Hotline: [877-427-7317](tel:877-427-7317) *(Revised 05/2011)*

Appendix L: Disease Intervention Specialist (DIS) Assignment Areas

