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Pilot Program to Provide HIV PEP to Sexual Assault Survivors

By

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Thesis Summary

This senior thesis focuses on sexual assault, a crime that has become a pressing issue in America recently. Even here on USC’s campus, there are high rates of sexual assault/rape that affect students of all ages, ethnicities, and backgrounds. Organizations such as “It’s On Us” have been formed here on our campus in order to allow students to speak out against sexual violence. There have also been cases in which USC students walking home from campus or the Five Points area whom have been assaulted and raped in the past. This shows the predominance sexual assault has not only nationwide, but within the college area.

The aftermath of sexual violence can consist of a multitude of things. Survivors of rape can experience depression, post-traumatic stress, physical trauma, and infections. One of the infections that can be acquired through rape is Human Immunodeficiency Virus (HIV). HIV is a chronic virus in which the body can not get rid of on its own, but drugs can help the suppress the virus so that the host does not get more sick. HIV is transmitted through bodily fluids, meaning it can be transmitted via rape. If a survivor of rape is at high risk of contracting HIV, a prophylactic drug regimen can be taken within a certain time frame of the assault in order to prevent the transmission of the virus. The regimen is around 28 days and can cost a few thousand dollars if survivors are uninsured. This high cost can present a barrier to access of prophylaxis for survivors.

Many states are more developed in this area of prophylactic treatment, specifically New York and California. New York has clear guidelines that coincide with the Centers for Disease Control and Prevention (CDC) 2016 guidelines for prescription of HIV prophylactic treatment. This ensures that the state’s clinical decisions for survivors possibly exposed to HIV is sound. Also, New York includes sections on reimbursement for provided services in the event that a
survivor cannot pay for the medications. California is slightly more outdated than the CDC and New York recommendations in regards to their regimen; however, the state includes considerations for different populations such as pregnant women, children/adolescent survivors, etc.

Currently, South Carolina has no standardized guidelines for the prescription and financial obligations for HIV prophylactic treatment post sexual assault. With South Carolina’s high rates of sexual assault and HIV/AIDS, there should be implementation of a program to address these issues. In 2014, South Carolina Office of Victim Assistance (SOVA) contacted the USC Immunology Clinic along with Palmetto Health Richland hospital in order to implement a pilot program in order to provide funding for sexual assault survivors’ treatment preventing HIV. Much communication had to take place in order for all aspects of the process to work efficiently. Emergency departments first seeing sexual assault survivors had to ensure they referred the survivors to the clinics for follow up. Also, the clinics and emergency department had to submit paperwork to SOVA in a timely manner in order to be reimbursed for their services/medication.

This program ultimately helps to solve many issues around access to healthcare for those who may be unable to afford but are in need. This research focuses around implementing this program as solution for those survivors of sexual assault.
Background/Purpose

In South Carolina, sexual assault is a significant issue. Untreated survivors of sexual assault have the potential to contract multiple infectious diseases, such as HIV. Effective post-exposure prophylaxis (PEP) can prevent HIV transmission; however many survivors experience financial barriers to afford PEP, such as limited resources or limited/no health insurance. South Carolina has minimal measures set in place for sexual assault survivors who cannot afford PEP. Considering South Carolina’s high rates of sexual assault and HIV, this issue must be addressed.

Methods

State guidelines and policies for New York, California, and South Carolina were researched to compare current HIV PEP guidelines. Additional methods utilized included observation and interviews with key stakeholders.

Results

SOVA, the state agency providing help to sexual assault survivors, in cooperation with local hospitals and infectious disease providers, initiated a pilot program in 2014 to address PEP funding for sexual assault survivors. This program will ultimately help decrease incidences of HIV transmission via sexual assault.

Conclusion/Implications

Reducing HIV infections associated with sexual assault will improve quality of life statewide. Although HIV is no longer fatal, it remains a chronic illness that requires lifelong treatment. This pilot program reduces a major barrier to PEP and should achieve broad availability of PEP for survivors in need. The SOVA pilot program plans on seeing an initial 50 patients and then hopefully being expanded statewide.
The Problem: Sexual Violence

In February 2016, a female college student attending University of South Carolina in Columbia, SC was sexually assaulted at 3:15am. According to The State, the armed perpetrator forced the victim onto a street where he then assaulted her. The survivor made it back to her residence, where her roommates helped her to seek out help at a nearby hospital (Cahill, 2016).

In the United States, over the past two decades, female sexual assault incidences have actually declined. In 2005, the overall rate of sexual assault incidences against females 12 and older decreased by 64%, compared to the total cases reported in 1995. The rate of sexual assault against males was lower than against females, with male cases estimating at 0.1 per 1,000 people and female cases at 2.1 per 1,000 people in 2010 (Planty et al., 2013). Although these numbers reflect reduced sexual assault occurrences, sexual violence is still a predominant issue in the United States. Roughly 1 in 6 women and 1 in 33 men have been survivors of attempted/completed sexual assault in the United States (South Carolina Coalition, 2016).

Sexual violence does not discriminate against particular lifestyles, as shown by the case at the University of South Carolina campus. These crimes happen on college campuses, in rural areas, urban areas, and often, the survivor knows their perpetrator. In 2015, 5,152 survivors sought help/treatment in South Carolina, and 2,545 of these survivors reported assault by a friend, acquaintance, or family member (South Carolina Coalition, 2016). In the United States, every 3 in 1,000 females in rural areas are estimated to be survivors of sexual violence, compared to every 2.2 per 1,000 estimated female survivors in urban areas (Planty et al., 2013). This reflects the possibility of sexual violence occurring in some of the most unlikely circumstances.
Sexual assault is often used as an umbrella term, as it can include many situations such as molestation, victimizations, or rape. Rape is “the unlawful penetration of a person against the will of the victim” (Planty et al., 2013). This includes situations such as vaginal/oral/anal penetration of the survivor by the offender or penetration with a foreign object such as a bottle. On the other hand, sexual assault includes attempted attacks or attacks such as fondling, molestation, verbal harassment, or grabbing (Planty et al., 2013). Although these two terms are distinguishable, it can remain difficult to decipher what happened in the situation. This could be due to sexual assault survivors not remembering the encounter or not being willing to share.

Survivors of rape can experience a multitude of health complications. The Centers for Disease Control (CDC) outlines several health consequences of sexual violence, including contraction of Human Immunodeficiency Virus (HIV), sexually transmitted diseases (STIs), cervical cancer, and chronic pain. At least 32,000 pregnancies occur annually from rape. Moreover, the psychological response ranges from denial or anger to withdrawal or guilt (CDC, 2016).

In an effort to reduce these complications, healthcare systems work to assist in ensuring the individual’s safety after being sexually assaulted via rape. From running diagnostic tests, physical exams, and offering support, healthcare professionals look to promote recovery for a survivor of sexual assault. Sexual Assault Nurse Examiners (SANEs) are often one of first providers to see a survivor of sexual assault. These providers are Registered Nurses who have completed more training and become certified to assess sexual violence survivors. The SANE assesses the patient, and then collaborates with other members of the healthcare team, such as the ED physician or the OB/GYN for female survivors (International Association of Forensic
Nurses, 2015). The physician will determine the needs of the patient as far as any immediate medical concerns, prophylactic treatments, or therapy.

Unfortunately, the measures taken by hospitals and providers for sexual violence survivors vary. States are not mandated to have one common measure in place by the federal government. This presents further consequences for untreated survivors. Survivors of sexual assault are potentially at risk for many infections or diseases, one of which is Human Immunodeficiency Virus (Centers for Disease Control and Prevention, 2016).

**Human Immunodeficiency Virus**

Human Immunodeficiency Virus (HIV) weakens the body’s immune system. The virus attacks the body’s CD4 cells, which are a specialized type of White Blood Cell (WBC), cells that fight off infection. This immunosuppression makes it easier for those with HIV to contract other infections and illnesses. HIV is spread person-to-person through bodily fluids, such as blood, semen, vaginal fluids, or breast milk. Thus, HIV can be spread by unprotected anal or vaginal sex, sharing used needles, or mother-to-child during pregnancy or breastfeeding. While there is currently no cure for HIV, treatment options for patients include prescribed antiretrovirals, medications that suppress viral replication. If left untreated, HIV can become Acquired Immunodeficiency Syndrome (AIDS). AIDS is one of the latest stages of HIV. At this point, the disease has almost fully destroyed the host’s immune system. HIV progression can be slowed before becoming AIDS with proper treatment; however, it remain a challenging chronic disease (U.S. Department of Health and Human Services, 2015).

The CDC outlines specific risk factors for HIV transmission. The top three highest risk types of exposures are blood transfusions (9, 250 per 10, 000), receptive anal intercourse (138 per 10, 000), and needle sharing during injection drug use (63 per 10, 000). Lower exposure risks
recognized were needle sticks, insertive anal intercourse, and receptive/insertive penile-vaginal intercourse (CDC, 2016). Fortunately, HIV infection can be prevented with proper prophylactic treatment and strict adherence to treatment guidelines. Survivors determined to be at high-risk for contracting HIV can receive a medication regimen that helps prevent the contraction of HIV. HIV post-exposure prophylaxis (PEP) is known to reduce rates of HIV infections in high-risk situations (McDougal et al, 2014).

**PEP: The Solution**

Post-exposure prophylaxis (PEP) is defined as taking antiretroviral medications after a possible exposure to HIV, such as sexual assault or sharing needles, in order to prevent infection with HIV. According to the CDC guidelines, PEP must be started within the first 72 hours of exposure in order to be effective in prevention. This is due to the window of opportunity in which HIV replication is most likely prevented, typically between one hour and up to 48-72 hours after exposure. PEP is not guaranteed 100% effective, however, the quicker PEP is started, the better the likelihood of prevention. Patients usually take a specific antiretroviral therapy regimen for 28 days, followed by lab checkups for up to 6 months after completion (CDC, 2016). These labs continue to check for the presence of HIV after the preventative therapy.

PEP is divided into non-occupational PEP (nPEP) and occupational PEP (oPEP). nPEP is used in order to reduce the risk of HIV transmission in situations outside of the work place, such as unprotected sex, sharing needles, or contact with infected bodily fluids. oPEP, however, describes prevention of HIV through work-related exposures, such as accidental needle sticks or contact with blood. Although similar on a clinical level, the difference between nPEP and oPEP often lies in the aspect of payment. Where as oPEP is often covered by workers’ compensation,
nPEP is not (CDC, 2016). In other words, occupational exposures are likely to be addressed immediately whereas treatment of non-occupational exposures may be delayed due to financial implications.

The CDC most recently updated nPEP recommendations in 2016. In these updated guidelines, there is “additional evidence regarding use of non-occupational post-exposure prophylaxis (nPEP) from animal studies, human observational studies, and consideration of new antiretroviral medications that were approved since the 2005 guidelines” (CDC, 2016). Some of the additional features include updated medication regimens, use of rapid antigen-antibody HIV tests and a recommended 3-drug therapy. The guidelines suggest a standard 28-day regimen consisting of three drugs. The preferred 28-day therapy regimen for healthy adults and adolescents is tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg once daily plus raltegravir 400 mg twice daily or dolutegravir 50 mg daily (CDC, 2016). Medication recommendations are also included for those with kidney impairment, children/adolescents, and pregnant women. The CDC also discusses an individualized approach for cases where the HIV status of the source is unknown. In these cases, high-risk behaviors as well as situational criteria are investigated. These updates were made in effort to give providers nationwide a better idea of how to approach nPEP for those at risk of contracting HIV.

**New York’s nPEP**

Many states in the U.S. have standard practices for possible HIV exposure in sexual assault survivors. New York, for example, proves to be a developed state in this area. Last updated in October 2014, the HIV Clinical Resource, implemented by the New York State Department of Health AIDS Institute & Johns Hopkins University Division of Infectious Disease, designed a preferred program for HIV prophylaxis for sexual assault survivors (HIV
Clinical Resource, 2014). This plan includes the medication regimen necessary for assault survivors to prevent HIV. Furthermore, the guidelines include recommendations when considering the timing of post-exposure prophylaxis (PEP), the HIV status of the perpetrator, the role of the sexual assault examiner, circumstantial evidence, follow-up visits and testing, and payment methods (HIV Clinical Resource, 2014). New York’s detailed prophylaxis program could potentially serve as a model for other states as well. The following is an overview of the state of New York’s guidelines for HIV prevention post-sexual assault based on the HIV Clinical Resource.

The medication regimen set in New York’s guidelines is tenofovir 300 mg & emtricitabine 200 mg taken by mouth daily, along with either raltegravir 400 mg or dolutegravir 50 mg twice by mouth daily (HIV Clinical Resource, 2014). Changes can be made to these medications dependent on the patient’s current health status. This regimen is also used in diagnosed HIV patients on a daily basis for chronic treatment of HIV and prevention of AIDS (U.S. Department of Health and Human Services, 2015).

Hospitals in the state of New York are required to have the initial 7 days of medication on-site. This guarantees the start of prophylaxis within 2 hours of arrival to the ED for survivors who present to the hospital after sexual assault, falling in the preferred window of treatment commencement recommended by the CDC. If a survivor presents 36 hours or more after an assault, the clinician should thoroughly assess the patient and the projected effectiveness of beginning the regimen. Follow-up visits are to be scheduled in professional healthcare settings within 24 hours after the patient’s first dose to reevaluate the patient, answer questions, and reiterate the importance of medication adherence (HIV Clinical Resource, 2014). Survivors receiving PEP according to New York’s guidelines should be treated in a nothing less than a
professional healthcare setting (HIV Clinical Resource, 2014). This ensures all medical necessities and personnel needed are involved and available. This is an important recommendation considering in the wrong setting or with uneducated clinicians, PEP could be ineffective (HIV Clinical Resource, 2014).

In addition, the prescribing health professional should consider various aspects of the assault. Some circumstantial evidence could contribute to the necessity of PEP, for example, the likelihood of exposure from the assault. High-risk exposures are “direct contact of the vagina, penis, anus, or mouth with the semen, vaginal fluids, or blood of the alleged assailant” (HIV Clinical Resource, 2014). Other situational assault exposures, such as blood/semen contact with broken skin or mucous membranes, are considered risks that are more moderate but should still be offered PEP. According to the CDC, low-risk/negligible exposure include kissing, biting and spiting (CDC, 2016). In summary, according to the protocol, any possible contact with blood or semen from the assault is grounds for prophylactic treatment (HIV Clinical Resource, 2014).

Another consideration is the HIV status of the survivor’s perpetrator; although more often than not, the perpetrator’s HIV status cannot be easily determined. Survivors may attest to knowing their attacker and their HIV status, but this should have not influence the clinician’s course of treatment, although it may alter the survivor’s willingness to accept the treatment (HIV Clinical Resource, 2014). Due to the perpetrator’s status being largely unknown, treatment is started immediately in accordance with the circumstances of the assault, such as the route of the transmission and extent of assailant/survivor contact. However, PEP should be stopped, after patient consultation with the prescriber, if multiple HIV tests of the perpetrator return as negative (HIV Clinical Resource, 2014).
The New York guidelines also outline the payment/insurance coverage aspects of PEP. The treatment is covered through various insurances, from private plans to Medicaid/Medicare. A means of payment must be provided for the assault exam and the medication regimen, and coverage for uninsured survivors can be difficult and expensive. New York’s Office of Violence Services (OVS) helps to ensure patient’s access to PEP after the initial seven days so that the 28-day course can be completed. In the event that the survivor cannot afford to continue PEP, providers can apply for an “emergency award” through OVS. If OVS deems the care necessary, they will reimburse the provider for services for the survivor. This helps ensure that prophylaxis can be completed in recommended high-risk situations (HIV Clinical Resource, 2014).

With these guidelines, New York is effectively able to protect sexual assault survivors potentially exposed to HIV. Rates of HIV have decreased from 2005-present. Programs set in place by New York such as nPEP have likely contributed to this decline (New York State Health Department, 2012).

**California’s nPEP**

California is another state that has clear recommendations for HIV PEP after sexual assault. Prior to implementing a statewide PEP program, approximately 38% of counties in California did offer a PEP program similar to New York’s. However, as rates of sexual assault with potential HIV exposure increased, California determined that the entire state needed a proper protocol. Their guidelines, “Offering HIV Prophylaxis Following Sexual Assault,” are similar to New York’s guidelines, outlining the importance of the assault circumstances, HIV status of the perpetrator, the timing of PEP, and the medication regimen chosen (Myles & Bamberger, 2001).
In “Offering HIV Prophylaxis Following Sexual Assault,” California focuses on the circumstances of the assault situation, similarly to New York. Both states agree that determining the likelihood of transmission from perpetrator to survivor is important in determining the need for PEP thereafter. Unlike New York, however, California divides the risk of HIV transmission to the survivor into three categories based on the type of contact: “no risk (i.e. kissing, object penetration), possible risk (victim biting, oral penetration and ejaculation), and measurable risk (anal/vaginal penetration, contaminated needle injection)” (Myles & Bamberger, 2001, p. 11). Dependent upon the assessed risk category, PEP may or may not be indicated.

Another factor of California’s protocol is the assailant’s HIV status. California does not recommend PEP if the perpetrator is known HIV negative (Myles & Bamberger, p. 14). On the other hand, if the perpetrator is known HIV positive, PEP is then recommended/not recommended based on the risk of transmission category. If the circumstances of the assault indicate no risk of transmission, PEP is not recommended. If the survivor has a possible risk of transmission, the provider then looks at situational co-factors that may have been present, such as multiple assailants, presence of blood, presence of STDs, or ejaculation by the assailant (Myles & Bamberger, 2001). For a possible risk situation with one or more of these co-factors present, PEP would be encouraged. For a possible risk situation with none of these co-factors present, PEP would be offered but not recommended. For a measurable risk situation, such as vaginal/anal penetration, PEP would be recommended (Myles & Bamberger, 2001).

California’s “Offering HIV Prophylaxis Following Sexual Assault” additionally considers high-risk behaviors the assailant may have previously engaged in, including “drug use, homosexual men, multiple sex partners, known sex offenders, or those with a criminal history/incarceration” (Myles & Bamberger, 2001, p. 15). If known to be present, these
behaviors indicate a higher possibility that the assailant may be HIV positive (Myles & Bamberger, 2001).

The following table is included in California’s recommendations. It summarizes where PEP is recommended/offered/not indicated based on the risk category, situational co-factors, and the assailant’s high-risk factors. Situational co-factors investigated are number of assailants, presence of blood, STD status, or ejaculation, whereas the risk categories based on the type of contact that occurred (kissing, anal/vaginal penetration, or biting).

Adapted from “Offering HIV prophylaxis following sexual assault: Recommendations for the state of California” by Myles, J.E. & Bamberger, J., 2001, Housing and Urban Health of the San Francisco Department of Public Health, California HIV PEP after Sexual Assault Task Force, & The California State Office of AIDS, p. 16.

California’s protocol for initiation of PEP coincides with New York. The PEP guidelines state, “in no case should PEP be offered after 72 hours following the assault” (Myles &
Bamberger, 2001, p. 9). Also, optimal timing for initiation of PEP is within 1-2 hours of the possible transmission via assault (Myles & Bamberger, 2001). After the conduction of animal studies, PEP was shown to be ineffective after 72 hours of exposure and minimally effective even after 24-36 hours. For survivors seeking medical attention 72 hours post-assault, HIV-antibody testing and counseling is recommended, and if diagnostic tests are HIV-positive, consults to HIV specialists are initiated (Myles & Bamberger, 2001).

Unlike New York’s guidelines, California also includes some pediatric guidelines. California recommends that if the survivor is under the age of 12, a pediatric HIV specialist should be consulted for care. The parents of the child should also be consulted before the initiation of PEP (Myles & Bamberger, 2001). This helps to individualize care based on age indications.

Another difference between New York and California’s PEP guidelines are the medication regimens recommended. While New York’s regimen includes tenofovir, emtricitabine, and either raltegravir or dolutegravir, California recommends zidovudine 300 mg and lamivudine 150 mg twice daily for a total of 28 days. This difference in recommendations can be attributed to the timing of each state’s most recent updates. Where New York has recently updated their guidelines in 2014, California’s guidelines were written in 2001. California’s guidelines go on to emphasize that two-medication therapy “is acceptable because it is used to reduce the likelihood of transmission following exposure to HIV, not to treat established infection” (Myles & Bamberger, 2001, p. 18). Survivors initiating PEP should be thoroughly educated on medication adherence and side effects, as well as the schedule for follow-up testing (U.S. Department of Health and Human Services, 2015).
California’s recommendations also recognize the payment issue for PEP. Payment should not inhibit any survivor from obtaining these medications if indicated. There are state sources of payment, according to California, that can aid survivors in affording medication, such as the Victim Witness Program or county health departments (Myles & Bamberger, 2001). According to California’s guidelines, “the cost of PEP medications has prevented county rape treatment programs from prescribing HIV PEP medication in the past” (Myles & Bamberger, 2001, p. 21). This shows how affording medication proves to be a barrier in prescribing PEP, maybe not just in California, but nationwide.

South Carolina’s Situation

South Carolina healthcare lacks a statewide policy for treatment of individuals who experience non-occupational exposure to HIV. This is an immediate concern, considering South Carolina’s high rates of reported sexual assault, as well as high rates of sexually transmitted infections (STIs) and HIV. South Carolina’s Department of Health and Environmental Control (DHEC) outlines statistics on South Carolina’s rates of STIs and HIV/AIDS. As of 2015, South Carolina has 18,120 HIV cases. Many healthcare disparities exist among the HIV-positive population in South Carolina. For example, although African-Americans represent only approximately one third of South Carolina’s population, 67% of persons living with HIV in 2015 were African-Americans. Young adults were more prominent in HIV infections, with 38% of new HIV cases in 2015 occurring in individuals between the ages of 20-29 (South Carolina DHEC, 2015). Also, according to SC DHEC, South Carolina falls at #13 among the 50 states for highest number of AIDS cases. More specifically, compare to all U.S. Metropolitan areas, Columbia, SC ranks 11th in highest rates of AIDS. These STI/ HIV/AIDS statistics paired with the high rates of sexual assault in South Carolina pave the way for risk of HIV transmission.
Currently, South Carolina has no standardized state source of funding for sexual assault survivors in need of nPEP. This prevents many survivors from obtaining nPEP when indicated, possibly contributing to more HIV infections due to sexual assault. In past years, sexual assault survivors either had to have health insurance coverage or pay for nPEP medications out of pocket. The CDC recommends tenofovir and emtricitabine once daily plus either raltegravir or dolutegravir for HIV nPEP for 28 days. The estimated cost for this medication regimen out of pocket is between $3,300-$3,500 depending on the specific prescription (Panel on Antiretroviral Guidelines, 2017). This was a barrier for many uninsured survivors to HIV nPEP for whom it was indicated.

**SOVA’s Response**

South Carolina’s State Office of Victims Assistance (SOVA), a state funded entity involved in aiding survivors of violent crime, noticed these incongruities in South Carolina between sexual assault incidences and no access to nPEP. Gail Washington, a quality assurance manager at SOVA, explains that “our crime victims, who were sexually assaulted/raped and who presented to the ED with an expectation that medical assistance would be available, were instead met with unrealistic challenges” (personal communication, November 1, 2016). According to Washington, SOVA has been struggling for years to provide funding for survivors at risk for contracting HIV (personal communication, November 1, 2016). This was brought to the SOVA advisory board, prompting the organization to fund a pilot program for HIV non-occupational PEP in survivors 18 and older. Prior to the origins of this pilot program, SOVA’s Sexual Assault Program would occasionally retroactively reimburse survivors for costs associated with nPEP. Survivors who could not pay up front for the medications were often left with inadequate treatment. Washington states that with this emerging pilot program, “the service should be
standardized and should be provided at no cost to all survivors of sexual assault who meet the criteria for being ‘at risk’ for contracting HIV. The objective is to standardize the process for survivors and to provide the service free of charge (personal communication, November 1, 2016). One of the goals for this pilot program was to provide survivors financial access to nPEP when indicated. Funding from SOVA for uninsured patients or patients unable to afford nPEP sets the program apart. Participating clinical organizations are to follow guidelines recommended by the CDC regarding necessity of nPEP as well as the drugs prescribed, while SOVA provides payment.

Organizations such as Palmetto Health Richland Hospital and the Medical University of South Carolina (MUSC), observed these challenges with sexual assault and HIV transmission risk as an ongoing issue. Therefore, a committee was created in July 2012 with Palmetto Health, MUSC and SOVA representatives in order to address these issues and begin brainstorming the beginnings of the nPEP program. This committee included SOVA employees, ED physicians, hospital pharmacists, Sexual Assault Nurse Examiners (SANEs), laboratory specialists, clinic providers, clinic administration, and case managers. The committee met periodically for almost two years, creating standardized screening tools, protocols and algorithms for the program. Palmetto Health-University of South Carolina Infectious Disease (PH-USC ID) clinic providers and Medical University of South Carolina (MUSC) were chosen to host the pilot HIV PEP program for sexual assault survivors. In summer 2014, the first survivor was accepted into the program at PH-USC ID. One year later, MUSC accepted their first survivor. SOVA along with PH-USC ID and MUSC had to collaborate extensively in order for this program to be a success. Not only did both entities have to ensure that the program was clinically sound, but they also had to ensure the financial aspects were sound as well. SOVA representatives worked diligently to
affirm that uninsured survivors of sexual assault, if indicated for HIV nPEP, are financially supported by SOVA. Furthermore, the hospitals must communicate with SOVA when they have candidates for the program.

The Current Program Process

Similar to California and New York, the ED staff at the SOVA pilot sites follows specific guidelines in order to prescribe a patient nPEP. First, the ED nurse/physician determines whether or not a significant sexual exposure to potentially HIV infected fluid occurred (i.e. anal, oral, vaginal). As part of the general physical exam/testing, the survivor also receives fourth generation antigen-antibody testing to ensure he/she is not already previously infected with HIV. If not, nPEP is not recommended for this patient and no follow-up is indicated. If a significant exposure occurred, the timing of exposure is then determined. If the exposure was 72 hours ago or more, which is outside the recommended window for nPEP, nPEP is not prescribed but the patient will be encouraged to have follow-up HIV testing. If the patient presents within 72 hours of exposure, it is then determined if the source of exposure is available/consents to be tested. If the assailant is available, rapid HIV testing is done on the source, and if found to be positive, a 28 day regimen nPEP is prescribed for the patient. If the source is unavailable/does not consent to be tested, the ED personnel will use certain determinants to define the source as either high risk/not high risk. If the source is high risk or unknown/unsure, the 28 day regimen is prescribed for the patient. If the source is not high risk, nPEP is not recommended (CDC, 2016). Once prescribed, the patient will receive the first five days of medication from the ED pharmacy. Follow-up is conducted at the outpatient clinic.
The patient will then follow up in the PH-USC ID clinic for the next ten days’ worth of medication. Finally, after those ten days, the clinic will contact the patient and assess adherence to the regimen. The patient is then prescribed the last thirteen days of medication. This process helps ensure that the patients being distributed medication are adhering to the regimen, minimizing the distribution of expensive medication that may not be used. This also gives the patient time to consult with providers with any questions or concerns they may have with nPEP. Lab testing is then completed at the clinic at intervals of 6 weeks and 6 months after HIV nPEP is initiated (SOVA, 2016). This is to ensure that nPEP is effective and patients remain HIV negative.

These guidelines parallel those recommended by the CDC. If the source is later determined to be uninfected or the patient is found to already have HIV, nPEP can be discontinued (CDC, 2016). The CDC also states that after the initial 72 hour window post-exposure, nPEP is not suggested; rather, follow-up testing should be done to determine if HIV was transmitted. A case-by-case basis is also suggested, specifically if the assailant is unknown, relying on factors such as method of transmission, risk factors of the assailant, and number of assailants involved (CDC, 2016).

**Funding for nPEP**

Financially, the survivor is not responsible for any cost associated with nPEP after sexual assault in this pilot program. Follow up is needed not only in the clinical setting but also with SOVA as well in order for the ED/associated clinical settings to be reimbursed for their provided services to survivors. The clinics/ED must submit applications for the survivors presenting for treatment and qualifying for nPEP. Then, reimbursement decisions are made by SOVA. Rules
and regulations outlined by SOVA for reimbursement of medications and services include the following:

- "All patients in the HIV nPEP and Follow-Up program will have been a victim of sexual assault,
- The patient will have been identified as a ‘high-risk’ patient,
- The crime will have happened within 72 hours [prior to] the initial ED visit,
- The patient must visit the clinic within 5 to 7 days of the initial ED visit,
- The victim will have been referred by a SANE, FNE, or ER Physician,
- The victim was not confined in any correctional facility at the time of the crime,
- The crime happened in South Carolina,
- And all applications and billing statements will be submitted to SOVA within 30 days from the date of service”

(State Office of Victim Assistance, 2016).

Once hospitals submit the application, they are reimbursed for the prescription costs, follow-up treatment and other associated services provided (State Office of Victim Assistance, 2016).

Within SOVA, funding for overall care for the patient is split between two areas of SOVA. Washington explains “SOVA’s Sexual Assault Program covers the cost of nPEP treatment and SOVA’s Compensation Program covers the cost of the follow-up care, lab work and clinic visits” (personal communication, November 1, 2016). As far as law enforcement goes, the survivor of sexual assault has no obligation to report the crime in order to receive services. This is part of SOVA’s policy, and EDs/clinics will still be reimbursed for services regardless of law enforcement involvement.

**Nursing Role Considerations: The SANE**
One of the key personnel in caring for sexual assault survivors and nPEP initiation is the Sexual Assault Nurse Examiner (SANE). SANEs are the first provider to assess survivors in the ED and ultimately provide the patient with pertinent information alongside the primary provider. Gina Dyer-Goss is one of the main SANEs involved in the SOVA pilot program. She has been a SANE at Palmetto Health Richland hospital for 10 years. After receiving a bachelor’s in criminal justice then going back for her nursing degree, Dyer-Goss decided that she wanted more of a one on one, personal experience with patients.

SANE certification includes many aspects more than just nursing. During training, SANEs must go through didactic courses as well as meet with law enforcement, judicial systems, and forensic teams. This ensures that SANEs are prepared to deal with all facets of a sexual assault rather than just nursing care. These types of nurses are the first line for sexual assault cases that come into the Emergency Department (ED). They assess the patients and help refer them to appropriate follow up care. According to Dyer-Goss, the hardest part about the job is “dealing with these traumatic cases but not always getting to see them through. The job sometimes lacks closure.” Survivors who come in qualifying for HIV nPEP follow up with the clinic after intial ED treatment, and the SANEs do not receive notification if they followed with the nPEP regimen. Dyer-Goss says that it is difficult for the SANEs to keep track of patients who show up to the clinic for the follow up medications and who do not.

She also went on to describe the patient interaction with survivors of sexual assault at risk for contracting HIV. SANEs, forensic nurse examiners and physicians screen sexual assault survivors who present to the ED to see how high risk he/she is for contracting HIV. Each survivor is treated in a standardized way and given opportunity for treatment as recommended by healthcare personnel. According to Dyer- Goss, the first thing in question is always the time
frame. If the assault occurred outside the 72-hour window, the patient should be referred to other services such as follow up HIV lab testing, and not recommended for nPEP. Next, the point of contact and type of assault is determined (i.e. vaginal, anal, oral), as well as assessment of the assaulter. Depending on the screening, if the survivor presents on the higher risk side, nPEP is strongly encouraged for the patient, and based on the patient’s choice, they are either entered into the program or not. Some patients are compliant with starting/completing nPEP, while others do not want nPEP due to the possibility of associated side effects (i.e. nausea/vomiting), says Dyer-Goss. This is another hardship in the job, she says, as she has seen some patients encouraged for nPEP refuse it.

SANEs play a vital role in establishing the necessity for nPEP alongside forensic nurse examiners and ED physicians. In addition to patient care and assisting the survivor, SANEs are responsible for paperwork involved with reimbursement from SOVA. After the survivor receives five days of medication in the ED and clinic referral, SANEs help to fill out the proper paperwork that is billed to SOVA, as explained before. SOVA then reviews the paperwork and reimburses the healthcare facility for their services.

**Conclusions**

As a pilot program, the SOVA funding for nPEP for sexual assault survivors will remain active for 50 survivors. So far, since the first survivor seen in summer 2014, SOVA has provided services and funding through nPEP for approximately 30 survivors. After the first 50 survivors, SOVA plans to implement the program as a standard protocol, as carried out in states such as New York and California. Considering South Carolina’s high numbers of sexual assault and high rates of HIV, this program would be beneficial to implement statewide. Not only is the
program clinically sound, as compared to guidelines recommended by the CDC, but also funding provided by SOVA will allow for more survivors to have access who normally would not.

Gail Washington ultimately foresees inviting other facilities into the nPEP program, i.e. areas of South Carolina such as Spartanburg Regional Medical Center and Aiken Regional Medical Center, progressing toward implementing the program statewide. “To ensure that the nPEP program can succeed outside of a controlled pilot program, SOVA will use hospitals that have trained providers (Forensic Nurse Examiners or Physicians with experience in collecting forensic evidence) on staff, who would be able to perform the appropriate exams, follow the protocol, and work out the processes with clinic, lab and pharmacy,” says Washington, explaining how this will ensure program success (personal communication, November 1, 2016).

Although new, the SOVA nPEP program could reduce South Carolina’s rates of HIV transmission; however, there would be implications to implementing statewide. SOVA would have to increase funding as well as ensure that the participating institutions are properly staffed. Also, as Gina Dyer-Goss mentioned, there are patients who do not adhere to the program after their initial ED visit. Some patients follow up in order to complete their nPEP regimen, while other may not. Furthermore, there are many sexual assault survivors, according to the SOVA staff, that do not initially present to the ED at all. This is a barrier to providing nPEP to sexual assault survivors. Despite these challenges, moving towards a statewide-standardized program to fund nPEP for sexual assault survivors has the potential to positively impact both individuals and the health of South Carolina. Preventing as many sexual assault-related HIV transmissions as possible is the ultimate goal of the SOVA nPEP program.
References


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