

2020

Moderate-Intensity Risk Reduction Counseling and Acquisition of Sexually Transmitted Infection

Cindy M. Farina
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Walden University

College of Social and Behavioral Sciences

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Cindy M. Farina

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Walden University
2020

Abstract

Moderate-Intensity Risk Reduction Counseling and Acquisition
of Sexually Transmitted Infection

by

Cindy M. Farina

MSN, Case Western Reserve University, 2000

BSN, State University College of New York at Brockport, 1979

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Human Services with Specialty in Public Health

Walden University

May 2020

Abstract

Sexually transmitted infections (STIs) are a public health problem in the United States, with adolescents and young adults to age 25 bearing a disproportionate burden of infection. Risk reduction counseling (RRC) as a strategy to decrease STI incidence has been a focus of scholars. Research examining RRC efficacy has suggested that RRC is effective for 6 to 12 months after treatment. However, study samples have varied by age, ethnicity, race, gender, and geographic location. Whether RRC is effective for more than 1 year is unknown. The purpose of this post hoc chi-square study was to examine the efficacy of moderate-intensity RRC among adolescents and young adults at 1 and 2 years post treatment. Longitudinal data from an urban public health clinic were analyzed for 300 individuals who received RRC and 176 individuals who did not. The study sample encompassed individuals aged 13 to 26 years and reflected the demographics of the geographic location as well as race, ethnicity, gender, and partner gender preference. There was a statistically significant decrease in the number of STIs reported among those who received RRC at 1 year and 2 years post treatment compared to the group that did not. Moderate-intensity RRC is an effective strategy for decreasing STI acquisition among 13- to 26-year-old individuals for at least 2 years. This study contributes to positive social change by decreasing individual STI acquisition as healthcare providers, counselors, and educators incorporate RRC into their interactions.

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Chapter 1: Introduction to the Study

Sexually transmitted infections (STIs) are a pressing public health problem in the United States, and the U.S. Surgeon General has declared sexual and reproductive health a national priority (Braxton et al., 2017; Satcher, Hook, & Coleman, 2015). In 2013, public health officials estimated that there were 110 million STIs in the United States (Braxton et al., 2017; Brookmeyer, Hogben, & Kinsey, 2016). The annual economic burden of these infections is \$16 billion (Braxton et al., 2017; Owens, 2017). The populations most affected by STIs consist of males and females from 15 to 26 years of age (Braxton et al., 2017; Braxton et al., 2018; Friedman et al., 2014). Between 2010 and 2015, about 25% of the population aged 15 to 26 years had an undiagnosed STI, and the number of negative consequences from STIs, such as infertility, is increasing (Braxton et al., 2017; Braxton et al., 2018). Decreasing the number of STIs may decrease the economic burden and negative consequences of STIs.

Background

STI rates among adolescents and young adults increased between 2013 and 2017 (Braxton et al., 2018; Government of the District of Columbia, 2018). Between 2010 and 2015, 10,698 cases of pelvic inflammatory disease (PID) were diagnosed among young women aged 12 to 21 years (Government of the District of Columbia, 2018). In 2017, nearly 2.3 million new cases of STIs were diagnosed, marking a significant increase from previous years (Braxton et al., 2018). On August 30, 2018, the Centers for Disease Control and Prevention (CDC) announced that resistance to the antibiotic azithromycin had emerged in gonorrhea, noting that the rate of such resistance had increased from 1%

in 2013 to more than 4% in 2017, making gonorrhea more difficult to treat (“New CDC Analysis,” 2018). The director of the CDC’s National Center for Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Prevention reported that the established systems for preventing, diagnosing, and controlling STIs were inadequate (“New CDC Analysis,” 2018).

Young women diagnosed with PID are tested for syphilis and HIV less than 28% of the time (Jichlinski, Badolato, Pastor, & Goyal, 2018). Yet syphilis and HIV increase the risk of chlamydia and gonorrhea, the two most common causes of PID in the United States (Risser, Risser, & Risser, 2017). The potential consequences of PID include infertility (Apari, de Sousa, & Müller, 2014; Pachori & Kulkarni, 2016; Stewart et al., 2020); increased infant morbidity and mortality, including preterm birth and stillbirth (Glidden et al., 2017; Manabe et al., 2015; Sangkomkamhang et al., 2015); and threat to the adolescent’s life by spread of pelvic infection to systemic disease such as myocardial dysfunction (Morgan et al., 2018).

Focusing on avoidance of STI acquisition is one approach to addressing problems related to STIs. Risk avoidance is cost effective (Chesson et al., 2017) and empowering (Pinheiro et al., 2017). An extensive literature review regarding the use of STI risk reduction strategies by adolescents following individual risk reduction counseling (RRC) yielded little information (Graham, 2014; Henderson, 2014; Long et al., 2016). Study samples varied by age (Borawski et al., 2015; Dinaj-Koci et al., 2014), ethnicity (Espada et al., 2015; Graham, 2014), race (Billings et al., 2015; Bradley et al., 2015), gender

(Anderson et al., 2013; Bradley et al., 2015; Stein et al., 2015), and geographic location (DiClemente et al., 2014; Long et al., 2016; Mustanski, Greene, Ryan, & Whitton, 2015). There are reports of some positive effect with sexual RRC as a strategy to reduce STIs (De Vasconcelos et al., 2018; Eaton et al., 2012; Long et al., 2016, O'Connor et al., 2014; Scott-Sheldon et al., 2011). O'Connor et al. (2014) reported that high-intensity RRC decreased the occurrence of STIs in adults (odds ratio, 0.70 [CI, 0.56 to 0.87]) and adolescents (odds ratio, 0.38 [95% CI, 0.24 to 0.60]). However, these authors reported that they found little information about the efficacy of moderate-intensity RRC among adolescents (O'Connor et al., 2014). Few studies of RRC efficacy meet the U.S. Preventative Services Task Force (USPSTF) criteria for fair or good research methodology (O'Connor et al., 2014). None of the studies cited by O'Connor et al. (2014) followed subjects for longer than 12 months after receipt of RRC. Brookmeyer et al. (2016) conducted a meta-analysis of RRC for adolescents. The most current research in the meta-analysis was from 2013. I conducted a literature search on moderate-intensity RRC efficacy for works published since 2016 and found very little research about the acquisition of STIs after moderate-intensity RRC for urban adolescents attending Title X clinics. Data on moderate-intensity counseling are sparse (Brookmeyer et al., 2016; Graham, 2014; Henderson, 2014). There is little information about the efficacy of moderate-intensity RRC among adolescents (Brookmeyer et al., 2016; Eaton et al., 2012; O'Connor et al., 2014). Females and men who have sex with men have been the subject of most RRC studies (Brookmeyer et al., 2016; Long et al., 2016). Additional information

is needed about effective ways to provide risk avoidance education to adolescents and young adults.

Problem Statement

STIs are an urgent public health problem in the United States, and the U.S. Surgeon General has declared sexual and reproductive health a national priority (Satcher et al., 2015). In 2013, public health officials estimated that there were 110 million STIs in the United States (Braxton et al., 2018). The economic burden of these infections is \$16 billion annually (Braxton et al., 2017; Braxton et al., 2018). The populations most affected by STIs consist of males and females aged 15 to 24 years (Braxton et al., 2017; Friedman et al., 2014). The adverse consequences of STIs for individual health include increased risk of contracting additional STIs such as HIV (World Health Organization [WHO], 2016), ongoing disease states such as PID (Greydanus & Dodich, 2015; Svenstrup et al., 2014), and permanent loss of fertility (Apari et al., 2014; Pfennig, 2019). Additional risks are increased infant morbidity and mortality, including preterm birth and stillbirth (Johnson et al., 2014; Manabe et al., 2015; Pfennig, 2019; Sangkomkamhang et al., 2015).

Certain behaviors mitigate STI risk acquisition (CDC, 2013). Risk reduction behaviors include mutual monogamy, limiting the number of concurrent partners, condom use, avoiding alcohol or drug use, and routine periodic screening for STIs (CDC, 2013). Strategies to decrease the incidence of STIs among reproductive-age males and females include the promotion of individual risk avoidance behaviors such as abstinence (Anderson et al., 2013; Long-Middleton et al., 2013), condom use (Scott-Sheldon et al.,

2011), prompt treatment of diagnosed STIs (CDC, 2013), and combinations of these strategies (Goesling et al., 2014). The efficacy of these individual behaviors varies (Chin et al., 2012; Eaton et al., 2012; Goesling et al., 2014). Additional strategies are group RRC (Borawski et al., 2015; Chin et al., 2012) and personal RRC (Champion & Collins, 2012; Hauer, Carney, Chang, & Satterfield, 2012). One purpose of RRC is to educate individuals at risk for STIs in behavioral prevention strategies (Brookmeyer et al., 2016; Widman et al., 2016).

An extensive literature review regarding the use of STI risk reduction strategies by adolescents following individual RRC yielded little information (Brookmeyer et al., 2016; Gooden et al., 2016; Graham, 2014; Henderson, 2014). Study samples varied by age (Borawski et al., 2015; Chambers et al., 2016; Dinaj-Koci et al., 2014), ethnicity (Chambers et al., 2016; Espada et al., 2015; Graham, 2014), race (Billings et al., 2015; Bradley et al., 2015), gender (Anderson et al., 2013; Bradley et al., 2015; Stein et al., 2015), geographic location (DiClemente et al., 2014; Mustanski et al., 2015), partner gender preference (Brookmeyer et al., 2016), and recreational drug use (Gooden et al., 2016). Researchers reported some positive effect with sexual RRC as a strategy to reduce STIs (Lee et al., 2016). There is little information about the efficacy of moderate-intensity RRC among adolescents (McNellis, Ory, Lin, & O'Connor, 2015). O'Connor et al. (2014) reported that high-intensity RRC decreased the occurrence of STIs in adults (odds ratio, 0.70 [CI, 0.56 to 0.87]) and adolescents (odds ratio, 0.38 [95% CI, 0.24 to 0.60]). However, these authors reported that they found little information about the efficacy of moderate-intensity RRC among adolescents (O'Connor et al., 2014).

Few studies of RRC efficacy meet the USPSTF criteria for fair or good research methodology (O'Connor et al., 2014). None of the studies cited by O'Connor et al. (2014) followed subjects for longer than 12 months after receipt of RRC. I have found very little research that has longitudinally examined the acquisition of STIs after RRC. I conducted a literature search on moderate-intensity RRC efficacy for works published since 2014 and found very little research that examined the acquisition of STIs after moderate-intensity RRC. I found no research on STI acquisition following RRC for urban adolescents attending Title X clinics. O'Connor and colleagues (2014) indicated that data on moderate-intensity counseling are sparse.

STIs occur at disproportionate rates across demographic groups (Henderson, 2014; Hogben, Dittus, Leichter, & Aral, 2020; Patterson-Lomba et al., 2015), with non-Hispanic Black people bearing the highest rate of disease, followed by Hispanics (Hamilton & Morris, 2015). Disproportionate rates of STI are an indicator of social inequity (Cooper et al., 2015). Health disparities that run along racial and ethnic lines, disproportionately affecting poor and under resourced populations, are examples of inequalities that arise from discrimination or marginalization (Hogben et al., 2020; Matthews, Smith, Brown, & Malebranche, 2016; Siek, Veinot, & Mynatt, 2019). African American men who have sex with men are more likely to become HIV positive than men of other ethnicities (Matthews et al., 2016). A variety of factors, such as stigma, inadequate health insurance, and mistrust of medical institutions and physicians, are likely the cause of these disparities (Matthews et al., 2016). Poverty and structural inequality in American society are two factors that are associated with disparate STI rates

in adults and adolescents (Hogben et al., 2020). Individuals who come from generational poverty tend to experience fewer resources, with less health care and less supportive networks, than individuals who come from more advantaged backgrounds (Jensen, 2009; Metzler, 2017). Health disparities result in increased morbidity and mortality rates among affected populations (Braveman, 2014; Metzler, 2017), particularly among adolescents (DiClemente et al., 2014; Norris et al., 2019). The problem is that despite intervention strategies, STIs occur at disproportionate rates among adolescents and young adults (Gottlieb & Johnston, 2017; Poston, Gottlieb, & Darville, 2017).

Purpose

The purpose of this post hoc chi-square study was to examine the distribution of STIs between two groups of adolescents and young adults, one that received moderate RRC and a comparison group that did not. This approach enabled me to determine with increased certainty if RRC affected the outcome variables of this study. The outcome variable was the acquisition of one or more of the following STIs: chlamydia, gonorrhea, trichomonas, syphilis, and HIV. The efficacy of moderate-intensity RRC was determined by the presence of one or more of these STIs at 1 year and at 2 years after receiving the counseling. If receipt of moderate-intensity RRC decreases STI acquisition, then moderate-intensity RRC may be a useful strategy to decrease STI risk for adolescents and young adults. This knowledge may help health care professionals to develop and implement programs or interventions for the population most vulnerable for long-term morbidity (Borawski et al., 2015; Leichter, Seiler, & Wohlfeiler, 2016; Teng, Kong, & Tu, 2015).

Significance

Knowledge about the efficacy of RRC for adolescents and young adults is incomplete (Carmack, Lewis, & Roncancio, 2015; Epstein et al., 2014; McNellis et al., 2015; Sagherian et al., 2016; Wang et al., 2014). Knowledge about RRC efficacy for subjects between the ages of 13 and 24 years is limited to location (Boyer et al., 2000), interventions to reduce STI acquisition (Espada et al., 2015), and acquisition of STIs (Carmack et al., 2015; Pinheiro et al., 2017). Each study was limited to 12 months or less of follow-up after RRC (O'Connor et al., 2014; Pinheiro et al., 2017; Sagherian et al., 2016). This study is significant because this appears to be the first study designed to examine whether moderate-intensity RRC decreases the acquisition of HIV and STIs in adolescents and young adults over 2 years following RRC.

Nature of the Study

The study was a post hoc study of adolescents and young adults who received testing and treatment in a city health department urban reproductive health clinic funded by Title X. The original purpose of data collection was to evaluate the efficacy of an HIV prevention program. Efficacy was determined by the numbers of clinic visits a subject had before and after RRC. RRC was considered effective if the numbers of visits decreased following RRC. I used this secondary data set to compare rates of STI acquisition between two nonequivalent groups, a group that received individual moderate-intensity RRC and a group that did not.

The program included the provision of individual moderate-intensity RRC to individuals at risk for STIs and HIV based on age or self-reported behavior, such as

inconsistent condom use, multiple concurrent sexual partners, and use of drugs or alcohol before sex. The self-reported behavior of inconsistent or no condom use, multiple partners, and same-sex sexual intimacy determined the subjects considered at high risk. Adolescents were eligible for moderate-intensity individual RRC based on age. Young adults were eligible based on self-identified risk factors. Clinic staff offered potential subjects RRC, and those who accepted the opportunity received the counseling. There was no randomization.

RRC, the independent variable, was measured dichotomously as yes/no. The presence of STI encompassed trichomonas, chlamydia, gonorrhea, syphilis, and HIV for all time periods and was measured as yes/no. STI presence was measured three times, at the first study visit and 1 and 2 years post RRC. All testing was performed in a Level 3 Clinical Laboratory Improvement Amendments (CLIA) certified lab. The Centers for Medicare & Medicaid Services regulate and monitor CLIA-certified laboratories. Chlamydia and gonorrhea were tested using standard Roche COBAS AMPLICOR amplified nucleic acid testing. Chlamydia testing had a sensitivity of 100% and a specificity of 99.4%; gonorrhea testing had a sensitivity of 100% and a specificity of 99.7% (Chernesky et al., 2014; Taylor et al., 2012). A CLIA-certified Level 3 lab performed the point-of-care serum HIV tests. The sensitivity of the OraQuick HIV test was 93.64% (95% CI 82.46-98.66%), specificity 99.87% (99.28-100%), positive predictive value 97.78% (88.27-99.94%) and negative predictive value 99.61% (98.87-99.92%; Figueroa et al., 2018; Pavie et al., 2010). Trichomonas was measured by clinical laboratory microscopy (Aluma, 2015). The sensitivity of wet mount microscopy ranges

from 36% to 75% (Gaydos et al., 2017; Nye, Schwebke, & Body, 2009; Toskin et al., 2017). Syphilis laboratory testing was done using a rapid plasma regain (RPR) test. The sensitivity and specificity of the RPR test ranges from 78% to 100% and 98% to 100%, respectively (Gliddon et al., 2017; Saral et al., 2012).

I used chi-square to examine the differences in the distribution of STI presence between the two individual groups of adolescents and young adults at the time of entry into health care services. Chi-square was also used to analyze to what extent the distribution of STIs was decreased among individuals who received moderate-intensity RRC at 1 and 2 years following the intervention.

The presence of infection was determined by clinical laboratory testing at the time of RRC, at 1-year post RRC, and at 2 years post RRC. There was one dichotomous independent variable for this study, RRC, coded as yes or no. There was one dichotomous dependent variable, the presence of STI, coded as present or not present. The presence of STI, measured as present/not present, included trichomonas, chlamydia, gonorrhea, syphilis, and HIV for all time periods.

Using GPower to calculate sample size for a one-tailed test with 1 degree of freedom, an $\alpha = .05$, $\beta = .95$, and medium effect size of .5 results in a sample size of 88. There were 476 participants aged 13 to 26 years in the subsample that I used for this post hoc chi-square study. I used gender, age, race, ethnicity, education, income, and sexual preference for descriptive purposes only.

Post Hoc Study

This post hoc chi-square study included the use of two nonrandomized, nonequivalent groups of adolescents and young adults. One group received state-health-department-required HIV/STI RRC, and one group did not. I used a secondary data set collected by a city health department Title X reproductive health clinic to evaluate the efficacy of a state-health-department-required HIV/STI prevention program. The reproductive health clinic staff offered RRC to all clinic clients aged 19 to 24 years who were at risk for STIs based on self-reported behavior, such as inconsistent condom use. RRC was also offered to all adolescents age 13 to 18 based on age.

In this study, I examined the effect of RRC on the acquisition of STI at 1 and at 2 years after RRC. The independent variable for this study was RRC. The dependent variable was laboratory-confirmed presence of STI (gonorrhea, chlamydia, trichomonas, syphilis, or HIV) at 1 and 2 years after RRC. I also compared the two groups of adolescents and young adults for distribution of the same STIs at the RRC visit. I used chi-square to examine the distribution between individual moderate-intensity RRC and the acquisition of STI over the following 2 years. The demographic variables, gender, education, race, ethnicity, and sexual orientation, were used to describe the sample only.

Research Question

To what degree was the distribution of sexually transmitted infections among adolescents and young adults who received moderate-intensity risk reduction counseling less than the distribution of sexually transmitted infections among individuals who did not receive moderate-intensity risk reduction at 1 and 2 years following the intervention?

Hypotheses

I tested the following hypotheses for the post hoc chi-square study of STI acquisition in adolescents and young adults.

Ho1: There was no statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 1 year post intervention.

Ha1: There was a statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 1 year post intervention.

Ho2: There was no statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 2 years post intervention.

Ha2: There was a statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 2 years post intervention.

Framework

Public health officials have used social ecology theory to generate knowledge for implementing programs to decrease rates of disease and infection transmission (Aral &

Cates, 2013; Atkins et al., 2016; DiClemente, Brown, & Davis, 2014; Golden & Earp, 2012; Holt-Lunstad, Robles, & Sbarra, 2017; Ockene et al., 2007). Interventions need to be effective for STI rates to decrease (Long et al., 2016). Social ecology theory involves individual, interpersonal, organizational, community, and policy levels of understanding (Baral et al., 2013; Baron et al., 2014). Multilevel understanding contributes increasing understanding of sexual risk behavior dynamics (Rana et al., 2015; Sallis & Owen, 2015).

Sexual risk and risk avoidance behaviors take place at the individual level; however, interpersonal- and community-level factors may influence individual behaviors. Individual sociodemographic factors such as age, gender, ethnicity, race, education, and sexual orientation are also associated with the probability of contracting infection (Dembo et al., 2009; Pflieger, Cook, Niccolai, & Connell, 2013). Understanding individual risk reduction efforts adds to understanding STI avoidance at a fundamental level (Baron et al., 2014; Hickson et al., 2015). Interpersonal factors, the second tier of social ecology theory (Baral et al., 2013; Moran et al., 2016), influence and are influenced by individual-level factors (Bronfenbrenner, 1994; Moran et al., 2016). Interpersonal factors include the number of partners and condom use. Individual RRC is an interpersonal-level approach to the problem of STIs, while efforts of public health departments are community level (Baron et al., 2014). Values and norms within a community are affected by neighborhood safety, resources, residential mobility, and employment rates (Dembo et al., 2009; Pflieger et al., 2013).

Operational Definitions

The following were the operational terms for this post hoc chi-square study.

Adolescents: Individuals aged 13 to 18 years.

Young adults: Individuals aged 19 to 24 years.

Sexually transmitted infection (STI): The presence of chlamydia, gonorrhea, trichomonas, syphilis, and HIV, individually or in combination, detected by clinical laboratory testing with or without signs or symptoms of disease (Anderson, 2019).

Risk reduction counseling (RRC): The state department of health HIV/STD curriculum for reducing risk in high-risk individuals provided by a state-department-of-health-trained health care professional directly to the individual (Aluma, 2015).

Assumptions

There were several assumptions for this study. First, participants were motivated to improve or maintain health because they sought STI screening, diagnosis, and cure. Second, participant motivation varied according to background and life circumstances. Third, the Ohio Department of Health HIV/STD risk reduction curriculum was evidence based and effective for adults. The curriculum mirrored the evidence-based CDC Comprehensive Risk Counseling Services (CRCS) for Persons at High-Risk for HIV Infection, a peer-reviewed curriculum provided by the CDC Division of HIV/AIDS Prevention. Fourth, RRC sessions followed this curriculum. Health department administrators and supervisors monitored this expectation. Fifth, subjects were residents of the Midwestern metropolitan area where the data were collected in the public health department. Finally, I assumed that the precepts of social ecology theory are valid.

There were also methodological assumptions for this study. First, relationships discerned in the post hoc analysis are exploratory (Srinivas, Ho, Kang, & Kaplan, 2015).

Second, the two groups that comprise the study are independent. Third, data from the two groups would be normally distributed. Finally, if the data were not normally distributed, chi-square is robust to the violation of normal distribution if there is little skewedness and no outliers in the data for each sample (McDonald, 2014).

Limitations

As a retrospective post hoc chi-square study, this study had several restrictions. The first was that the analysis used a subset of the study population. Using a small subset of a population increases the risk of spurious findings if the statistical significance of the subgroup difference varies from the larger population (Higgins & Green, 2011, Higgins, & Altman, 2011). Additionally, multiple analyses of the same subgroup increased the risk of a Type I error of false-positive findings (Stephens, 2001). The second concern for this study was that data collected between May 2012 and May 2016 for program evaluation were used to examine the relationship between RRC and STI in sexually active individuals aged 13-24 years. Lack of randomization also limited generalizability of this study (Simons, Shoda, & Lindsay, 2017). Individuals were offered RRC and were free to choose to participate. Thus, self-selection bias was present in the data set (Cleave, Nikiforakis, & Slonim, 2013).

Scope and Delimitations

The scope of this study included the 13- to 24-year-old people who sought healthcare services for STIs in an urban Midwestern Title X clinic. The individuals in this study were interviewed and tested by clinic staff for STI risk factors and the presence of chlamydia, gonorrhea, trichomonas, syphilis, and HIV. Participants with subsequent

visits were re-interviewed for STI risks and retested for the same STIs. Clinic staff followed the participants for up to 2 years following the first visit depending on individual return to the clinic for ongoing healthcare.

Summary

Chapter 1 contains information about the background of the disparate acquisition of STIs among adolescents and young adults and the potential efficacy of RRC to decrease STI acquisition. STIs have been a societal problem for centuries, although understanding of their consequences has developed only in more recent times (Gruber, Lipozenčić, & Kehler, 2015; Wilcox, 1949). Chapter 2 contains a review of literature about how STIs developed over the centuries and human responses to these infections.

Chapter 2: Literature Review

Background

STIs have been a problem since ancient Mesopotamia (Algaze, 2009; Cook, 2010; Gest, 2004; Oppenheim, 2013). STIs are a known source of long-term health consequences, including infertility, PID, and preterm birth (Apari et al., 2014; Greydanus & Dodich, 2015; Svenstrup et al., 2014). For pregnant women, STIs contribute to fetal death, congenital anomalies, preterm birth, and infant mortality (Johnson et al., 2014; Manabe et al., 2015; Sangkomkamhang et al., 2015).

Understanding the connection between STIs and health consequences was an accomplishment achieved between 1870 and 2016 (Dahlberg et al., 2017; Gest, 2004; Gruber et al., 2015; Thorburn, 1974). The purpose of this post hoc chi-square study was to examine the distribution of STIs among 15- to 24-year-old individuals who received moderate-intensity RRC and compare that distribution to the STI distribution of 15- to 24-year-old individuals who did not receive the intervention. Men and women aged 15-24 years bear disproportionate burdens of disease, as the majority of STIs occur in this age group (Henderson, 2014; Patterson-Lomba et al., 2015). This literature review includes a brief history of STIs, adolescence, and young adulthood from ancient times to the modern era. This chapter also contains current literature about STIs, including trichomonas, chlamydia, gonorrhea, syphilis, and HIV, as well as strategies to avoid contracting an STI.

Literature Search Strategies

I searched PubMed, CINAHL, Medline, Web of Science, and ProQuest using the terms *sexually transmitted infection, sexually transmitted disease, adolescent, young adult risk factors, counseling, risk reduction, social ecology, human immune deficiency virus (HIV), chlamydia, gonorrhea, trichomonas, and syphilis*. I reviewed approximately 350 peer-reviewed journal articles, two dissertations, and three books. Finally, I identified additional sources of information by scrutinizing the reference lists of journal articles and books. The historical overview includes findings of ancient times and progresses to 2010-2016.

Historical Overview

Ancient Mesopotamian cuneiform writing, the first known written record, contains descriptions of STIs (Gruber et al., 2015). From these writings, STIs appear to have been a problem since 3500 BC (Gruber et al., 2015). This review begins with the oldest known STIs and proceeds to HIV, first described in 1981 (Becker & Joseph, 1988).

Sexually Transmitted Infections

Ancient writers from Mesopotamia and Egypt described gonorrhea, chlamydia, and syphilis (Gruber et al., 2015; Wilcox, 1949). Other STIs, such as trichomonas (Thorburn, 1974) and HIV, the cause of acquired immune deficiency syndrome (AIDS), appear to have developed in the 19th and 20th centuries, respectively (Gilbert et al., 2007; Montagnier, 2002). This brief history covers five common STIs: gonorrhea, chlamydia, trichomonas, syphilis, and HIV.

Gonorrhea, Chlamydia, and Syphilis

The clay tablets of ancient Mesopotamia, the first recorded civilization (Algaze, 2009; Von-Der-Muhll, 2007), include the description of symptoms that suggest the presence of gonorrhea, chlamydia, and trichomonas infections in males and females (Gruber et al., 2015). Ancient people thought the acquisition of these diseases came from gods as punishment for individual transgressions (Gruber et al., 2015). Medical treatment of STI symptoms consisted of prayers and incantations as well as some plant remedies (Gruber et al., 2015). Mesopotamian writers also recorded the presence of male and female prostitutes (Gruber et al., 2015). Prostitutes may provide a reservoir of infection in a network, increasing exposure to STIs among a social group (Jennings, Curriero, Celentano, & Ellen, 2005).

Ancient Egyptian writers described the presence of similar STIs as early as 1550 BC (Gruber et al., 2015). The Talmud and the Bible contain descriptions of STIs in the Hebrew community (Gruber et al., 2015). Greek and Roman documents BC and AD contain descriptions of gonorrhea, chlamydia, and trichomonas infections (Gruber et al., 2015). Ancient authors also recorded the existence of prostitution (Glazebrook, 2015). Even though ancient writers gave detailed descriptions of gonorrhea, chlamydia, and trichomonas from the Mesopotamian through the Roman era, no one recognized the mode of transmission from one individual to another as sexual contact until the Middle Ages (Gruber et al., 2015). The concept of bacteria would come in the 1860s (Cook, 2010; Gest, 2004; Lederberg, 2000).

Syphilis

Controversy exists regarding the presence of syphilis in ancient Europe and Asia (Gruber et al., 2015; Rothschild, 2005). Oribasius, a physician who lived from 325-403 BC, described an infant condition that could be congenital syphilis (Gruber et al., 2015). Biblical stories (New International Version, 1984) and other writings (von Hunnius et al., 2007; von Hunnius, Roberts, Boylston, & Saunders, 2006) provide the bases for thinking that syphilis was present in the ancient world. However, others posited that characteristics of syphilis are absent in bone samples from pre-Columbian Europe, Africa, and Asia (Harper et al., 2008; Harper et al., 2011; Rothschild, 2005). Yaws, caused by *Treponema pertenue*, may have had a similar presentation to syphilis, caused by *Treponema pallidum*, leading medical anthropologists, bioarcheologists, and medical researchers to mistake Yaws for syphilis in ancient writing (Baker et al., 1988; DeWitte & Stojanowski, 2015; González-Beiras et al., 2017; Rothschild, 2005).

Syphilis is but one of a group of infections caused by *Treponema*. Subspecies of *Treponema*, such as *Treponema pallidum* and *Treponema pertenue*, may have mutated over time so that different presentations of *Treponema* infections exist (Crosby, 1969; Harper, 2008). There is evidence of syphilis in pre-Columbian North and South American Indian bones (Gruber et al., 2015; Rothschild; 2005). Spirochetes found in ancient teeth and jaw bones may have been *Treponema denticola* spirochetes rather than *Treponema pallidum* spirochetes, leading to the false conclusion that evidence of syphilis exists in ancient bone and teeth (von Hunnius et al., 2007).

Rothschild (2005) and González-Beiras et al. (2017) posited that syphilis came from the Americas to Europe starting with the crew of Christopher Columbus's ships. Syphilis spread widely in Europe during the Renaissance in the late 15th and early 16th centuries (Wilcox, 1949). The infection propagated largely through military troop movement and prostitution (Wilcox, 1949). Physicians of the time wrote about a new plague with no cure (Rollston, 1934; Waugh, 1991). The physicians thought that the transmission of syphilis was the result of air transmission, contact transmission with persons or objects, and intercourse with prostitutes (Rollston, 1934; Waugh, 1991). The understanding of disease transmission began to change when Robert Hooke and Antoni van Leeuwenhoek began describing bacteria and other microorganisms around 1665 (Gest, 2004). Louis Pasteur's experiments in the mid-1800s and Robert Koch's work in the 1870s achieved general acceptance of the germ theory of disease (Lederberg, 2000).

STIs From 1600 to the Modern Era

From about 1600 to the modern era, the understanding of gonorrhea, chlamydia, and syphilis transmission grew from the belief that venereal disease was punishment by gods (Gruber et al., 2015) to recognition that STIs spread through contact via microorganisms (Jackson, 2011; Lederberg, 2000; Schamberg, Kalodner, & Lentz, 1958). Scientists identified the disease-causing organisms of gonorrhea, chlamydia, and syphilis (Budai, 2007; Ligon, 2005; Sarbu, Matel, Benea, & Georgescue, 2014; Taylor-Robinson, 2017) and HIV (Quilter, Dhanireddy, & Marrazzo, 2017). Scientists now understand that STI transmission occurs through a chain of contact among social networks or clusters (Jennings et al., 2005).

Gonorrhea, Chlamydia, and Syphilis

Girolamo Fracastoro first articulated germ theory, the idea that minuscule living material can cause illness, in 1530 when he wrote about syphilis (Lederberg, 2000). However, physicians and scientists in the 1500s believed in spontaneous generation and not germ theory (Farley & Geison, 1974; Lederberg, 2000). Germ theory gained acceptance when microbes were visible through a microscope (Carpenter, 1856; Hajdu, 2002). Around 1590, the precursor of the microscope appeared. The apparatus consisted of a copper tube and two lenses (Hogg, 1861). The microscope-like apparatus primarily provided entertainment; the device was a curiosity, not for scientific inquiry (Carpenter, 1856; Cassedy, 1976). The advances in the microscope over the next two centuries enabled the work of Robert Hooke in 1667 and Antoni van Leeuwenhoek in 1673, as they explored the microscopic world of bacteria (Carpenter, 1856; Hajdu, 2002). The work of Louis Pasteur and Robert Koch in the 1860s demonstrated that the activity of microbes causes food spoilage and human disease (Lederberg, 2000). As germ theory gained acceptance, understanding grew concerning how STIs spread, but not how a person acquires the germs (Jackson, 2011; Lederberg, 2000).

By the time of the U.S. Civil War, the prevalence of syphilis and gonorrhea ranged from 2-11% of the U.S. population (Lowry, 2014; Murphy, 1985). STI patients represented almost 18% of admissions in one Confederate hospital (Lowry, 2014). During the Civil War, the prevalence of venereal diseases limited the availability of fighting forces because afflicted military personnel had to undergo the lengthy and painful treatment available (Lowry, 2014; Murphy, 1985; Parascandola, 2009). Military

strategies to decrease venereal disease rates included forcible movement of prostitutes to other locations, legalized prostitution with required periodic examinations and treatment, prohibition of alcohol, and interment of prostitutes (Jones, 1985; Murphy, 1985). These military strategies were developed because physicians thought women were harbors of venereal disease and that even uninfected women were able to transmit disease (Brandt, 1987; Murphy, 1985; Parascandola, 2009).

During the World Wars, almost 40% of potential U.S. military recruits presented symptoms of a venereal disease, rendering those recruits unfit for military service (Dmytruk et al., 2017). Military recruits in France (Aisenberg, 2001), the Netherlands (De Vries, 2001), Germany (Freund, 2001; Sauerteig, 2001), and Great Britain (Davidson, 2001; Hall, 2001) presented similar rates of venereal disease. Venereal diseases also affected the civilian population (Brandt, 1987). Public health officials approached the problem of venereal disease by requiring premarital testing and treatment with the goals of increasing marital accord and decreasing the adverse consequences of STIs (Brandt, 1987). New medical treatments appeared that were more effective but no less painful than the treatments used during the Civil War (Dmytruk et al., 2017).

Alexander Fleming (1929) discovered penicillin in 1928. However, recognition of its therapeutic implications for humans did not occur until 1943 (Chain & Florey, 1944; Chopra & Greenwood, 2001; Firth, 2012). Penicillin is highly effective for curing primary and secondary syphilis (Firth, 2012; Holmes, 2005; Watts, Greenberg, & Khachemoune, 2016). Syphilis rates after the introduction of penicillin in 1945 decreased to 4/100,000 from 75/100,000 (Holmes, 2005). Initially, penicillin was also useful for

gonorrhea, but the causative organism became resistant (Schamberg et al., 1958). Efforts to reduce gonorrhea rates focused on avoiding acquisition (through the use of condoms, marital monogamy, and abstinence) and prevention of transmission through antibiotic quarantine (Schamberg et al., 1958). *Antibiotic quarantine* refers to the time during which penicillin, an antibiotic, has at least a minimum inhibitory concentration in the body and reinfection is prevented (Brachman & Abrutyn, 2009; Garson & Barton, 1960; Schamberg et al., 1958).

In 1953, there were five acknowledged venereal diseases: syphilis, gonorrhea, chancroid, granuloma inguinale, and lymphogranuloma venerum (Fiumara, 1953). By the late 1990s, researchers and healthcare providers had recognized new venereal conditions, and the term *venereal disease* had changed to *STI* (Quilter, Dhanireddy, & Marrazzo, 2017). In 1907, von Prowazek and Halberstaedter identified the bacteria *Chlamydia trachomatis* as the causative organism of the disease chlamydia (Taylor-Robinson, 2017). The *Chlamydia trachomatis* organism is also the causative agent of lymphogranuloma venerum (Mishori, McClaskey, & Winklerprins, 2012).

Contemporary Chlamydia

Worldwide, chlamydia is the most common bacterial STI (Wind et al., 2016). Officials at the CDC reported that U.S. STI rates reached record highs in 2015 (Enomoto, Noor, & Widner, 2017). Genome sequencing of the causative microorganisms may lead to a specific understanding of host-pathogen interaction, particularly why some individuals become infected while others appear immune (Dahlberg et al., 2017; Yang et al., 2017). Genome sequencing may also promote the development of preventative

vaccines (Pal et al., 2017; Poston et al., 2017). Until vaccines to prevent STIs are available, efforts to control STIs will rely on risk factor identification, education, rapid treatment of infection, and individual behavior (Estcourt et al., 2017).

Contemporary Trichomonas

Trichomonas is the most common curable nonviral STI in the United States, followed by chlamydia (Gaydos & Hardick, 2014; Menezes, Frasson, & Tasca, 2016). Trichomonas is present with other STIs, such as chlamydia, gonorrhea, syphilis, and HIV (Gaydos & Hardick, 2014; Menezes et al., 2016). The prevalence of trichomonas in the United States exceeds the prevalence of chlamydia or gonorrhea (Gaydos & Hardick, 2014; Menezes et al., 2016). Officials at the WHO reported that there are approximately 265 million new trichomonas infections throughout the world each year (Menezes et al., 2016). One manifestation of trichomonas pathology is damage to the epithelial cells lining the reproductive and urinary tracts (Edwards, Burke, Smalley, & Hobbs, 2014). This damage enhances the ability of other pathogens to invade the host tissue, increasing susceptibility to other organisms (Edwards et al., 2014). There is an association between HIV acquisition and the presence of trichomonas (Workowski & Bolan, 2015).

Human Immunodeficiency Virus

HIV is a retrovirus and pathogen that infects humans and leads to AIDS (Gilbert et al., 2007; Kallings, 2008; Parekh, 2018; Sharp & Hahn, 2008). HIV damages the cells of the nervous and immune system so that the host loses the ability to fight infection or tumor growth (Kallings, 2008; Parekh et al., 2018). The effect on the nervous system is the development of dementia and profound weakness (Banerjee, McIntosh, & Ironson,

2019; Kallings, 2008). When the retrovirus has destroyed enough immune cells that the blood count for those cells drops below 200 cells/mm³, the infection develops into AIDS (Croxford et al., 2017).

The History of Human Immunodeficiency Virus

HIV began in Equatorial Africa in about 1930 (Gilbert et al., 2007; Kallings, 2008; Sharp & Hahn, 2008). There is no description of HIV infection in ancient times (Sharp & Hahn, 2008; Verdonck et al., 2007). HIV is a mutation from a group of similar lentiviruses that affect monkey, feline, horse, cattle, and sheep immune systems (Kallings, 2008; Thomas & Sharma, 2018; Walker, 1994). Most likely, the mutation came from the simian strain (Sharp & Hahn, 2008). Although scientists were interested in retroviruses that affect animal species as early as 1911 (Lederberg, 2000), scientists first identified HIV in humans in 1979 (Sharp & Hahn, 2008). As the result of phylogenetic testing of HIV, Sharp and Hahn (2011) reported that cross-species strains of the virus resulted in a mosaic of simian viral strains that mutated into HIV-1 group M in southeastern Cameroon. HIV-1 group M is the viral strain primarily responsible for the AIDS pandemic.

Physicians and scientists diagnosed HIV infection first in southern Africa (Sharp & Hahn, 2011; Thomas & Sharma, 2018) and then in France and Haiti (Kallings, 2008; Thomas & Sharma, 2018; Walker, 1994). From Haiti, HIV came to the United States through American sex tourists (Walker, 1994). Asymptomatic for years, the first cases of AIDS came to public awareness in the early 1980s (Kallings, 2008; Thomas & Sharma, 2018; Walker, 1994).

The transmission of HIV is through sex, intravenous drug use, and transfer from mother to baby, with sex as the most frequent mode of transmission (Hladik & McElrath, 2008; Ronen, Sharma, & Overbaugh, 2015). Once transmitted, the virus causes a breakdown of the immune system, and opportunistic infections begin to occur (Kallings, 2008; Manzardo et al., 2015). These opportunistic diseases, such as *Cryptococci meningitis*, pneumonia, and sarcoma, are usually fatal for the immune compromised host (Croxford et al., 2017; Hladik & McElrath, 2008; Kallings, 2008).

Contemporary HIV

The initial treatments for HIV delayed the onset of AIDS (Simen et al., 2009; Teeraananchai et al., 2017) and required a complicated regimen of multiple medications that caused undesired side effects (Haas et al., 2004). Patients often failed to adhere to the treatment regimens, which were complicated and required taking multiple pills of individual drugs daily (Ammassari et al., 2001; Catz et al., 2000). Patient adherence to the prescribed treatment regimens improved once the side effects of the treatment medications decreased and one pill contained all the medications (Antiretroviral Therapy Cohort Collaboration, 2017; Katz & Maughan-Brown, 2017). There appears to be no cure for HIV and even with treatment life expectancy is lower than the general population (Antiretroviral Therapy Cohort Collaboration, 2017; Teeraananchai et al., 2017). Public health officials consider the prevention of HIV and the use of medication as an optimal approach to controlling the spread of HIV/AIDS (Pelligrino et al., 2017; Robinson et al., 2017; Samandari et al., 2017).

Adolescence and Young Adulthood

In the times of ancient Mesopotamia, Egypt, Rome, and Greece, adolescence was the short time between reproductive system maturity to adult life (Bullough, 2006; Gruber et al., 2015). Childhood and adolescence were a time of training and preparation for adult life (Bullough, 2006; Gruber et al., 2015) Ancient Egyptian parents trained their children for adulthood, which occurred with marriage between 12 and 15 years of age (Morton, 1995). Life expectancy in Ancient Egypt was approximately 36 years (Morton 1995). Early marriage and childbearing, followed by childrearing, controlled adolescent sexual activity (Morton, 1995).

Prostitutes were available for single or widowed men and travelers (Morton, 1995). The ancients thought travelers and soldiers brought STIs, including gonorrhea and chlamydia, to prostitutes, who then transmitted the STIs to local inhabitants (El-Meliegy, 2008; Morton, 1995). The prostitutes then acted as a reservoir or pool of infection (Inhorn & Brown, 1997; Piercy, 2007).

In ancient Greece, the onset of reproductive capability signaled adult status (Gruber et al., 2015; Morton, 1995). Menarche was the beginning of adult status for females, and for males, it was the ability to ejaculate (Bullough, 2006; Morton, 1995). Girls married in their early teens, usually between 14 and 17; society encouraged boys to wait, often until age 30, to marry (Bullough, 2006; Morton, 1995). Early marriage and childbearing eliminated concerns about female adolescent sexuality in ancient times (Bullough, 2006; Morton, 1995). Males, however, used sexual outlets, such as masturbation, a friendly companion, or a prostitute of either gender, until marriage took

place (Gruber et al., 2015; Morton, 1995). The ancient Greek society also condoned pedophilia (Gruber et al., 2015; Morton, 1995). These alternatives were acceptable and without negative association, although excess sexual activity was discouraged (Morton, 1995). Ancient Greek society valued moderation and control in sexual practices (Morton, 1995).

Adolescence and Young Adulthood in the Modern Era

Adolescence is a developmental time of experimentation and risk (Steinberg, 2007). Health care professionals have been concerned about adolescent risky behavior through the twentieth century (Jessor, 1991; Kotchick, Shaffer, Miller, & Forehand, 2001; Romer, 2010). Over time, researchers' interest in the types of risks faced by adolescents changed (Alexander et al., 2014; Baldwin, 1976; Brunswick, 1971; Goodman & Cohall, 1989; Wong et al., 2017). In the 1970s, researchers focused on adolescent sexual behavior resulting in unintended consequences such as pregnancy and early childbearing (Baldwin, 1976; Brunswick, 1971), contraceptive use (Dembo & Lundell, 1979; Minkler, 1971), and transmission of STIs. STIs of interest included chlamydia, gonorrhea, and trichomonas (Darrow, 1979; Mårdh, Ripa, Svensson, & Weström, 1977). Chlamydia, gonorrhea, and trichomonas are curable STIs (Workowski & Bolan, 2015). In the 1980s, medical professionals became concerned about HIV contracted by adolescents as a result of risky sexual behavior (Becker & Joseph, 1988; DiClemente, Boyer, & Morales, 1988; Jemmot, Jemmot & Fong, 1992).

Contemporary Adolescence

Medical professionals concern about adolescent sexual risk behavior in the early twenty-first century continued to focus on prevention of Chlamydia, gonorrhea, and trichomonas as well as HIV/AIDS (Enomoto, Noor & Widner, 2017). Historically, the initial research in AIDS prevention focused on strategies to reduce the risk of acquiring AIDS among intravenous drug users (Des Jarlais, Friedman & Sotheran, 1986) and adolescent males who have sex with other males (Brooks-Gunn, Boyer, & Hein, 1988; DiClemente, Zorn, & Temoshok, 1986). Interest in risk reduction for HIV/AIDS in sexually active individuals then expanded to females (Stein, 1990), adolescents, and minorities (Goodman & Cohall, 1989). Eventually, health care professionals began to emphasize prevention as well as diagnosis and treatment of STIs (Estcourt et al., 2017; Lin et al., 2016).

Controlling the Spread of STIs

Throughout the 20th century, U.S. military and public health officials' efforts to control the spread of STIs consisted of education coupled with scare tactics and the promotion of marital monogamy (Brandt, 1987; Emmerson, 1997; Korzeniewski, 2012; May, 2015; Mayaud & Mabey, 2004). The components of comprehensive STI education includes anatomy, disease signs and symptoms, mode of transmission, and the importance of seeking treatment (Kirby et al., 2006). Health care officials emphasized education because they thought knowledge would motivate individuals to change behavior (Kirby, 1999). Once antibiotics were available, public health officials added

rapid treatment of disease to control infection rates (Emmerson, 1997; Mayaud & Mabey, 2004).

While education had some positive effect on STI acquisition, public health officials seek additional strategies (CDC, 2012; Kirby, Laris, & Rolleri, 2007; Mullinax, Mathur, & Santelli, 2017). Health professionals used health promotion counseling to control the spread of genetic diseases, nonsexually transmitted infections, and other conditions, such as diabetes and chronic obstructive pulmonary disease (Milio, 1976). Conversely, public health officials and health professionals did not appear to include the use of health promotion counseling to decrease risky sexual behavior. To address ambivalence or reluctance to change behavior, public health experts began to incorporate motivational counseling into health promotion curricula to mitigate or avoid disease (Boman et al. 2017; Carey et al., 2015; Foley et al., 2005; Mason, Pate, Drapkin, & Sozinho, 2011; Rietmeijer, 2007).

Health Promotion Counseling

Health professionals and health educators practiced health promotion counseling based on social learning theory (Miller & Stoeckel, 2017) and social ecology (Collins, Kugler & Gwadz, 2016; Kaufman, Cornish, Zimmerman, & Johnson, 2014). The goal of counseling is to provide the basis for the recipient to develop a new view of his or her behavior and to consider a behavior changes (Rollnick, Miller, Butler & Aloia, 2008; Santa Maria et al., 2017) through interpersonal interaction, modeling, and identification of interpersonal risk factors and triggers of risk behavior. Avoidance of risk then comes through changes the individual makes in their interpersonal relationships. The counselor

acts as a model for the recipient to follow (Adelekan, 2017; Bronfenbrenner, 2005; Perry, Baranowski & Parcel, 1990). The health promotion counseling model was the basis for risk reduction counseling in the early 1980s when physicians began to diagnose the first HIV infections (Edelman, Mandle, & Kudzma, 2017; Morin, 1988; Peterman & Curran, 1986). Health promotion counseling includes education about the disease and behaviors that promote wellness or avoidance of disease (Boman et al. 2017; Carey et al., 2015; Milio, 1976; Rietmeijer, 2007). Health professionals initially used health promotion counseling with motivational interviewing to target smoking, illicit drug use, and alcohol use (Boman et al. 2017; Carey et al., 2015; McAlister et al., 1980). RRC is a type of health promotion counseling that is interactive and interpersonal while traditional health promotion counseling is didactic and one direction (Boman et al., 2017; Carey et al., 2015; Rietmeijer, 2007).

Risk Reduction Counseling

RRC is grounded in social ecology theory with the premise that the modeling that takes place by the counselor, the interpersonal relationship developed between the counselor and the recipient, and the identification of the recipient's individual risk behaviors will influence the individual to reduce specific intrapersonal and interpersonal STI acquisition risk behaviors and will control the spread disease (Alexander et al., 2014; Bronfenbrenner, 2005; Maticka-Tyndale et al., 2016; Rietmeijer, 2007). The components of RRC include the education provided in health promotion counseling (Alexander et al., 2014) as well as the assessment of individual behavior based on patient disclosed information, client-centered counseling, and follow up based on individual need

(Alexander et al., 2014; Brookmeyer et al., 2016; Rietmeijer, 2007). The education portion of RRC may be delivered through computer programs or by individual counselors to groups or individuals (Brookmeyer et al., 2016; Carey et al., 2015). The risk reduction component is often done by individual counselors in face to face interactions (Carey et al., 2015). The type of counselor may be an individual educated in the discipline of health promotion (Binkley & Hayden, 2017; McLeroy, Bibeau, Steckler, & Glanz, 1988), physician, nurse, or other type of professional counselor, and trained lay counselors (Dewing et al., 2014; van Loggerenberg et al., 2015).

RRC may vary in intensity from low, moderate, or high intensity (Lagakos & Gable, 2008; LeFevre, 2014; Romero et al., 2017). The duration and the number of counseling sessions determines counseling intensity (CDC, 2012; Romero et al., 2017). The efficacy of RRC based on intensity is discussed in the following section.

Intensity of RRC

RRC designations are low, moderate, and high intensity (Lagakos & Gable, 2008; LeFevre, 2014; Romero et al., 2017). Time determines the intensity of RRC. RRC over 120 minutes is high-intensity counseling, between 30 and 129 minutes is moderate-intensity, and less than 30 minutes is low-intensity (Gooden et al., 2016; LeFevre, 2014; Romero et al., 2017). The 120 minutes required for high-intensity counseling is divided over multiple sessions, while moderate or low-intensity RRC may be completed in one session (Carey et al., 2015; Gooden et al., 2016; LeFevre, 2014; Romero et al., 2017).

Efficacy of RRC

The USPSTF recommended high-intensity RRC based on literature supporting high-intensity RRC (LeFevre, 2014). However, there are reports of reduced risk of STI acquisition after moderate-intensity RRC (DiClemente et al., 2004; Jemmot, Jemmot & O'Leary, 2007; Johnson, Michie & Snyder, 2014; Chambers et al., 2016) and after low intensity RRC (Romero et al., 2017). Much of the research on RRC focused on sexually active adolescent girls and women (LeFevre, 2014; Romero et al., 2017). The USPSTF officials called for additional research on sexually active boys and young men as they are at risk for STIs (LeFevre, 2014). There are four studies of RRC for males: males, age 15-39 years old (Metcalf et al., 2005), African-American men (Henny et al., 2012; Hickson et al., 2017), and African-American men age 18-29 year (Crosby et al., 2009; Hickson et al., 2017). The RRC studies located had follow-up time post-RRC of fewer than 12 months (Brookmeyer, Hogban & Kinsey, 2016; Jemmott et al., 2007; Long et al., 2016).

The rates of STIs, the severity of disease, and treatment access are the subjects of research effort (Alcaraz et al., 2017). Investigators have conducted studies about counseling to avoid STI acquisition; however, there is still a lack of information about moderate-intensity RRC and adolescents over a time period longer than one year. Researchers have also reported contradictory findings about the efficacy of individual moderate-intensity RRC with adolescents (Chin et al., 2012; Goesling et al., 2014; Tibbits, Rosen, & Rajaram, 2017). Additionally, researcher's report that few studies have been replicated (Alcaraz et al., 2017).

Summary

In summary, this chapter contains a brief history of STIs, adolescence, and RRC. Also included is information about the apparent lack of research about individual moderate-intensity RRC with adolescents. The next chapter includes the research method and design elements for this post hoc chi-square study.

Chapter 3: Research Method

For this post hoc chi-square study of moderate-intensity RRC and adolescent and young adult acquisition of STIs, I examined the distribution of STIs between two groups of adolescents and young adults, one that received moderate RRC and a comparison group that did not receive moderate RRC. Chi-square was used to determine to what degree two variables were related by testing for distribution differences between expected and observed data. The independent variable for this study was RRC, and the dependent variable was the STI test result measured as positive or negative. The dependent variable was measured at three points: upon entry to the health care services, at 1 year, and two years following RRC. I examined the distribution of STIs acquired between the two groups, the group of adolescents and young adults whose members received RRC and the group of adolescents and young adults whose members did not. I also examined the distribution of STIs between the two groups on entry to the health care services, before receiving RRC. For this study, STI encompassed chlamydia, gonorrhea, trichomonas, syphilis, and HIV because those were the infections tested at the clinic where the data were gathered. Additional information recorded at the RRC visit were gender, education, race, ethnicity, and sexual orientation. This information was used only to describe the two groups of adolescents and young adults.

Research Method

This study was a post hoc chi-square design with nonequivalent comparison and treatment groups. I used the chi-square to determine differences in the distribution of variables between the two groups of adolescents and young adults, one whose members

received RRC and one whose members did not. Chi-square is used to examine how the distributions of categorical or nominal variables differ from one another (Eck & Ryan, 2012). The independent variable for this study was RRC. As a variable, RRC had two categories, yes or no. The dependent variable was laboratory-confirmed presence of STI at 1 and 2 years after RRC. The variable for STI had two categories, present or not present.

The participants of each group were tested for STIs at point of entry into the health services (Aluma, 2015). The intervention group received the treatment, RRC, at the entry into the health services visit (Aluma, 2015). I used the laboratory STI test data from the entry visit as a pretest administered before an intervention. Laboratory test data have been used for the pretest–posttest research design in healthcare research (Chang & Little, 2018; Singh, Jha, Tiwary, & Agrawal, 2018; Szumilewicz et al., 2017).

Participants were tested again at 1 year and at 2 years after the health services visit. I used the test results from 1 year and 2 years after the health services visit as posttests to compare the number of STIs in the group that received RRC to the group that did not. The STI tests were the laboratory-confirmed presence of gonorrhea, chlamydia, trichomonas, syphilis, HIV, or some combination of these STIs. The laboratory tests for gonorrhea, chlamydia, and trichomonas were reported as positive or negative. The syphilis and HIV tests were reported as reactive or nonreactive. Positive and reactive laboratory reports were categorized as yes for this study. Negative and nonreactive laboratory reports were categorized as no for this study.

Justification for Method

The study aim was to compare two groups regarding the acquisition of STIs (dependent variable) and receipt of RRC (independent variable). The intervention group did receive RRC, and the comparison group did not. For this study, I used chi-square to compare the dependent variable of the groups. Chi-square is useful for comparing observed outcomes with expected outcomes according to hypotheses (Malone & Coyne, 2017). The pretest, posttest nonequivalent comparison group design is an accepted social science and health care research method (Chang & Little, 2018; Singh et al., 2018; Szumilewicz et al., 2017) to provide generally interpretable information about group differences when randomization is not possible (Cook & Campbell, 1979).

The similarity of the two groups was determined with the baseline STI test and demographic variables. I expected the number of positive STI tests to be similar in both groups at point of entry into the health services. I used chi-square to determine whether there is a meaningful relationship between two categorical variables—in this case, the receipt of RRC (yes/no) and the presence of STI (yes/no) at the first and second visit after the RRC visit. I used the post hoc chi-square method for this study because it allowed for the opportunity to examine the efficacy of RRC and to manage moderate-intensity RRC programs.

Purpose

The purpose of this study was to examine the distribution of STIs between two groups of adolescents and young adults, one that received moderate RRC and a comparison group that did not. This approach enabled me to determine with increased

certainty whether RRC affected the outcome variables of this study. The outcome variable was the acquisition of one or more of the following STIs: chlamydia, gonorrhea, trichomonas, syphilis, and HIV. I determined the efficacy of moderate-intensity RRC by the presence of one or more of these STIs at 1 year and at 2 years after receiving the counseling. If receipt of moderate-intensity RRC decreases STI and HIV acquisition, then moderate-intensity RRC may be a useful strategy to decrease STI risk for adolescents and young adults. This knowledge may help health care professionals to develop and implement programs or interventions for the population most vulnerable to long-term morbidity (Borawski et al., 2015; Leichter et al., 2016; Teng et al., 2015).

Research Question

To what degree was the distribution of sexually transmitted infections among adolescents and young adults who received moderate-intensity risk reduction counseling less than the distribution of sexually transmitted infections among individuals who did not receive moderate-intensity risk reduction at 1 and 2 years following the intervention?

Hypotheses

I tested the following hypotheses for the post hoc chi-square study of STI acquisition in adolescents and young adults.

Ho1: There was no statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 1 year post intervention.

Ha1: There was a statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 1 year post intervention.

Ho2: There was no statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 2 years post intervention.

Ha2: There was a statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 2 years post intervention.

Framework

For this post hoc chi-square study, I determined whether RRC decreased the probability of acquiring STIs 1 and 2 years after receiving the counseling. The interrelationship between RRC and acquisition of STIs is explained by social ecology theory (Hong, Voisin, & Crosby, 2015; Li et al., 2017). Social ecology theory is systems based and includes interpersonal relationships that influence individual behavior (Bronfenbrenner, 2005; Maticka-Tyndale et al., 2016; Stokols, Allen, & Bellingham, 1996). The process–person–context model is an example of social ecology theory (Bronfenrenner, 2005). RRC in the health care setting includes three domains: modeling by the RRC counselor, context of the health care visit, and identification of intrapersonal

and interpersonal characteristics placing the individual at risk (Bronfenbrenner, 2005). If some individuals receive an interpersonal interaction and others do not, then according to social ecology theory, those who received the interpersonal interaction may behave differently than those who did not. The chi-square statistic tests for variable distribution between two groups. A chi-square study may be used to examine the distribution of behavior variables related to differences in process. Thus, social ecology theory appears useful for understanding sexual risk behavior changes following the interpersonal interaction of RRC (Holt-Lunstad et al., 2017; Hong et al., 2015; Li et al., 2017).

Sample

The sample was recruited from an urban Midwestern Title X clinic for a program evaluation (Aluma, 2015). For the program evaluation, clinic staff identified potential participants according to a written list. The criteria for participant selection encompassed the following groups: men who have sex with men, bisexual individuals, individuals with multiple partners, adolescents and young adults to age 25, patients with three or more STD visits in 18 months, individuals reporting unprotected intercourse with unknown partner(s), individuals reporting intravenous drug use, and individuals with a partner who was HIV positive or hepatitis positive (Aluma, 2015). Participants self-selected whether to receive RRC (Aluma, 2015).

For this post hoc chi-square study, I accessed a subset of previously collected program evaluation data. The focus of this study was the STI acquisition of adolescents and young adults. Study participants aged 13-26 years comprised the sample for this

study. The upper limit of this age range was set at 26 years to ensure inclusion of participants who were under age 26 for the majority of the 2-year time period.

Sample Demographics

Study participants ranged in age from 13 to 26 years and were cisgender males, cisgender females, and one transgender male. Sexual partner gender preferences included opposite and same-sex partners. Self-identified racial categories of White, Black, mixed, Asian, Hispanic, and non-Hispanic were included in the demographics. Also included in the demographic data were last school grade completed and income category. Income category was determined according to Title X guidelines.

Title X is a federal program for reproductive health care and contraception for individuals of reproductive age, defined as age 13 to 45 years (Office of Population Affairs [OPA], 2014). Fees for health care provided under Title X are determined on the basis of a five-category fee scale according to Federal Poverty Guidelines (OPA, 2014). Federal Poverty Guidelines are updated yearly, and the fee scale is adjusted accordingly every April (OPA, 2014). The income/fee categories are presented as percentages of the Federal Poverty Level, as follows: 100% and under, 101% to 156%, 157% to 191%, 192% to 200%, and over 200% (U.S. Department of Health and Human Services [HHS], 2018). Health care fees for individuals with incomes equal to 100% or less of Federal Poverty Guidelines are covered at 100% by the Title X program without regard to income category, as are health care fees for adolescents 18 years of age and under (OPA, 2014).

Sample Size Calculation

Using GPower to calculate sample size for a one-tailed test with an $\alpha = .05$, $\beta = .95$ and medium effect size of .5 resulted in a sample size of 88 participants. The subset of data I used contained two groups: One group had 300 adolescent and young adult participants, and the other group contained 176 adolescent and young adult participants. Chi-square is robust to unequal-sized groups if the sample size is large enough (Malone & Coyne, 2017). A one-tailed test was appropriate for this study because I was testing for the possibility of the relationship in one direction, reduction of STI in the intervention group (Murphy, 2018). The research question concerned the degree to which RRC decreases STI acquisition. I employed descriptive statistics using gender, age, race, ethnicity, and sexual preference for the purpose of describing the two groups. I tested for significance of distribution differences between the two groups for STI acquisition at 1 and 2 years post RRC, as well as for demographic factors.

Instrumentation

The instruments used to determine the dependent variable, presence of STI at 1 and 2 years post RRC, were Food and Drug Administration (FDA)-approved clinical laboratory tests. The clinical laboratory tests were conducted in a CLIA-certified laboratory housed within the Title X clinic. The clinical laboratory tests used for this study included nucleic-acid amplification tests (NAAT) to identify small amounts of chlamydia and gonorrhea DNA or RNA in clinical laboratory test samples, HIV type 1 and 2 enzyme immunoassay, RPR syphilis tests followed by confirmatory treponemal testing when needed to confirm RPR results, and laboratory microscopy for trichomonas.

Chlamydia and Gonorrhea NAAT Testing

The data included *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG) test results using the Roche Molecular Systems COBAS AMPLICOR NAAT. The Roche NAAT for CT detected the presence of CT plasmid DNA and the NG diplococcus DNA in urine, endocervical swab samples, and male urethral swab samples (Roche Diagnostics, 2003). The established sensitivity and specificity of the Roche CT/NG test were 93% and 96.5%, respectively (Roche Diagnostics, 2003). Nucleic acid detection, when used in conjunction with a staining method, increases the likelihood of confirming an infection (Roche Diagnostics, 2003).

The COBAS AMPLICOR CT/NG test for CT isolates and amplifies specific regions of DNA. An internal control is provided with each test kit. This noninfectious control containing recombinant DNA helps to confirm that no inhibitors to CT or NG target DNA amplification are present (Roche Diagnostics, 2003). Additional external quality control was done at the laboratory for positive and negative samples (Roche Diagnostics, 2003). Strict adherence to procedures for collection, transportation, storage, and processing were necessary to assure reliable results (Roche Diagnostics, 2003).

CT and NG samples were collected and labeled in the health department clinic by an advanced practice registered nurse (APRN) and sent to the CLIA-certified health department laboratory. A laboratory technician performed a stain test on site and then packaged the day's samples in an overnight delivery container according to Roche procedure. An external CLIA-certified laboratory received the previous day's samples and ran confirmatory COBAS AMPLICOR CT/NG tests. The results of the CT/GC

NAAT tests were returned to the health department laboratory electronically. The health department lab then notified the collecting APRN of the confirmatory test results.

HIV Testing

The laboratory technician performed HIV and syphilis testing during clinic visits. The laboratory technician used OraQuick Advance rapid HIV1/2H to test serum obtained during the clinic visit using the plasma procedure described in the OraQuick Advance rapid HIV 1/2H package insert. OraQuick Advance rapid HIV 1/2H has been FDA approved for use with serum. OraQuick Advance rapid HIV 1/2H using plasma is 98% sensitive and 99.5% specific (OraSure Technologies, 2004; Pavie et al., 2010).

Syphilis Testing

The laboratory technician also used the serum obtained during the clinic visit to perform the RPR test, a screening test for syphilis. The RPR is a nontreponemal test used for screening (Saral et al., 2012; USPSTF, 2004). The sensitivity and specificity of the RPR varies by stage of syphilis (Gliddon et al., 2017; Saral et al., 2012). Sensitivity is 78% to 86% for stage 1 syphilis, 100% for stage 2, and 95% to 98% for latent phase syphilis (USPSTF, 2004). Specificity is 98% to 100% for stage 1, stage 2, and latent syphilis (Gliddon et al., 2017; Saral et al., 2012). The laboratory technician then performed confirmatory treponemal testing on all positive RPR tests per laboratory protocol by performing a *Treponema pallidum* particle agglutination assay (TPPA). The TPPA has a stage 1 syphilis sensitivity of 85% to 100% and specificity of 98% to 100% (Gliddon et al., 2017). The sensitivity and specificity for stage 2 syphilis and latent stage syphilis are 95% to 100% and 98% to 100%, respectively (Gliddon et al., 2017).

Trichomonas Testing

APRNs collected vaginal samples using a cotton or rayon swab during the physical exam for STIs during the clinic visit. The collecting APRN then transported the sample in a test tube containing 2 to 3 milliliters of 0.9% saline to the unit-based laboratory. The laboratory technician analyzed the sample using standard wet-mount microscopy using low and high power and reported the wet-mount microscopy findings to the collecting APRN. The sensitivity of wet-mount microscopy ranges from 36% to 75% (Gaydos et al., 2017; Nye et al., 2009; Toskin et al., 2017). Despite the range of sensitivity, wet-mount microscopy is a useful point-of-care test for *Trichomonas* (Brown, Wigdahl, & Stebens, 2018; Drancourt et al., 2016).

Procedure

For this post hoc chi-square study, how initial data were collected is germane to this research. Staff members of the Title X clinic collected data between 2012 and 2016 for the purpose of program evaluation. The data contained demographic variables, STI risk factors, moderate-intensity RRC as the independent variable and presence of STI as the dependent variable for each sample member. Program evaluation plans and procedures were approved by the medical director and the clinical nurse manager of the Title X reproductive health clinic prior to recruiting participants. I used a subset of the program evaluation data for this post hoc chi-square study.

Clinic staff used the clinic registration forms to obtain demographic data (Aluma, 2015). Standard practice in the clinic was for individuals to complete their own registration forms (Aluma, 2015). Thus, demographic data were self-reported. The same

form was used throughout the period of data collection (Aluma, 2015). Individuals with limited literacy were assisted privately by clinical staff reading the registration form questions out loud and recording the individual's response (Aluma, 2015).

Once the demographic form was completed the participant was escorted to the clinical laboratory where the laboratory technician/phlebotomist drew blood for syphilis and HIV testing. Next, the participant was seen by an APRN. The APRN reviewed the participant's medical history and assessed the participant for STI acquisition risk factors. The APRN then offered RRC to participants with STI risk factors. For individuals who accepted the APRN's offer of RRC, the APRN entered an order for RRC into the participant's electronic medical record. Then the APRN physically examined the participant and collected genitourinary laboratory specimens according to a standardized medical protocol approved by the clinic Medical Director (Aluma, 2015). Following the examination and collection, the APRN delivered the specimens to the clinical laboratory. The laboratory technician processed the specimens according to CLIA approved laboratory standards. Preliminary laboratory results were recorded in the electronic medical record of the participant. The APRN reviewed the preliminary results and determined the appropriate treatment according to Center for Disease Control guidelines for the participant. The APRN entered treatment orders into the electronic medical record for the clinic staff Registered Nurse (RN) to administer.

The RN administered ordered treatment to the participant and notified the Risk Reduction Counselor that there was a participant for counseling. The Counselor met with the participant for a 20 to 30 minute individual counseling session during which the

counselor reviewed the participant's risks, discussed ways to avoid or mitigate risks, and encouraged the participant to change risky behavior. The RRC was based on the *HIV Counseling, Testing & Referral Protocol 2012* by the Ohio Department of Health HIV Prevention Program (Aluma, 2015).

Participants were free to return to the clinic according to self-determined need for additional reproductive health care. Clinic staff followed the participants for two years following the visit during which RRC was received.

Secondary Data Collection Procedure

Upon receipt of Walden University IRB approval (number 11-20-19-0360607), I requested information on a subset of participants ages 13 to 26 for this post hoc chi-square study of the effect of RRC on STI acquisition. The information requested was limited to descriptive data: age, gender, education, race, ethnicity, and sexual partner gender preference, and the study variables, RRC and STI. Health department personnel provided de-identified data on an Excel spreadsheet. The Excel spreadsheet with the requested data was transmitted to me electronically. The cases were identified with a research number only and the personally identifying information was removed before I received access to the cases. The data included a vulnerable population; individuals less than 18 years of age who presented to the Title X clinic for STI. Data was stored in a password protected computer.

Data Management

Health department personnel entered de-identified data of participants onto an Excel spreadsheet. A second Excel spreadsheet was created from the first Excel

spreadsheet. The second Excel spreadsheet contained de-identified data of participants age 13 to 26, the demographic data of those participants, and the variables of the proposed secondary analysis. Worksheets and forms used to collect the original data are maintained in the clinic where the data was collected in a locked filing cabinet in the locked office of the clinical nurse manager (see Appendix C).

Processing

I transferred the data from the Excel spreadsheet to SPSS. Then I examined the data for accuracy and completeness. I compared data that appears inaccurate with the Excel spreadsheet and, if necessary, with the original data collection forms maintained by the clinic. I made corrections in SPSS so that the data in SPSS matched the data contained in Excel or on the original data collection forms.

Data Management

The Commissioner of Public Health provided an Excel spreadsheet containing the study data bereft of personal information. I used a password protected computer for data storage. Data was stored on a removable USB flash drive dedicated for this project. I stored written documents created for this study in a dedicated locked filing cabinet. I will keep the records for the time period required by the Institutional Review Board of Walden University. When that time period is completed, I will shred written records and delete computer records.

Analysis

I used chi-square to examine the distribution between individual moderate-intensity RRC (yes/no) and the acquisition of STI (present/not present) across time

periods. I also used chi-square to analyze the means of two independent groups of adolescents and young adults. Chi-Square is a robust test for examining the association between two categorical variables and for determining the difference between two group means (Plichta, Kelvin, & Munro, 2013). I used the laboratory testing to determine the presence of STI at the time of RRC, at one-year post-RRC, and at two-years post-RRC. There was one dichotomous independent variable for this study, RRC, coded as yes or no. There was one dichotomous dependent variable, the presence of STI, coded as present or not present. The STI's tested for were trichomonas, chlamydia, gonorrhea, syphilis and HIV for all time periods.

Validity

Validity refers to whether the concepts contained in the research were accurately measured (Heale & Twycross, 2015). Variables should accurately represent the concepts of interest for a study to be valid. In this case the concepts of interest were RRC and presence of STI at one- and two-years post RRC. These variables follow logically from the research question of to what degree RRC decreases STI acquisition.

Validity of the Method

The threats to validity of the chosen research method included the interaction effect of testing and instrumentation, maturation, and the threat of history (Wisdom, Cavaleri, Onwuegbuzie, & Green, 2012). Pretesting and posttesting of the groups yielded information that increased interpretability and helped control for those internal threats to validity (Campbell & Stanley, 2015). Control of threats to validity increases as the pretest similarity between the groups increases (Campbell & Stanley, 2015). Using an $\alpha = 0.05$

and $\beta = 0.95$, a sample of 44 subjects per group has adequate power for analysis. These parameters limit the risk of a type 2 error to $1 - \beta = 0.05$ and a type 1 error to 0.95%. A smaller risk of error could be achieved with a larger sample size but this is a post hoc secondary analysis and the sample size could not be increased. Treating the laboratory test results as a pretest is supported by other health care studies that used physiologic or clinical laboratory measures as pretests (Chang & Little, 2018; Singh et al., 2018; Szumilewicz et al., 2017).

Validity of the Data

The clinic staff recorded the demographic variables reported by the participants. Thus, participant veracity was a potential threat to validity (Ary, Jacobs, Sorensen, & Walker, 2014). In addition, the nonrandom sampling used in this study means the findings are not generalizable but can only be applied to the population attending urban Title X clinics in the Midwest. The sensitivity and specificity reported in the instruments section of this chapter promotes the instrument validity used to test for STIs. Each laboratory test was specific for the detection of the particular STI the test was designed to identify and did not detect other STIs.

Validity of Chi-Square

Chi-square was an appropriate statistical test to determine differences in the distribution of variables between two groups of adolescents and young adults when the variables are nominal (McHugh, 2013). This statistical test was also appropriate for detecting the differences in observed versus expected values (McHugh, 2013). In this case, the difference examined was the acquisition of STI at one year and at two years post

RRC as a dichotomous variable with a response of present or not present. Chi-square is a nonparametric test that is robust to violation of the assumptions of chi-square (McHugh, 2013). Nonparametric tests are useful for analyzing data with unequal group size (McHugh, 2013).

Reliability

Interrater reliability, test or instrument reliability, and statistical reliability were pertinent to this study. Reliability refers to the consistency of the measurement or test. Information in the subsequent section includes the three attributes of reliability, homogeneity, stability, and equivalence.

The limited number of clinical laboratory technicians employed full-time in the clinic supported instrument reliability by decreasing the number of differences between users. There were only two clinical laboratory technicians employed throughout the data collection (Aluma, 2016). The laboratory director documented clinical competency of laboratory technicians through biannual testing according to CLIA standards and established interrater reliability. Consistent test results between the two users, the laboratory technicians, indicated equivalence is present (Heale & Twycross, 2015). Since the laboratory tests for STI each measure, or detect, only one specific STI with a stable sensitivity and specificity, the instruments used to measure the dependent variable were stable. The same FDA approved tests were used throughout the data collection period (Aluma, 2016). Homogeneity, or internal consistency, was achieved because only one instrument is used to measure the independent variable, receipt of RRC (yes/no) and each laboratory test measures only one type of STI to determine presence at time of testing.

The types of STI, gonorrhea, chlamydia, trichomonas, syphilis and HIV, were collapsed into one dichotomous dependent variable, STI present or not present.

The reliability of the chi-square statistic is established when the assumptions of the chi-square test are true (Heale & Twycross, 2015; McHugh, 2013). The assumptions of chi-square are the sample is random, observations are independent, and frequencies are large (Yockey, 2017). However, chi-square is robust to the violation of nonrandom sampling (McHugh, 2013). Because chi-square is a significance statistic I evaluated the strength of the statistic with Cramer's V , a strength statistic (McHugh, 2013).

Ethical Procedures

I obtained the Walden University Institutional Review Board (IRB) approval (number 11-20-19-0360607) prior to study initiation. This was a post hoc chi-square analysis using information from adolescents and young adults contained in the data. The age of consent for reproductive health services in Ohio is 13 (Physicians for Reproductive Choice and Health®, 2005). Adolescents are recognized as a vulnerable population by the Department of Health and Human Services (DHHS). De-identified health data collected are not subject to Health Insurance Portability and Accountability (HIPAA) regulations. Subsequent publications or presentations of this study will present and include only aggregated data (National Institute of Health, n.d.).

In the Health Department program evaluation, participants were protected through the use of a protocol and each participant was offered the opportunity to participate (Aluma, 2015). There were no negative consequences for declining to participate (Aluma, 2015). Participation had the possible benefit of gaining knowledge about how to avoid

the risks associated with sexual activities (Aluma, 2015). Whether an individual chose to participate in the health department sexual risk education program had no effect on the care he or she received (Aluma, 2015). I informed the Health Department of who was handling the information, what the analysis of the data searched for and any applications, and why the study was necessary. I was the only researcher to handle the data and I maintained ongoing communication with the agency. I did not share the data with any other parties.

Summary

The purpose of this post hoc chi-square study was to examine the distribution of STIs acquisition among 13-24 year old individuals who received RRC and those who did not. I expected to find that individuals who received RRC had fewer subsequent STIs measured at one and two years following the RRC. In this chapter, I described the quantitative design of this study, including sample, instruments, procedure and analysis. Finally, I offered the validity and reliability, ethical considerations and human subjection protection for this study. I present the study results in Chapter 4.

Chapter 4: Results

Introduction

The purpose of this quantitative post hoc chi-square study of two nonequivalent groups was to determine if moderate-intensity RRC decreased the acquisition of STIs in adolescents and young adults. I accessed data containing longitudinal information from May 2013 to 2016 about two groups of adolescents and young adults, one that received RRC and one that did not. Biological samples of both groups were analyzed with standard FDA-approved tests for the presence of STIs. Biological samples taken at Time I (before RRC) served as the pretest for this study, and biological samples taken at Time II and again at Time III served as the posttests. This chapter contains the study research question, hypotheses, and results of the chi-square analysis. This chapter also contains the data collection procedure, descriptive and demographic characteristics of the sample, and representativeness of the sample in relation to the population.

Research Question

To what degree was the distribution of sexually transmitted infections among adolescents and young adults who received moderate-intensity risk reduction counseling less than the distribution of sexually transmitted infections among individuals who did not receive moderate-intensity risk reduction at 1 and 2 years following the intervention?

Hypotheses

I tested the following hypotheses for the post hoc chi-square study of STI acquisition in adolescents and young adults.

- Ho1: There was no statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 1 year post intervention.
- Ha1: There was a statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 1 year post intervention.
- Ho2: There was no statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 2 years post intervention.
- Ha2: There was a statistically significant decrease in the distribution of STIs between the group of adolescents and young adults that received moderate-intensity RRC and the group of adolescents and young adults that did not at 2 years post intervention.

Results

To test whether the proportions of STI at Times I, II, and III were different between the two groups of adolescents and young adults, I used a χ^2 test of independence with alpha $\alpha = .05$ for significance. At Time I, before RRC was received, there was no statistically significant difference in the number of STIs between the treatment group and the comparison group, $\chi^2(1, n = 466) = .683, p = .409, ns$. Thus, there was no

statistically significant difference in the distribution of STIs between the treatment and the comparison group before receiving RRC. One year after RRC was received, there was a statistically significant decrease in the distribution of STIs between the treatment group and the comparison group, $\chi^2(1, n = 466) = 9.543, p = .002$. Thus, the null hypothesis is rejected. There was a statistically significant decrease in the distribution of STIs in the treatment group compared with the comparison group at 1 year after receiving RRC. There was also a significant decrease in the distribution of STIs between the two groups 2 years after RRC was received, $\chi^2(2, n = 466) = 11.275, p = .002$. The null hypothesis is rejected. There was a statistically significant decrease in the distribution of STIs in the treatment group compared with the comparison group 2 years after receiving RRC.

I used Cramer's V as a measure of effect size. The effect size at 1 and at 2 years after receiving RRC was statistically significant. There was no statistically significant difference in the distribution of STIs prior to receiving RRC, so the effect size was not important.

Table 1

Effect Size and Statistical Significance Before and After RRC

| Variable | Cramer's V | Significance |
|-------------------|--------------|--------------|
| Before RRC | .038 | .409 |
| 1 year after RRC | .143 | .002 |
| 2 years after RRC | .156 | .004 |

Note. $p < .05$.

Statistical Assumptions

There were three assumptions for chi-square pertinent to this study. First, the analysis was between two categorical variables. Second, observations were independent. Third, the expected cell frequencies were greater than five for at least 80% of the cells (Field, 2009; McHugh, 2013).

The assumptions of chi-square were met for this study. I analyzed dichotomous variables for RRC and STI. I entered study participants into SPSS by participant number; each number was used only once, and there was no duplication of participant numbers. I verified that 86% of the time cell frequencies were greater than five.

Secondary Data Collection Procedure

The public health department staff provided the study data, collected from 2012 to 2016, in a Microsoft Excel document. The cases were identified with research number only; personally identifying information was removed before I received access to the cases. The data included a vulnerable population: individuals less than 18 years of age who presented to the Title X clinic for STIs. The data were cleaned and transferred to SPSS. Participants 13 to 26 years of age were included. The data of participants were examined for descriptive information (age, gender, education, race, ethnicity, and sexual partner gender preference) and the study variables, RRC and STI. Data were stored in a password-protected computer.

Demographic and Descriptive Data

There were 476 study participants aged 13 to 26 years. Demographic information was self-reported and reflected categories used by the U.S. Census Bureau. The sample

was 21% White with 96 participants, 56% Black/African American with 260 participants, 0.4% American Indian with two participants, 0.4% Asian with two participants, 1.5% Mixed with seven participants, and 21% Other with 97 participants. Two participants (0.4%) did not identify race so were classified as unknown. The U.S. Census Bureau (2019) reported the racial demographics of the city where the study site was located as 40% White, 50% Black/African American, 0.5% American Indian, 2.4% Asian, 4% Mixed, and 4% Other. Participants identified as Hispanic (24%) or non-Hispanic (76%). The population in the neighborhood surrounding the city is 23% Hispanic according to a local government website. Educational achievement data for the city indicate that 70% of residents have a high school diploma or higher and 17% hold a bachelor's degree or higher (U.S. Census Bureau, 2019). Fifty-one percent of the study participants had achieved a high school diploma or higher, and 8% had a bachelor's degree or higher. Gender identification data for study participants were as follows: 39% cis female, 60% cis male, and < 1% were transgender male. Gender data for the city indicated that 52% of residents are female (U.S. Census Bureau, 2019). Male and transgender data were unavailable.

Table 2

Sample Demographic and Descriptive Data

| Characteristic | Treatment group | Comparison group | <i>P</i> |
|------------------------------|-----------------------------------|--|----------|
| Race | | | 0.090 |
| Race: White | 21% (62) | 20% (34) | |
| Race: Black/African American | 56% (168) | 55% (93) | |
| Race: American Indian | 0.7% (2) | | |
| Race: Asian | 0.7% (2) | | |
| Race: Mixed | 0.3% (1) | 3.6% (6) | |
| Race: Other | 21% (62) | 21% (35) | |
| Race: Did not answer | 0.7% (2) | | |
| Race: Hispanic | 24% (72) | 76% (127) | 0.797 |
| Age in years (Mode) | 13-26 (21) | 14-26 (19) | 0.021 |
| Gender | | | 0.028 |
| Gender: Male | 65% (195) | 53% (89) | |
| Gender: Female | 35% (105) | 46% (77) | |
| Gender: Trans male | | 0.6% (1) | |
| Education | 2nd grade - master's (HS grad) | 8th grade - 1-year post bachelor's (HS grad) | 0.034 |
| Sexual preference | | | 0.027 |
| Sexual preference: Opposite | 79% (237) | 68% (114) | |
| Sexual preference: Same | 13% (40) | 19% (32) | |
| Sexual preference: Both | 8% (23) | 13% (21) | |

Note. $p < .05$.

The number of participants in the treatment group (adolescents and young adults who received RRC) was 300, and the number of participants in the comparison group (adolescents and young adults who did not receive RRC) was 176. I used chi-square analysis to determine group similarity with Cramer's *V* to determine the strength of the chi-square statistic. There were no statistically significant differences in demographic or descriptive variables between the treatment group and the comparison group.

Table 3

Differences Between the Treatment and Comparison Groups

| Variable | $\chi^2 (df)$ | Significance | Cramer's V | Significance |
|---------------------------|---------------|--------------|--------------|--------------|
| Age | 25.341(13) | .021 | .233 | .021 |
| Gender | 7.132(2) | .028 | .124 | .028 |
| Sexual partner preference | 7.202(2) | .027 | .124 | .027 |
| Hispanic | .066(1) | .822 | .012 | .797 |
| Race | 10.958(6) | .090 | .153 | .090 |
| Education | 23.653(13) | .034 | .225 | .034 |

Note: $p < .05$

Summary

The research question that drove this study concerned the degree to which the distribution of STIs among adolescents and young adults who received moderate-intensity RRC was lower than the distribution of STIs among adolescents and young adults who did not receive moderate-intensity RRC at 1 and 2 years following RRC treatment. Based on a Cramer's V at 1 year of .143 ($p = .002$) and at 2 years of .156 ($p = .004$) after receiving RRC, I concluded that RRC had a small but statistically significant effect on the decrease in distribution of STIs among the treatment group compared to the comparison group.

This chapter summarized the findings for this post hoc chi-square study about the distribution of STIs among adolescents and young adults who received moderate-intensity RRC. These findings have implications for reducing the rate of STIs among

adolescents and young adults. Chapter 5 includes a discussion about these implications and the potential social change that could be achieved through the use of RRC.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this post hoc chi-square study was to examine the distribution of STIs between two groups of adolescents and young adults, one that received moderate RRC and a comparison group that did not. Public health officials have identified STIs as an urgent public health problem that affects adolescents and young adults disproportionately. CDC officials have reported that there are approximately 10 million new STIs in adolescents and young adults every year (Braxton et al., 2018). Adolescents and young adults who received RRC for this study had fewer STIs 1 year (19% vs. 32%) and 2 years (7% vs. 12%) following RRC than the comparison group of adolescents and young adults who did not receive RRC.

Results

To test whether the proportions of STIs at Times 1, 2, and 3 were different between the two groups, I used a χ^2 test of independence with alpha $\alpha = .05$ for significance. At Time 1, before RRC was received, there was no statistically significant difference in the number of STIs between the treatment group and the comparison group, $\chi^2(1, n = 466) = .683, p = .409, ns$. Thus, there was no statistically significant difference in the distribution of STIs between the treatment and the comparison group before receiving RRC. One year after RRC was received, there was a statistically significant decrease in the distribution of STIs between the treatment group and the comparison group $\chi^2(1, n = 466) = 9.543, p = .002$. Thus, the null hypothesis is rejected. There was a statistically significant decrease in the distribution of STIs in the treatment group

compared with the comparison group at 1 year after receiving RRC. There was also a significant decrease in the distribution of STIs between the two groups 2 years after RRC was received, $\chi^2(2, n = 466) = 11.275, p = .002$. The null hypothesis is rejected. There was a statistically significant decrease in the distribution of STIs in the treatment group compared with the comparison group 2 years after receiving RRC.

I used Cramer's V as a measure of effect size. The effect size at 1 year (.143, $p < .002$) and at 2 years (.156, $p < .004$) after receiving RRC was statistically significant. There was no statistically significant difference in the distribution of STIs prior to receiving RRC, so the effect size was not important.

Interpretation of the Findings

Researchers have reported contradictory findings about the efficacy of individual moderate-intensity RRC with adolescents (Chin et al., 2012; Goesling et al., 2014; Tibbits et al., 2017). There has been no information about RRC efficacy over a time period longer than 1 year. Additionally, researchers have reported that few studies have been replicated (Alcaraz et al., 2017). The findings in this study confirm the efficacy of RRC in adolescents and young adults up to 1 year after treatment and extend knowledge to 2 years after treatment. Based on the difference in distribution of STIs between the treatment and the comparison group, I conclude that moderate-intensity RRC decreases the number of STIs for 2 years after the counseling is received. Additionally, because there is no significant difference between one year and two years post RRC, I conclude there is no *washout* effect. Rather, the efficacy of RRC is consistent for two years without additional intervention (Nguyen et al., 2019).

Changes in sexual risk behavior following the interpersonal interaction of RRC may be explained through social ecology theory (Holt-Lunstad et al., 2017; Hong et al., 2015; Li et al., 2017). RRC in this study included the three domains of social ecology theory: modeling by the RRC counselor, context of the health care visit, and the identification of intrapersonal and interpersonal characteristics placing the individual at risk (Bronfenbrenner, 2005). Individuals who received an interpersonal interaction behaved differently than individuals who did not. The change in behavior may have allowed adolescents and young adults to avoid or mitigate risk for acquiring an STI.

Limitations of the Study

This retrospective post hoc chi-square study had several limitations. First, a subset of the study population was created based on age. This post hoc study used a subset of the sample, consisting of 13- to 26-year-old people who sought healthcare services for STIs in an urban Midwestern Title X clinic for analysis. This subset was analyzed for differences in distribution of STIs. Using a small subset of a population increases the risk of spurious findings if the statistical significance of the subgroup difference varies from the larger population (Higgins & Green, 2011). However, the subset was 476 individuals, a large enough sample to overcome the risk. Additionally, multiple analyses of the same subgroup increase the risk of a Type I error of false-positive findings (Stephens, Smith, & Donnelly, 2001). To mitigate this risk, I analyzed the data for 1 year post RRC and 2 years post RRC separately.

Additionally, this study used data collected between May 2012 and May 2016 for program evaluation to examine the relationship between RRC and STI in sexually active

individuals aged 13-26 years. Lack of randomization and self-selection bias limit the generalizability of this study (Cleave, Nikiforakis, & Slonim, 2013; Simons et al., 2017).

This study is generalizable to Midwestern urban Title X clinic clients, ages 13 to 26 years. White, Black, and Hispanic individuals were represented in adequate numbers for generalizability and mirrored the racial and ethnic background of the geographic area surrounding the clinic. There were too few Asian, mixed ethnicity, and Native American participants in the sample for generalizability. Males and females were represented, as were various sexual partner preferences.

Recommendations

More research is needed to build a comprehensive understanding of the efficacy of moderate-intensity RRC. Randomized studies are needed to control for the limitation of self-selection bias present in this study. Additional studies in Title X clinics and other healthcare settings, such as family practice and pediatric practices and clinics, are needed to include members of all socioeconomic groups. Research is also needed to examine the efficacy of moderate-intensity RRC for Asian, Native American, and mixed ethnicity adolescents and young adults, as they were not well enough represented in this study. This study had only one self-identified transgender participant, so no information for the transgender population was discerned. The efficacy of RRC for transgender individuals also needs additional research. Finally, adolescents and young adults in suburban and rural areas also need to be studied for RRC efficacy.

This study also needs to be replicated in order to verify consistency of findings. This post hoc chi-square study could be replicated using moderate-intensity RRC to

examine the efficacy for transgender individuals. I recommend replication of this study in rural areas and in other geographic regions of the United States. This study took place in a Midwestern urban clinic. To increase knowledge about the efficacy of moderate-intensity RRC, research is needed in the Northeast, Southern and Western cities, and rural regions of the country.

Implications

The findings of this study have implications at the individual level for improving individual health. The avoidance of one STI mitigates the acquisition of a second concomitant STI (Plan, 2018). These study findings also have potential for creating positive societal change. The cost of diagnosing and treating STIs is estimated to be \$16 billion annually (Braxton et al., 2018; CDC, 2013). STI avoidance has the potential to reduce this economic burden.

A disproportionate number of STIs are contracted by adolescents and young adults with significant medical sequelae (Braxton et al., 2018; CDC, 2013; Friedman et al., 2014). The sequelae of STIs include PID; infertility (Apari et al., 2014; Braxton et al., 2018); increased infant morbidity and mortality, including preterm birth and stillbirth (Johnson et al., 2014; Manabe et al., 2015; Sangkomkamhang et al., 2015); and threat to the adolescent's life by spread of pelvic infection to systemic disease, such as myocardial dysfunction (Morgan et al., 2018). Additionally, the presence of one infection predisposes the individual to acquisition of additional infections, such as HIV, as a result of biochemical processes in the body (Risser et al., 2017). Incorporating moderate-intensity RRC has the potential to improve individual health by decreasing the acquisition

of STIs in adolescents and young adults. Fewer STIs may, in turn, lead to the decreased frequency of associated adverse sequelae.

Recommendations for Practice

The RRC referred to in this study was an established program with consistent evidence-based content provided by one person. The provision of individual assessment and educating the at-risk individual about risk avoidance or mitigation is an effective way to decrease the number of STIs in sexually active adolescents and young adults (Brookmeyer et al., 2016). For individuals who have not reached coitarche, generalized education on risk factor avoidance may be more appropriate than an assessment of individual risk factors and risk avoidance (Marcell et al., 2018). A health care provider, educator, or counselor should provide an assessment and consistent evidence-based RRC at least once (Hogben et al., 2020). Moderate-intensity RRC is an effective way to convey essential information to most adolescents and young adults.

Conclusion

Moderate-intensity 1:1 risk reduction counseling is a low-cost and effective way to decrease the number of STIs in urban adolescents and young adults attending Title X clinics. Education about individual risk factors for acquiring an STI allows individuals to change their behavior to mitigate risk. Moderate-intensity RRC has the potential to positively impact the social and economic social burden of STIs. These study findings also have potential for creating positive societal change by effecting disparate health outcomes and lowering cost.

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Appendix A: Risk Reduction Counseling Program at [REDACTED] Summary

The program was initiated in May 2012 based on the consensus reached in March of 2012 between Karen Aluma, M.D., Lucinda Farina, M.S.N. and Ann Avery, MD. Dr. Aluma requested the March 2012 meeting to share her idea of providing preventive counseling for Reproductive Health Clinic patients using the curriculum provided by the Ohio Department of Health (see Appendix A). Based on the consensus reached by Aluma, Farina, and Avery, Dr. Aluma created the list of criteria for individuals most at risk for acquiring a sexually transmitted infection (see Appendix B). The goal of the program was to increase individual client knowledge about sexual risk factors and infection prevention. It took from March to May to educate staff on the project and to gain buy-in from the staff. We piloted the program from May 2012 to September 2012. From the pilot study data, we determined that 97% of the clients who had received risk reduction counseling did not return to the clinic in the three months following the counseling. We considered this a success because clients did not need to return due to symptoms of infection or lack of knowledge. Based on this preliminary data for program evaluation, we decided the program should continue and that we should expand our definition of program success to avoiding acquisition of sexually transmitted infections for six months.

Clients Served by Program

In the sample of the first 186 clients with complete data during the first year of the program, there were 137 males and 48 females in the data set. Client age ranged from 14 to 62 years of age. Ninety-four percent were unmarried and 73% reported income less

than 100% of the Federal Poverty Level. The average level of education was 12th grade or equivalent. All sexual preferences are represented in the data, although at unequal group numbers. Heterosexual orientation is recorded at 63%, Homosexual orientation is recorded at 22%, Bisexual orientation is 11%, and 4% declined to provide that information. As of February 11, 2016, there were 862 clients who received risk reduction counseling. Further analysis will be needed to include the larger data set.

Neighborhoods of residence were also recorded by zip code. Almost 26% of the clients reside in the [REDACTED] neighborhoods ([REDACTED]). The next largest group, 11%, resides in zip code [REDACTED], representing the [REDACTED] and [REDACTED] neighborhoods as well as part of the southern parts of the [REDACTED] and [REDACTED] neighborhoods. Approximately 6% of clients reside in each of the following: zip code [REDACTED] ([REDACTED] and [REDACTED] neighborhoods), [REDACTED] ([REDACTED] and [REDACTED]), [REDACTED] ([REDACTED] and the southern portion of [REDACTED]) and [REDACTED] ([REDACTED] and [REDACTED] neighborhoods). This accounts for 61% of the [REDACTED] Reproductive Health Clinic's client population. The remaining 39% of clients are drawn from 35 additional zip codes.

Preliminary Program Efficacy Results

Our analysis is based on comparing simple percentages; 61% of clients who received risk reduction counseling did not return to the clinic for additional services during the six months following risk reduction counseling. Of the clients who did return, 21% returned once, 9% returned twice, and 8% returned three or more times. The

majority of the clients who returned more than once were seeking ongoing contraception, such as Depo-Provera injections or birth control pill refills.

There was no significant change in percentage for use of condoms or number of sexual partners in the last 60 days before the six month visit. Having only one sexual partner in the past year, as opposed to having more than one sexual partner, increased by 7%. There was a 32% decrease between use of alcohol or drugs before sex for from the time of risk reduction counseling and six months later. Almost 47 % of the clients who received risk reduction counseling had a sexually transmitted infection at the risk reduction counseling visit. Of the clients who returned for a subsequent visit six months later, 13% had a sexually transmitted infection representing a 33% decrease in infection. Breaking down the rates of the individual sexually transmitted infections, there was a 14% decrease in Chlamydia, an 11% decrease in Trichomonas, a 16% decrease in gonorrhea, a 1% decrease in syphilis, and a 7% decrease in clients with a combination of sexually transmitted infections.

Discussion

The efficacy of risk reduction counseling using the curriculum provided by the Ohio Department of Health appears to be beneficial to the clients served by the [REDACTED] Reproductive Health Clinic. It may be equally effective at the [REDACTED] clinic. Having a dedicated counselor at [REDACTED] makes it possible to provide 1:1 moderate-intensity counseling during a client visit for testing and diagnosis. This is particularly important since the majority of our clients access the clinic as walk-in patients.

Identification of the neighborhoods the majority of patients reside in helps [REDACTED] to determine where the [REDACTED] vehicle should be located on Monday afternoons for maximum impact. Recreation centers and other public gathering places in the [REDACTED] [REDACTED], and the southern parts of the [REDACTED] and [REDACTED] neighborhoods may increase the number of people accessing reproductive health services through [REDACTED].

Lucinda Farina, MSN, CNM

Appendix B: Risk Reduction Counseling Program Participant Referral Criteria

Criteria for Counseling Referral (May be referred by APN or RN)

Men who have sex with men.

Bisexual

Multiple partners

All adolescents (13 -19 years old) and young adults to age 25-

Patient with 3 or more visits for STD testing in the past 18 months

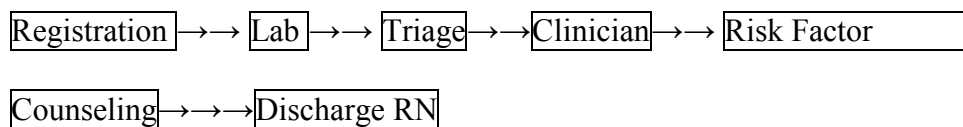
UPI with unknown partner/s

Intravenous drugs using (IDU)--

Partner who is HIV Positive (HIV+)-

Partner who is Hepatitis B/C Positive

Clinic Flow



Appendix C: Data Collection Worksheet

Risk Reduction Counseling Program at [REDACTED]

Data Collection Worksheet: RRC Program Evaluation

Subject Number _____

This number is assigned by the data collector. These numbers should run 001-600.

Date of Index Visit _____ Format as 03152012 (mo/day/year)

This is the visit the subject **received** Risk Reduction Counseling (RRC) with K Aluma or **should have received** Risk Reduction Counseling (RRC) with K Aluma.

Number of visits to clinic in 12 months **before** Index Visit _____Number of visits to clinic in 12 months **after** Index Visit. _____

Subject received RRC 1. (Yes) 2. (No) How many times? _____

Circle 1 if yes, Circle 2 if no.

1 will be intervention group and 2 will be comparison group.

Demographic Data

Age in years _____

Gender 1 Male 2 Female 3 Transgender M ->F 4 Transgender F ->M

marital status 1 Married 2 Not Married

Hispanic 1 Yes 2 No

Weekly Income _____

Record dollar amount of weekly income provided by patient on demographic intake form in medical record. Convert to ABCDEF category according to corresponding Federal Poverty Level per Title X guidelines.

sexual preference 1 Opposite 2 Same 3 Both

Education _____

Highest grade completed as provided by patient on demographic intake form or as recorded by Clerk in EMR demographic page. Record as whole number (10, 11, 12, 13, 14, etc.)

Race 1 white
 2 Black/African American
 3 American Indian/Alaskan Native
 4 Asian
 5 Mixed
 6 Pacific Islander/Hawaiian Native
 7. Other
 8 Unknown

Record information provided by patient on demographic intake form or as recorded by Clerk in EMR demographic page. If no information is recorded choose 8 unknown.

Zip Code _____

88 out of County limits

99 unknown

Neighborhood See map to identify neighborhood (Inclusion criteria : Resident of ██████ County, including college students who reside in ██████ County during school)

Risk Avoidance Behaviors

| Index visit (time 1) | last Subsequent Vs. within year index of index vs (time 2) | 2 years after (time 3) |
|--|--|--|
| Use of Condoms: use 99 for unknown 1 Always 2 Sometimes 3 Never 99 Unknown | Use of Condoms: use 99 for unknown 1 Always 2 Sometimes 3 Never 99 Unknown | Use of Condoms: use 99 for unknown 1 Always 2 Sometimes 3 Never 99 Unknown |
| Number of partners in last 60 days _____ | Number of partners in last 60 days _____ | Number of partners in last 60 days _____ |
| Number of partners in last year _____ | Number of partners in last year _____ | Number of partners in last year _____ |
| Sex with alcohol or drug use 1 yes 2 no | Sex with alcohol or drug use 1 yes 2 no | Sex with alcohol or drug use 1 yes 2 no |
| Sex for money or drugs 1 yes 2 no | Sex for money or drugs 1 yes 2 no | Sex for money or drugs 1 yes 2 no |

Outcomes

Presence of STI during 12 months prior to index visit or at index visit 1 Yes 2 No

99 unknown

Which one(s): 1 Chlamydia 2 Trich 3 Gonorrhea 4 syphilis 5 Combination

circle all that apply

Presence of STI during 12 months after index visit: 1 Yes 2 No 99 unknown

Which one(s) : 1 Chlamydia 2 Trich 3 Gonorrhea 4 syphilis 5 Combination

circle all that apply

STI at 2 year visit (+ or – 6 mos) 1 yes 2 no

HIV testing R=1 NR = 2

Index visit 1 2 1 year after vs 1 2 2 years after vs 1 2