

Reducing Reoccurrence and Complications of Gc/Ct

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Submitted: 20 July 2017; Accepted: 29 July 2017; Published: 29 Nov 2017

Introduction

Gonococcal Neisseria (GC) and Chlamydia Trachomatis (CT) infections account for the largest number of reported cases of any infectious disease in the United States. The rates at which these infections occur are on the rise. Gonococcal Neisseria (GC) and Chlamydia trachomatis (CT) infections are also among the commonly curable sexually transmitted infections (STI)(California Department of Public Health, 2011). Though subsequent infections are preventable, reinfection rates are high [1]. As many as 20% of patients, especially females, reacquire GC or CT within six months after the initial positive test and treatment, and it is estimated that as many as 40% of adolescents get re-infected after an initial episode of GC and/or CT annually [2]. Chlamydia represents the most common reportable disease in the United States, and has comprised the largest proportion of all sexually transmitted infections (STIs) reported [3].

The Center for Disease Control and Prevention (CDC) reported a total of 1,526,658 chlamydia infections in 2015. This case count represents an increase from the 2000-2011 report, with a rate increase from 251.4 to 478.8 cases per 100,000 people [3]. One of the leading contributors to these high rates of reinfection is risky sexual behavior [4]. It has been demonstrated that adolescents and young adults who have greater knowledge about STIs do better in identifying the difference between symptoms of curable (gonorrhea, chlamydia, syphilis, etc.) and incurable (HIV, Herpes, etc.) STIs [5]. Clark et al elaborated on the need for educational intervention and its benefits in addressing risky sexual behaviors. Stressing further on the importance of improving and balancing STI education in a way that the adolescents will receive and retain detailed age appropriate STI information, and also the need for information that is consistent with their risk for disease. Educational interventions targeting risky sexual behaviors may play a role in addressing these high rates of infections and reinfections.

Background/Significance

According to the United States Preventive Services Task Force (USPSTF), there are 19 million new cases of STI annually; 50% of these new cases occur among individuals between the ages of 15 and 24 years [4]. This population also has a high frequency of re-infection rates of GC/CT. Adolescent women especially those between the ages of 15 to 19 years are at high risk of contracting and transmitting STIs especially GC/CT [4]. In 2013, the CDC reported that women between 15-24 years of age had the highest

prevalence of GC/CT infections [3].

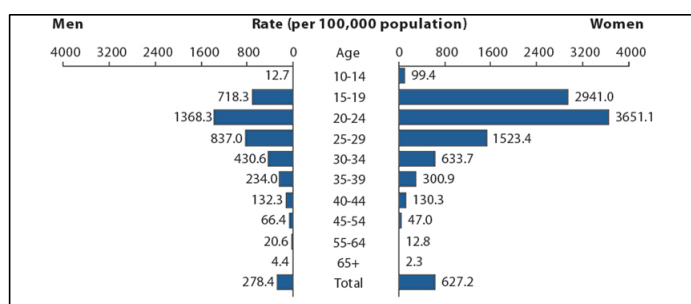


Figure 1: Chlamydia rates of reported cases by age and sex, United States [6].

The cost of managing STIs is high. In 2008, there was an estimated direct cost ranging from \$182 to \$546 per case of chlamydia in women with an average of \$364 per case, and \$15 to \$45 in men with an average cost of \$30 per case. Direct costs for treating GC infections ranged from \$182 to \$546 in women and \$40 to \$119 in men respectively (USPSTF, 2014). Although \$365 for the treatment of one case of chlamydia seems a reasonable cost, the cost is high when considering the total annual number of cases. In addition when each individual case is multiplied by the number of reoccurrences per year, the actual cost and burden to the society and U.S health care system is significant.

Similar to the national data reported by the CDC, GC and CT infections are high in New Jersey. From 2010 to 2014, there had been a significant increase in the number of new and repeated cases of GC/CT infections. In 2010 there were 5, 872 reported cases of Gonorrhea and 26,142 Chlamydia infections in New Jersey. In 2014, the total number increased to 7, 859 reported cases of gonorrhea, and 29,950 reported Chlamydia infections [7].

Risky sexual behaviors are highly correlated with rates of STI and are a major health concern among adolescents and young adult women in the United States. These behaviors include multiple sexual partners, sometimes within the same group in a community. The pattern of sexual partner acquisition, the number of partners and the behaviors of these partners have been established as a major risk factor in the spread of STI among adolescent women [8]. This pattern creates a sexual web, where a partner who decides to move

on, moves to another person in the same group of friends, and the cycle continues. This cycle fast tracks the spread of the infection throughout the sexual web [8]. In other words, an adolescent with two or more sexual partners in any established sexual web can infect all members with STI within the web in a short period of time [8].

Another cause for concern is that the symptoms of gonorrhea and chlamydia may be mild and not easily recognizable in women until complications occur. GC and CT are highly curable when early intervention and proper treatment regimens are instituted. A common complication associated with GC and CT is Pelvic Inflammatory Disease (PID). PID can lead to tubal scarring, which is a major cause of infertility, chronic pelvic pain and ectopic pregnancy in women [9]. The direct medical cost of PID and its two major sequelae (ectopic pregnancy, and infertility) were estimated to be \$2.7 billion. This analysis also suggested that both the direct and indirect cost of PID would grow to \$10 billion annually in the future [10].

Problem Statement

Gonorrhea and Chlamydia infections have been on the rise in United States, despite the advanced prevention, treatment and management guidelines in place. The rate at which the incidence is rising has become a public health threat. Also, the largest populations at risk are predominantly adolescents and young adults ranging from ages 15 to 24 years. Both infections may lead to complication such as PID that put women at risk for chronic pelvic pain, ectopic pregnancies, tubal scarring, and eventually infertility. Additionally, the cost of managing GC/CT and the associated complications are also high. The spread of STIs has been associated with risky sexual behaviors, and educational interventions that target such behaviors may help in addressing this problem[8]. The purpose of this proposed project is to test the feasibility of using such an intervention in an inner city school based health center.

Needs Assessment

The annual number of diagnosed cases of GC and CT in Newark is alarming compared to other cities in New Jersey. For example in 2013, there were a total number of 7016 GC, and 28328 CT recorded cases in New Jersey. Of these numbers, Essex County (Newark is the county seat and the largest city in New Jersey) had 1448 GC and 5259 CT cases. These numbers far exceeded other counties. For example, in the same year (2013), Sussex County had only 4 cases of GC and 183 cases of CT [7].

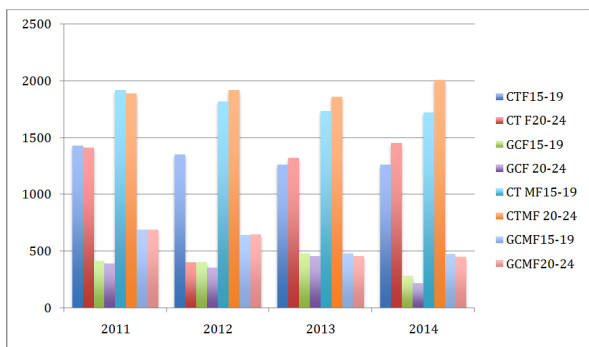


Figure 2: Number of cases of GC/CT in Essex county from 2011 to 2014 [7].

According to the New Jersey Department of Health, in 2011 there were 416 cases of GC cases among female ages 15-19 (GCF15-19), and 387 reported cases among young adult female ages 20-24 in Essex County. In addition, female between the ages of 15-19 (CTF 15-19) had a total number of 1432 reported cases of chlamydia. Among young adult females, ages 20-24 (CTF20-24), there were 1414 reported CT cases. Overall, adolescent females had higher occurrences of STIs when compared to their male counter parts. Distributions of CT were similar. When combined, males and females ages 15-19, had a total of 1919 CT cases, of which 1432 were females between the ages of 15-19 [7].

The importance of the need to address the high rates of gonococcal and chlamydia infections among the adolescents in the Newark community cannot be over emphasized.

Proposed Project Site

The proposed site is a school based health center in Newark, New Jersey. The center sees 8 to 10 cases of GC and or CT on a monthly basis. In 2015, 85% of those diagnosed with GC and or CT were females between the ages of 14-25 years. Of these, 40% of those diagnosed did not return to be treated or for follow-up as recommended.

Purpose of the Project

The purpose of this project is to test the feasibility of implementing an educational and behavioral counseling intervention in this population.

Objectives and Aims

The aim is to test the feasibility of an educational and behavioral intervention to increase participants' knowledge about the spread, symptoms, complications, and preventive strategies associated with GC and CT. In order to achieve this aim an educational and behavioral intervention will be developed and pilot tested among the study population.

Outcome Measures

Aims	Outcome measures
Test the feasibility of such an intervention	Responses to a patient satisfaction survey and change in scores on posttest
To increase participants' knowledge about the spread, symptoms, complications, and preventive strategies associated with GC and CT.	

Review of Literature

The review of literature of this study was conducted using the following key words; gonorrhea among teens and young female adults, chlamydia in teenagers and young female adults, complications of gonorrhea and chlamydia, and economic burden of GC/CT on US health system. Articles used were retrieved from nursing and medical sources, such as CINAHL, EBSCO (nursing reference center plus) PUBMED, MEDLINE, Google Scholar, and OVID.

The adolescent population represents 25% of sexually active population in the United States. The United States Preventive Services Task Force reported that this segment represent 50% of

the 19 million cases of STIs diagnosed annually [11].

Tarr and Gilliam (2008), in a cross sectional population based analysis of asymptomatic women, found a high prevalence of GC (0.61%) and Chlamydia (3.4%) among the adolescent sub-population age of 14 to 19 years (Tarr & Gilliam, 2008). They concluded that, risky sexual behavior, multiple sex partners, and serial monogamy, having older male partners, and inconsistency in condom usage, contributed to the high rates of GC/CT. In addition, gonorrhea was more prevalent among young single women of lower socioeconomic status, who were inner city residents and minorities (African Americans, Latino or Native American etc) [4].

Goyal, Hayes and Mollen found that female adolescents who presented to emergency department (ED) with symptoms such as lower abdominal pain, and genitourinary complaints were more likely to test positive for STI. Out of those who tested positive, 77.9% were blacks or African American [12].

Katz et al. studied 242 women (ages 14-21) who were at high risk for gonorrhea and chlamydia. The women maintained a coital diary for 7 months. By the conclusion of the study, 81.7% of the participants had contracted an STI. The researchers concluded that the association between sexual behavior and STI was highly significant ($p < 0.001$) (Katz et al, 2001).

Manhart, Marrazzo, Fine, Kerani, and Golden studied young women in Washington State who were routinely tested for GC/Chlamydia. The question posed by this study was whether ethnicity, race and geographic segregation contributed to higher rates of GC/Chlamydia in Washington State. This study found that African American and Native American women were 4.4 more likely to contract gonorrhea than women of other ethnicities and races. It was concluded that, although the prevalence of gonorrhea in the United States has remained high among adolescents and young women, African Americans women were twice as likely to contract GC/CT when compared to Caucasians women [13].

Among adolescent and young women, unprotected sexual intercourse is associated with high rates of reinfection with STIs. As many as 40% of annual new cases of GC/CT infections occurred in adolescents who were previously infected with those organisms [2]. Fortenberry et al. identified factors associated with successive reinfection with Gonorrhea, Chlamydia and Trichomonas within one year of initial infection among adolescent ages 15 to 19 years. They found that more than 40% of the infected adolescents women had at least a re-infection within 1 year of the initial infection [2]. The study concluded that although subsequent STI frequently followed an original infection, there seemed to be a substantial variation among the cause; therefore it is important that STI prevention program targeting adolescents be more comprehensive. That should rather be the focus rather than other specific interventions [2].

The U.S. Preventive Services Task Force (USPSTF) recommended that high intensity behavioral counseling be incorporated in the care of adolescents and adults who are at increased risk for sexually transmitted infections. The rationale behind this recommendation was based on the facts that despite all the strategic screening, diagnoses, and treatment of STIs, these infections still remain one of the most common causes of mortality and morbidity in United States [11].

Further more, there have been documented benefits and convincing evidence that a concentrated behavioral counselling intervention, targeting adolescents and young adults with high rates of risky sexual behaviors, actually reduced the frequency of STI [11]. These results were noticed after a six months, and twelve months interval of behavioral counselling [11].

LeFevre examined the benefits of high intensity behavioral counseling delivered through multiple sessions lasting about 3 to 9 hours. The study found a statistically significant reduction in subsequent STIs. They found that there was a statistically significant decrease in five out of six biological testing outcomes for STIs within 6 and 12 months after the intervention. This study also reported no significant benefits associated with counseling that lasted less than 30 minutes or a single session counseling. In other words, for behavioral counseling to be successful, participants in the counseling exercise should attend more than one counseling session, and each session should last more than 30 minutes [11].

Gonorrhea and Chlamydia infections can result in costly complications [10]. Rein et al. estimated the direct medical cost for PID, which is one of the major complications associated with GC/CT. In this study, an analysis of three years' claims data of privately insured individuals was conducted to determine what it will cost to treat PID and associated symptoms such as chronic pelvic pain, and ectopic pregnancy, per individual. It was estimated that direct medical cost for PID and its sequelae was \$1.88 billion in 1998, \$1.06 billion attributed to PID direct medical cost, \$166 million for chronic pain, \$295 million for ectopic pregnancy, and \$360 million for infertility caused by PID (Rein et al., 2000). This study concluded that, there were substantial medical costs associated with treating PID, and other associated complications. The study suggested that strategies that prevent PID would be highly cost effective in comparison.

Strategies that incorporated education about STIs can help in addressing this problem. Clark et al examined how age, self-perception, and the level of STD knowledge of a group of adolescents correlated with their STD knowledge test scores when compared to those who listed only one source for their STD education ($p < 0.0004$). Most importantly the results indicated that overall adolescents' knowledge about STIs was very low when compared with Sexuality Information Education Council of the United States (SIECUS) guidelines. These findings highlight the need to improve education about STIs and the way the adolescents receive and retain detailed age appropriate STD information [5].

Though the prevalence and incidence of STIs is high, evidence shows that educational and behavioral intervention could be effective in the reduction of the number of new cases, reinfection rates and reduction in the complications associated with GC/CT.

Theoretical Framework

The Social Cognitive Theoretical Framework

The Social Cognitive Theory Framework will be used to evaluate and implement a teaching and behavioral intervention about GC/CT in adolescents and young adult women. Social cognitive theory was first proposed by Albert Bandura in 1986. It proposes that individuals will learn either by direct experiences, human discussion, communication and observations which helps in understanding how people acquire and maintain certain behavioral patterns.

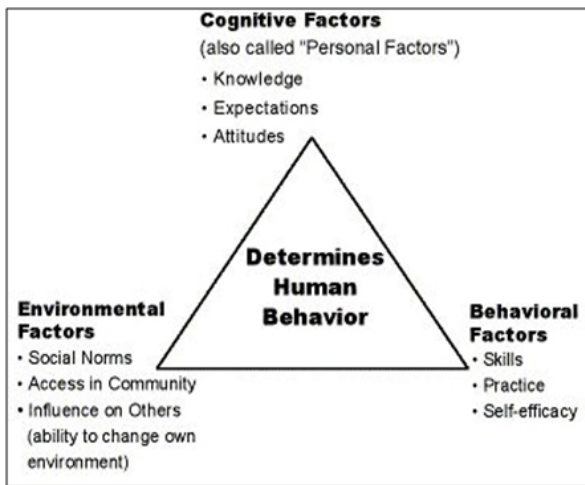


Figure 3: Social Cognitive Framework. copyright @2011 by American Association of Critical-Care Nurses [14].

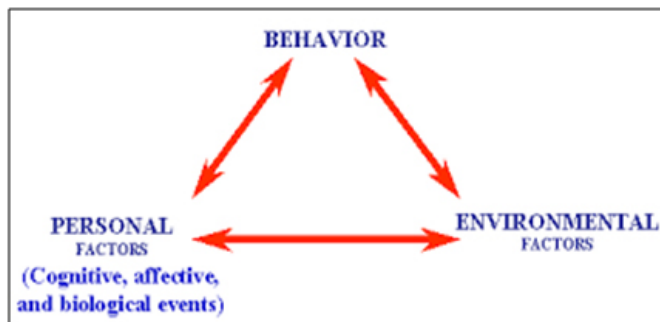


Figure 4: Bandura's Triadic Reciprocal Determinism [15].

The theory proposes that three major factors determine human behavior.

- Cognitive factors also known as personal factors (knowledge, expectations, and attitude).
- Environmental factors (social norms, access in community, influence on others, and ability to change own environment) and,
- Behavioral factors (skills, practice, and self efficacy) [14].

In context of this proposed study, it is hypothesized that the proposed educational and behavioral intervention will influence cognitive factor (e.g. knowledge about STIs), behavioral factors (e.g. choices, practices of preventive measures and safe sexual behaviors) and environmental factors (e.g. social norms about sexual practices).

Methodology

Design

In this exploratory study a one group, pre-test /post-test evaluation study design will be used. To assess the feasibility, both pre and post questionnaires and patient satisfaction survey will be used.

Procedure

All patients at the center, who fit the inclusion criteria, will be invited to participate. Consented/Assented participants will complete a pretest questionnaire. The participants will receive four sessions of educational and behavioral counseling on GC and CT. The intervention will focus on the spread of GC and CT; risky sexual behaviors associated with these infections; the complications associated with untreated and

non-compliance with proper treatment of GC and CT; preventive strategies. Each session will last about 40-60 minutes and will be held once a week for four weeks. At the completion of the sessions participants will take the posttest and a patient satisfaction survey. Participants will also receive a folder that will contain a notepad and a pencil for taking notes during the sessions and keeping handouts. Bus passes will be given to the participants to enable them participate fully in the educational sessions.

Pre-test/Post-test questionnaire and a patient satisfaction survey will be used to:

- Measure changes in knowledge level about spread, symptoms, complications, treatment and preventive strategies for gonorrhea and chlamydia
- Assess the feasibility of the intervention

Setting

The study will be conducted at Jewish Renaissance Medical Center, a Federally Qualified Health Center located at 333 Clinton Place in Newark NJ. The Center is located within Newark public school. This center primarily serves the local community, providing health care services such as well child examinations, physical exams, sick visits, asthma care, contraceptive counseling, STD screening and routine wellness guidance to children and young adults. Most of the populations are low income, and predominantly African American.

Study Population

A sample of 15 adolescents and young adult female patients will be recruited. This is considered sufficient for pilot studies to establish feasibility [16].

Inclusion criteria

Adolescent and young adult females between the ages of 14 to 24 years will be invited to participate. Participants will be patients at the study site, and should be able to speak and understand English, and be able to read and write.

Exclusion criteria

Participants who are younger than 14 years or over 24 years, who are wards of the state and those who are cognitively impaired will be excluded from this study.

Subject selection

It will be a sample of convenience. A poster, advertising the study, will be posted in the patients' waiting room at the health center. The PI, who serves as a practitioner at the Center, will also provide general information about the study to patients who fit the inclusion criteria.

Study Intervention

Those who meet the study criteria and have willingly given their consents and assents with parental consent to participate in the study group will complete a pretest questionnaire. They will then attend learning sessions that will include about 40-60 minutes of educational material on GC and CT in four sessions. The intervention will include information on the signs and symptoms of GC and CT and how they are spread and acquired. In addition, the risks associated with undiagnosed and untreated infections, and complications such as PID, ectopic pregnancy and infertility will also be discussed in detail. In addition, preventive strategies will be discussed. Participants will be given a posttest questionnaire and a patient satisfaction survey to complete at the last day of the

educational/behavioral counseling intervention.

Outcome Measures

The primary outcome measure will be an assessment of the feasibility of an educational and behavioral intervention to increase knowledge

Intervention	Outcome measure	How it will be measured
Four educational and behavioral sessions lasting 40-60 minutes	Responses to a patient satisfaction survey and change in knowledge level about spread, symptoms, complications, treatment and preventive strategies for gonorrhea and chlamydia.	Will be measured by differences in pretest-posttest scores.
	Feasibility	Will be measured by responses to patient satisfaction survey questionnaire and pretest- posttest scores.

Benefits

Majority of sexually active adolescents and young adult females are at risk for STIs especially GC and CT. They are also at an increased risk of getting re-infected within one year (LeFevre, 2014). This intervention will increase their knowledge of the risky behaviors that could lead to GC and CT infections, symptoms, treatment, importance of compliance with the treatment, potential complications of these infections, how they spread and preventive strategies. This could have a significant impact on the number of repeat infections, and complications associated with GC and CT among the participants.

Risks

The risks associated with educational and behavioral counseling for STIs are minimal (LeFevre, 2014). Participants may feel uncomfortable or some discomfort with the information presented at the educational sessions. Other anticipated risks might be associated with concerns for privacy of the participants. All pre-test and post-test and survey responses will remain anonymous. The data collected will be stored in a secured encrypted password protected work computer. Once data entry is completed all links to personal identifiers will be destroyed. After data analyses are completed and the study closes, the study data will be downloaded into a safeguarded encrypted password protected jump drive at the Rutgers School of Nursing and maintained for six years and then destroyed permanently as per university policy.

Subject Recruitment

Adolescents and young female adults between ages 14yrs to 24yrs of age, who understand, speak, able to read and write English will be recruited during a visit at the health center. Participants who are younger than 14 years or over 24 years, who are wards of the states, and those who are cognitively impaired will be excluded from the study. The Primary Investigator will be responsible for obtaining consent and the recruitment processes. The study team will not have access to the participants' charts or other medical records.

A poster will also be posted in the patients' waiting room at the health center, which will include the primary investigator contact number.

Consent Procedures

Upon receiving IRB approval, recruitment will commence. The primary investigator will obtain an informed consent from patients who meet the inclusion criteria and are willing to participate during a visit to the health center. The Primary Investigator is involved in the care of the potential subjects and will share information about

of the risky behaviors that could lead to GC and CT infections (spread), symptoms, compliance with treatment regimens, potential complications of these infections, and preventive strategies (**Table 1**) **Intervention, outcome measures and how they will be measured.**

the study with those who qualify and parents whose daughters qualify. The consent form will be clearly written to include the purpose of the study, the process, associating benefits and possible risks (appendix A). The consent will be concise and will contain information pertaining to confidentiality and how to contact the researcher, if needed. The right to withdraw from the study at any time will be clearly stipulated in the consent. The consent will also include information on how participants' data will be protected as described under 'Risks' section of the study proposal. For minors, younger than 18, assent and parental consent, with the same information as the consent will be completed.

Subject Costs and Compensation

There will be no cost incurred by the participants during the process of this study. As an incentive, the participants will be given bus passes to cover their transportations costs to the sessions. Healthy snacks and water will be served during the educational sessions.

Project Timeline

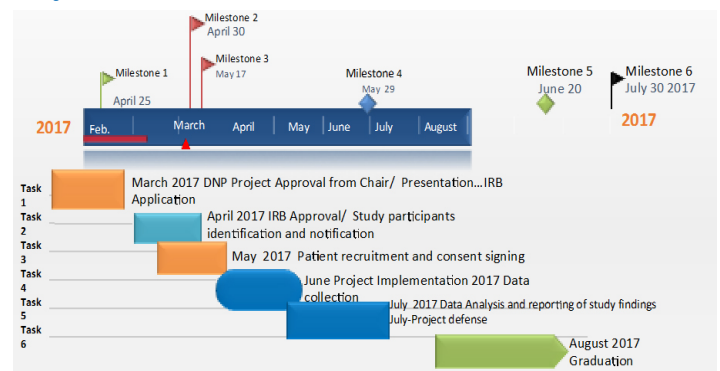


Figure 4: Showing a Gantt chart illustrating the project timeline. This study is expected to take about 3 months to complete, upon IRB approval the study will commence.

Resources Needed/Economic Considerations

Resources and Economic considerations needed for this project is estimated to cost \$480;

- Flyers and educational materials \$130
- Snack and water that will be served during educational sessions \$95
- Bus passes \$105
- Total cost: \$320

Data Maintenance / Security

The participants' data collected during this study will be stored

in a secured encrypted password work computer. Once data collection and analysis is completed, at the close of the study, links to identifiers will be destroyed. USB drivers containing any information or identifiers will be wiped clean and paper copies will be shredded according to Rutgers School of Nursing policy. Data and signed informed consent forms will be kept by the data steward at Rutgers University for a minimum of six years after the study closure.

For the safety and confidentiality the participants' name and identity will not be used when results are being reported, aggregate data will be reported and pseudonyms will be used. The health center's name will also be protected during any publication for confidentiality and safety purposes.

Data Analysis

Data collected will be nominal type of data and a descriptive analysis will be conducted.

The feasibility of using such an intervention will be assessed by analyzing the Pre-test and post-test scores and patient satisfaction survey responses. Statistical Package for Social Sciences will be utilized to analysis the data.

1. All variables including the demographic information will be summarized by using frequency or proportions.
2. McNemar (this test can compare the change of each individual question) and Wilcoxon tests (this will compare the total change from pre to post) will be conducted on Pre and posttest survey results.
3. Patient satisfaction survey responses will be summarized by percentage.
4. All statistical tests will be two side and p-value less than 0.05 will be considered as statistically significant.

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Citation: Chioma Afoke (2017). Reducing Reoccurrence and Complications of Gc/Ct. Journal of Medical & Clinical Research 2(4):1-6.

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