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DEPOT MEDROXYPROGESTERONE ACETATE DISCONTINUATION AFTER
WEIGHT GAIN IN 17-19 YEAR OLD ADOLESCENT GIRLS

A Project
Presented to the
Faculty of
California State University,
San Bernardino

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
in
Nursing

by
Donna Lea Church
June 2002

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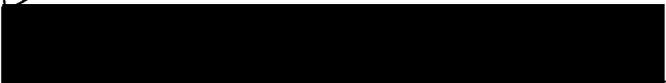


Dr. Ellen Daroszewski, Chair, Nursing

4/26/02
Date



Dr. Janice Layton



Kristine Blans

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ABSTRACT

Depot medroxyprogesterone acetate (DMPA) is a long acting progesterone only contraceptive agent. Side effects such as irregular bleeding patterns and weight gain are attributed to discontinuation.

The purpose of this study was to describe depot medroxyprogesterone acetate discontinuation after weight gain in 17 to 19 year-old adolescent girls.

A retrospective review of 26 medical records was conducted. Descriptive data reflected a mean subject age of 17.12, predominately white (88.5%) with Hispanic ethnicity (69.2%). The average weight change at the second injection was -.65 pounds, and at the third, 1.41 pounds. At the third injection a 15.38% (n = 4) method discontinuation rate was noted. Cumulative weight gain over six-months was .61 pounds.

Although a three-pound or greater weight gain was noted in seven girls in three months, only one chose to discontinue. This study did not provide evidence to support weight gain associated with discontinuation. Data suggests that although weight gain may be experienced, girls in this setting maintain adherence to this effective method at least up to six months.

ACKNOWLEDGMENTS

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A very special thank you to the members of my thesis committee, Dr. Janice Layton, who critiqued the study and provided valuable guidance, Kristine Blans for her expertise in women's health issues, and especially Dr. Ellen Daroszewski as thesis chair. Dr. Daroszewski provided professional honest appraisals, steady direction, and a friendly, supportive attitude from start to finish, without this help this thesis would not have been completed.

I would like to thank the Fontana Unified School District for allowing this research study to be conducted at their school-based clinics.

Lastly I would acknowledge my very special colleague and friend Mary Placencia who provided me with ideas encouragement, and a determination to succeed throughout this daunting endeavor.

DEDICATION

To my mother and the loving memory of my father

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CHAPTER ONE

INTRODUCTION

Background

Teenage pregnancy prevention continues to be a high priority public health issue. Four out of ten adolescent girls become pregnant at least once before age 20, that accounts for about one million pregnancies per year in the United States alone (Curtain & Martin, 2000). Finding effective ways of dealing with the problem is of concern to parents, schools, public health departments, and politicians across the nation (Satcher, 1999). The scope and issue of high-risk behaviors such as early sexual involvement is multi-faceted and includes teen pregnancy prevention, sexually transmitted disease (STD) and HIV prevention, and teen parenting education, all of which have implications for society at large (Kann, Kinchen, Williams, & Ross, 1998).

According to Jay, DuRant and Litt (1989), education combined with access to family planning services is imperative when dealing with pregnancy prevention. Recognizing the need for contraception and making it

available to adolescent girls is very important, but so is the follow up and method adherence.

Statement of the Problem

Depot medroxyprogesterone acetate [DMPA] (Pharmacia & Upjohn Company, 1995) is a progesterone-only hormonal injection. DMPA is given intramuscularly every three months to suppress ovulation. The 150 mg DMPA injection is administered within the first five days after the onset of menses. At that time follicle-stimulating hormone and luteinizing hormone are lower in the plasma, resulting in inhibition of ovulation (Archer, Irwin, Jensen, Johnson, & Rorie, 1997). When the DMPA contraceptive regimen is followed correctly a very low failure or pregnancy rate of 0.3-2.3% has been reported (Branden, 1998).

One significant problem with this method is the individual contraceptors compliance. Returning for follow-up injections and side effects are the most common reasons for method discontinuation (Lim, Rieder, Coupey, & Bijur, 1999).

Physical and psychological side effects to depot medroxyprogesterone acetate (DMPA) include weight gain,

irregular menstrual bleeding, amenorrhea, headache, nervousness, abdominal cramps, dizziness, bloating, swelling of the hands and feet, backache, depression, insomnia, acne, breast tenderness, facial hair and hair loss (Sangi-Haghpeykar, Poindexter, Bateman, & Ditmore, 1996; Pharmacia & Upjohn, 1995). The side effects most disturbing to adolescents are menstrual irregularities and weight gain (Lim et al., 1999; Matson, Henderson, & McGrath, 1997; Harel, Biro, Kollar, & Rauh, 1996).

Normal physical and sexual maturation described by Tanner (1962) varies in girls. Estrogen and Progesterone not only affect sexual development but aide in the completion of bone growth.

Zacharias and Rand (1983) reported on the rapid height and weight changes that occur during puberty over a two to three year period. The peak height velocity occurs at 11.63 years of age and culminates at 13.1 years of age in American girls. At the peak of growth, which generally occurs in the year before menarche girls can grow three to five inches. In the United States menarche occurs on average at age 12.5, about 2 to 2.5 years after the first breast changes appear. A girl is about 90 percent of her final height at menarche. By 14 or 15

years of age (Tanner, 1985), or two years after menarche, most girls have reached final adult height (see Appendix A). These girls usually gain from 10 to 15 pounds in the five years following menarche. By age 17 most adolescent girls in the United States have reached their final height and weight has stabilized.

Weight gain is an important concern to adolescent girls and contributes significantly to their decision to continue or choose another contraceptive method (Davis, 1996). Among adolescent girls approximately half reported discontinuing the method secondary to weight gain (Harel, Biro, & Kollar, 1995). Davis (1996) states it is unclear exactly why weight gain occurs but it may be due in part to DMPA accumulation stimulating the appetite, in addition to decreased physical activity, increase caloric intake, and slowing of the metabolic rate.

Purpose of the Study

The purpose of this study was to describe depot medroxyprogesterone acetate discontinuation after weight gain in 17 to 19 year-old adolescent girls.

Theoretical Framework

Theorists have conceptualized growth and development as a series of tasks that must be accomplished in order to transition from one stage to another. In a developmental theoretical model developed by Erikson (1968), the fifth stage is the adolescent stage (12-19 years of age), in which moral development occurs: Identity vs. role confusion. To successfully transition to the next stage the adolescent must develop an individual identity. The rapid, marked physical changes, preoccupation with appearance and need to integrate personal values with those of society must be achieved to attain a positive identity. Without positive identity achievement, low self-esteem may occur.

According to Mendelson, Mendelson, and Andrews (2000), body-esteem or appearance is an essential part of a person's identity or self-esteem, appearance is always immediately apparent to others. Preoccupation with physical appearance and physique is of greater concern to adolescent girls than any other age group (Bruch, 1981).

Body esteem refers to the self-evaluation of one's body or appearance and is the only self-esteem domain that has been studied extensively in overweight

individuals (Mendelson et al., 2000). Mendelson, Mendelson and White (1996) revealed age and gender modified weight-related deficits in self-esteem. Overweight adolescents were apt to have relatively low self-esteem. Being overweight also was found to affect girls in later adolescence, in contrast to early adolescence in boys. Martin, Housley, McCoy, Greenhouse, Stigger, Kenny, Shoffner, et al. (1988) support the conclusion that as weight increased self-esteem decreased. Research has shown that a more negative body image is related to lower self-esteem (Guinn, Semper, Jorgensen, & Skaggs, 1997).

Self-esteem and depression were studied by Kim and Kim (2001), findings reveal that girls who perceived their weight problem as more severe had lower self-esteem and experienced greater depression than those who perceived their weight problem as less severe. Thus, the perception of a weight problem, in other words, appearance, was meaningful in assessing self-esteem and depression.

According to Neel, Jay and Litt (1985) adolescent girls typically negotiate self-concept and autonomy at a time when they are becoming sexually active. The unstable

self-esteem during the adolescent years may be such that decision making is impaired (Papalia & Olds, 1981). A review of literature by Crockenberg and Soby (1989) on self-esteem and contraceptive use indicated that multiple studies have shown an association between poor contraceptive use and low self-esteem, and that no study they found showed low self-esteem related to proper use of contraceptives.

Contraception refers to a wide range of methods developed to prevent pregnancy. Methods available to the potential contraceptors range from barrier to hormonal methods. Pregnancy prevention is a personal choice and the girl must evaluate her own ability to adhere to the chosen method for success.

According to Jay, et al. (1989) contraceptive behavior has four components. The first component is the adolescent girls decision to use contraception. This decision, based on fear of pregnancy, motivates her to seek contraception. The second component is choice of contraceptive method. To choose a method the girl seeks information, is provided with education on action, efficacies, required follow up, and side effects of the method. Although verbal instruction and written materials

are provided regarding benefits and barriers to methods, the full impact of potential side effects may not be fully understood until the girl experiences them herself. The third component is contraceptive compliance. Contraceptive compliance can be defined as a regular pattern of adherence by using the method in a consistent and ongoing way to prevent pregnancy (Jay, Litt, & DuRant, 1984). Contraceptive compliance is essential for method success (Braden, 1998). However, concern over appearance may be so strong that a decision could be made to discontinue the use of contraception and risk pregnancy, despite the methods effectiveness in pregnancy prevention (Neel, et al., 1985). The fourth, and final, component is a decision to change methods or discontinue use. At this stage the girl may recognize physical or psychological side effects of the contraceptive method and choose to discontinue use or change methods.

Theory Application

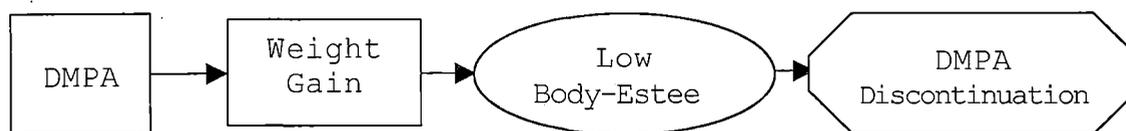
An existing theory that addressed contraceptive discontinuance in adolescent girls was not identified. The theoretical framework used in this study integrated the components of contraceptive use and compliance as

determined by Jay, et al. (1989) and body-esteem research conducted by Mendelson, et al. (2000). By integrating the concepts we were able to describe and explain contraceptive adherence.

This framework describes the linear process by which a girl chooses to initiate DMPA as a contraceptive method, confronts the side effect of weight gain, interprets the weight gain through body-esteem, and then makes a choice to discontinue the method.

The most important component in this theory affecting the continuance of contraception is low body-esteem. It is reasonable to assume that if low body-esteem is associated with weight gain and appearance, and if that body change is associated with a contraceptive choice, the girl will rethink her options and will choose to discontinue the method (Jay, et al, 1989).

Figure 1. Low Body Esteem as a Mediating Variable for the Discontinuance of Depot Medroxyprogesterone Acetate After Weight Gain in Adolescent Girls



Limitations of the Study

Study limitations included a convenience sample of students attending one of three school-based clinics. Thus, results could not be generalized to the overall population of adolescents. Data collection was performed as a retrospective chart review. Thus, some records may have had incomplete charting and did not provide all the detail required to be included in the study. Due to constraints by the California Education Code on surveys of students regarding sexual behavior and attitudes, and the fact that the clinical sites protect student confidentiality, a prospective study in this case would have been difficult to complete. Because the study was conducted at school-based clinics with vigilant school nurses, discontinuation due to missed appointments was lower than expected since accessibility was not an issue thus, discontinuation should not be compared with other community based clinic studies.

Definition of Terms

An adolescent girl was defined as a girl age 17-19 years of age.

Weight gain was defined as pounds over baseline weight, which was measured on calibrated weight scales, at the initial DMPA injection.

Discontinuation of DMPA was defined as girls who did not return for a follow-up injection after 104 days, or those who stopped use and either chose another method or used no contraceptive method.

Depot medroxyprogesterone acetate is a highly effective progesterone only long-term injectable hormonal contraceptive agent that is administered intramuscularly every three months.

CHAPTER TWO

REVIEW OF THE LITERATURE

One of the goals of Healthy People 2000 was reducing pregnancy among girls age 15-19 to no more than 50 pregnancies per 1,000 adolescents. In 1998, the live birth rate for girls age 15-19 was calculated to be 51.1 per 1,000. When live birth rates are added to information regarding abortions and fetal loss, the pregnancy rate in 1996 was estimated to be 98.7 pregnancies per 1,000 women. This total pregnancy estimate was down 15% from a high of 116.4 in 1991 (CDC, 2000). The State of California reported pregnancies for the same period and age group at 98 pregnancies per 1,000 in 1998. Reducing overall pregnancy rates continues to be a goal for the future. The objectives for Healthy People 2010 continue to target the teen pregnancy rate and set the goal at 43 pregnancies per 1,000 females age 15-17.

Strategies used in the effort against teen pregnancy include sex education in public schools, community efforts, support groups, and increased availability of contraceptive methods through confidential primary care and clinic providers. At this time a variety of

contraceptive methods are available ranging from barrier methods to hormonal methods. Hormonal methods are increasingly popular with the adolescent women who seek family planning services. All contraceptive methods have their own set of side effects, contraindications, effectiveness ratings, barriers to use, failure rates and benefits. Hormonal therapy, including daily oral contraceptives and long-term hormonal therapy, is popular with young women because of the effectiveness. Effectiveness of each therapy is dependent on a regular regimen of compliance with the method.

Contraceptive Use in the United States by Adolescents

Oral contraceptives and condoms are the most commonly used methods by adolescent girls in the United States; however, compliance is known to be poor. Middleman, Robertson, DuRant, Chiou and Emans (1997) conducted a study on contraceptive methods used by sexually active teens. Study subjects (N = 943) came from a school-based clinic and hospital based adolescent care clinic. Subjects were given a questionnaire to gather data. Findings included oral contraceptive use in 39 percent, DMPA or Levonorgestrel in 5.4 percent, and no

hormonal therapy in 55.6 percent. Other studies also support the popularity of oral contraceptives. Oral contraceptives are highly effective when taken properly. The problem with a method requiring daily compliance is that adolescents are noted to be poor at remembering the regimen. This data is reflected by the fact that "pregnancy rates for teens using oral contraceptives are almost double the rate experienced in adult women" (Davis, 1996, p.408). To reduce the overall pregnancy rates, condoms, spermicides and long-term hormonal methods including levonorgestrel (Norplant) and depot medroxyprogesterone acetate (Depo-Provera) appears to be effective and appropriate methods for teens.

Depot medroxyprogesterone acetate, while used worldwide for over 25 years, was not approved for use in the United States until 1992. DMPA is an injectable progesterone contraceptive that is administered intramuscularly every 12 weeks. Compliance with this method requires the user to return to her provider every 3 months (10-13 weeks) for DMPA administration. Because of the three-month intervals between injections, compliance would naturally seem to be easier, and thus be a very desirable method for teens. One study on DMPA use

indicates 30% of users were younger than 21 years of age, and three-quarters were unmarried (Sangi-Haghpehkar et al., 1996).

Continuation of Depot
Medroxyprogesterone
Acetate Use

Despite the effectiveness and ease of compliance with DMPA, its use continues to be a significant problem. Barriers to compliance in teens may include confidentiality issues, health care access, missed appointments, and lack of education on the method including possible side effects at the time of first injection. A family planning clinic in the midwest conducted a study to determine continuation with DMPA use (Westfall, & Main, 1996). Clinic clients were categorized as discontinuing if they did not return for a follow-up injection after 105 days. Results indicated that of the 5,178 women who initiated the method, only 57% returned for the second injection. Over the course of a year, only 23% continued DMPA therapy and received four injections in one year. This result is in stark contrast to continuation rates for other contraceptive methods, such as oral contraceptives, with rates from 70-90% compliance

over the course of one-year (Westfall, & Main, 1996). Researchers (Lim et al., 1999) studied the DMPA continuation rates and characteristics of long-term users in minority inner-city adolescents. The study showed DMPA continuation rates to be 70.3% at six months, 48.3% at nine months, 31.5% at 12 months, and 12.8% at 24 months. This accounts for about one third of those initiating the method continuing at one year. A missed appointment was the most common reason for discontinuation of DMPA (41.7%). Of the 156 adolescents who discontinued DMPA use 40% restarted the method later. Reasons for discontinuing DMPA included irregular bleeding patterns at 17.3%, followed by weight gain at 14%.

Polaneczky & Liblanc (1998) studied compliance and reasons for discontinuing the method. Record reviews and telephone interviews were conducted to gather data on DMPA users over a three-year period at two New York City clinics. The 159 females had a mean age of 17.7 (+/- 1.5) years, and a median of one pregnancy. Continuation rates for DMPA at three months was 71%, 48% at six months, and 27% at 12 months. Of those who discontinued use, 37% restarted the method with a mean time of 8.4 months after discontinuation. Menstrual irregularities (26%) were

cited as the primary reason for discontinuing followed by weight gain (18%). Although continuation statistics were low, of those who quit over a third restarted the method.

Weight Gain Associated With Depot Medroxyprogesterone Acetate Use

Side effects that cause the greatest concern for teens are menstrual irregularities, weight gain, headaches, and hair loss. Teens are particularly conscious of changes in their bodies. Weight gain is particularly disturbing to the group, as it is noticeable to themselves and others. The benefit of DMPA as a safe and effective contraceptive method is many times overlooked when weight gain is associated with hormonal therapy by the potential new contraceptive user. It remains unclear if DMPA causes weight gain in adolescent teens. The weight gain experienced by some teens may be associated with decreased physical activity, eating habits, slowing of the metabolic rate and increasing caloric intake rather than DMPA use itself.

Weight gain associated with DMPA use may be a result of a variety of factors however perception does influence a decision to use the method. Weight gain beliefs about DMPA among three groups of contraceptors, including oral

contraceptive users, DMPA, and Levonorgestrel users vary. However, after receiving education over half the responders in one study indicated they believed DMPA would cause menstrual irregularities and weight gain (Cushman, Kalmuss, Davidson, Heartwell, & Rulin, 1996).

Research on weight gain associated with DMPA use is mixed. Contradictory evidence is available to support no weight gain in women resulting from DMPA use. In a study comparing DMPA, oral contraceptives, and Levonorgestrel conducted by Moore, Valuck, McDougall, and Fink (1995), results differ from much of the research conducted on weight gain. Fifty women age 15-30 were represented for each of the three treatment groups. The mean weight gain after one year was as follows -0.93 kg (95% CI = -1.3 to -0.5) in the oral contraceptive group, -0.81 kg (95% CI = -1.6 to 0.1kg) in the Norplant implant group, and +0.06 kg (95% CI = -0.4 to 0.6kg) in the Depo-Provera contraceptive injection group. The weight gain in each group was either negative or not significantly different from zero.

Other reasons aside, many teens associate real or perceived weight gain with the use of DMPA itself. In a study conducted by Harel, et al. (1995) on effects of an

early second injection, half of all teens that discontinued DMPA reported doing so because of weight gain or increased appetite. The body mass index (BMI) increase experienced by the adolescents on a regular DMPA schedule showed an increase of 0.40 ± 0.14 in their BMI as compared to the baseline. Girls who received an early second injection had a greater change in BMI of 0.99 ± 0.22 . The girls themselves perceived the change with 70% of the early injection group reporting increased appetite and weight gain, compared to 39% of the regular scheduled group. In 1973, Schwallie and Assenzo studied the weight changes in 3,857 women in one of the largest studies conducted on DMPA in the United States. These women represented 72,215 women-months of experience. All received DMPA every 90 days. Progressive weight gain was noted with an average of five pounds by 12 months, 8.1 pounds by 24 months and 13.8 pounds by 48 months. This progressive weight gain was the reason 66 women (1.7%) gave for discontinuing the therapy.

Reasons for discontinuation of DMPA are consistent with findings in a study conducted by Harel, et al. (1996). Again, the study of 35 adolescents revealed irregular menstrual bleeding in 21 (60%), weight gain in

14 (40%), and increased headaches in 9 (26%). The increased BMI found at discontinuation of DMPA showed an increase of 1.1 ± 0.2 in their BMI that persisted up to six months after discontinuation. Risser, Geftter, Barrett, and Risser (1999) compared adolescents in two hormonal contraceptive groups. The two groups were comparable except the DMPA users (n = 44) had a greater mean BMI than the oral contraceptive (OC) users (n = 86). Mean and median weight gains in one year were 3.0 (4.5) and 2.4kg in the DMPA users and 1.3 (3.9) and 1.5kg in the OC users. Of adolescents using hormonal contraceptives, weight loss or weight gain of less than five percent was noted in 56% of DMPA users and 70% in oral contraceptive users. Excessive weight gain, which was defined as weight gain greater than 10% of baseline weight, was measured in 25% of DMPA users and seven percent of OC users. The significant findings that adolescents who gained less than five percent of their baseline weight at three months, 14 (93%) gained even more weight at 12 months. DMPA users were more likely than OC users to gain less than 10% of their baseline body weights. In another study, a cohort of 172 Navajo women in New Mexico was studied over a two-year period to

determine weight gain. At one year, a mean weight gain of six pounds was documented. At the end of the second year an 11-pound weight gain was observed (Espey, Steinhart, Ogburn, & Qualls, 2000).

According to Harel, et al. (1996), a trend toward BMI increase in adolescents has been noted. Findings indicate that the increase in BMI may persist up to six months after discontinuation of the therapy. The researchers indicate that although reasons for weight gain in adolescents using DMPA may be unclear, it may be that progestins, particularly DMPA, can accumulate in preoptic and hypothalamic neurons, and directly stimulate hunger centers at brain level. If the hunger centers in the brain are stimulated this would support the hypothesis that the weight gain may be from caloric intake associated with poor eating habits.

Summary of Literature Review

The literature reflects mixed results. Research on compliance with DMPA use indicated that only about one-third of those who initiate the method continue up to one year. This rate is due in part to missed provider visits and side effects. Side effects of greatest concern

to users include irregular bleeding patterns and weight gain. Although not all research indicates weight gain associated with DMPA, the majority of studies reviewed indicate a positive association between these two factors. Moreover, teenagers do associate weight gain with DMPA use. To boost adherence to this long-term hormonal method it is important to continue the study on the association between these variables.

Hypotheses

There will be a significant increase in contraceptive discontinuation for 17-19 year old girls who use depot medroxyprogesterone acetate if they experience a three-pound weight gain in 3 months.

CHAPTER THREE

METHODOLOGY

Introduction

This study used a descriptive retrospective chart review to examine weight gain and depot medroxyprogesterone acetate use. Medical record visits were reviewed at three-month injections.

Subjects

The convenience sample for this study was composed of adolescent girls age 17-19 that initiated DMPA as a contraceptive method at one of three high school-based clinics. Data was obtained through a retrospective chart review from September 1999 through June 2001. Girls were excluded from the study if they: 1) had delivered a baby in the last 12 months; 2) left school for any reason; and 3) any girl with a medical condition that would contribute to abnormal weight gain or loss. The medical records contained confidential information on overall health, vital signs, height and weight, parity, current and previous contraceptive use, history of sexually transmitted infections and subsequent treatment, morbidity reports, a variety of lab work including urine

analysis, hemoglobin, urine pregnancy test results, results from STD testing, Pap smears, wet mounts, detailed history of sexual activity, psychosocial factors and history of high risk behaviors such as same sex partners, drug and alcohol use, and contraceptive behaviors.

For the purposes of this study, the length of DMPA use was calculated at weekly intervals. Method continuation was calculated from start to stop dates. The start date was defined as the date of first injection. The discontinuation date was the day the girl made a choice to discontinue use or 104 days after the last injection. The 104-day mark was used as a discontinuation date because the manufacturer recommends a pregnancy test after that time, before restarting the method. Height and weight were measured using standard scales that were calibrated and certified as accurate on a yearly basis.

Setting

This study was conducted at three high school based health clinics. The clinics provided confidential counseling, general medical care, immunizations, acute

care, dental services, and family planning services to students enrolled at the schools.

The confidential services offered by the Fontana Unified School District are provided respecting minor consent laws for the State of California. Yearly Teen Health Center Consent Forms (see Appendix B) are sent to parents. The card provides accessibility to many health care promotion and preventative services. After the consent is signed by the parent or guardian, the student is afforded confidentiality as is clearly noted on the consent. If an adolescent chooses to access confidential family planning or sexually transmitted disease care through the school based clinics they are enrolled in the Family Pact, State-Only Family Planning Program. As part of the enrollment and eligibility certification process the enrollee signs an application allowing data collection for outcomes studies and program evaluation purposes (see Appendix C).

The high schools are located in a metropolitan urban area. The community is comprised of a primarily Hispanic population that is reflected in the student population. Socioeconomic status varies depending on which region of the city a high school may be located. The largest high

school with a population of 3,800 students was located in the lowest economic part of the city. Many students use the health clinics as their primary provider as they are uninsured or fall into the category of the working poor.

The clinics provide services to students across the district. The clinics are staffed with registered nurses, nurse practitioners and physicians who volunteer their time to the schools. The services rendered are free to the student under school district allotments, grants and reimbursement for billed services.

Study Variables

Socio-demographic data was collected on all subjects and included age in years, race (White, African American, Asian American, or Other), ethnicity (Hispanic or not), parity, and previous contraceptive use answered as "yes" or "no". Data collected at first visit and/or subsequent visits to assess weight change and DMPA use included height, weight, DMPA compliance in a timely manner and reason for method discontinuation if available.

Procedure

After obtaining written approval from the Comprehensive Health Department of the Fontana Unified

School District (see Appendix D), and approval from the California State University at San Bernardino Institutional Review Board (see Appendix E) data collection was initiated. Records were gathered and kept in a secure file cabinet housed in a locked records room. Data collection was done when no students or other staff were in the room to guard confidentiality. A standard chart-audit tool was used to collect data (see Appendix F). The data collection tool was pilot tested by two researchers on five medical records to determine interrater reliability and establish tool validity prior to data collection. Each medical record was pulled and if it met inclusion criteria, data was extracted individually. The data collection tools were numbered but contained no medical record number or any other information which could identify the subjects.

Records were reviewed for follow-up injections every 10-14 weeks. At follow-up visits, weight and any reported side effects were recorded. Method discontinuation was also recorded, including reason if indicated, and what contraceptive method was chosen to use following discontinuation.

CHAPTER FOUR
RESULTS AND DISCUSSION

Data Analysis

Data collected included demographics and data that described weight gain and discontinuation of DMPA. The convenience sample for this study was composed of adolescent girls age 17-19 who initiated DMPA as a contraceptive method at one of three high school-based clinics. Girls were excluded from the study if they: 1) had delivered a baby in the last 12 months; 2) left school for any reason before the second or third injection was scheduled; and 3) any girl with a medical condition that would contribute to abnormal weight gain or loss

Socio-demographic data was collected on all subjects. At the time of DMPA initiation, age in years was reported as a mean and standard deviation. Nominal data included race (White, African American, Asian American, or other) and was reported as a percentage. Through the data collection ethnicity was determined, Hispanic and not Hispanic and reported as a percentage. Percentage was used to measure parity. Data collected at

the first and subsequent visits reflected DMPA use and follow up. Nominal data on method discontinuation was collected as "yes" or "no" and reported as a percentage.

The Chi-Square test analyzes nominal data. It is used to determine significant differences between measured observed frequencies within the collected data and expected frequencies. The data collected tested the null hypothesis, that there is no significant difference in the number of girls who continue and discontinue DMPA use after weight gain. The Chi-square statistical test is designed to test group independence or relatedness and approximation. To adequately present the approximation, the total number of medical records was be greater than 20. A limitation for this test is that if differences in frequencies exist the analysis will not identify where in the data the differences occur.

Data was entered and analyzed using computer software SPSS 7.5 for Windows SPSS Inc, Chicago, IL.

Presentation of Findings

Collected and analyzed demographic data from 26 medical records provided overall information regarding the subjects. The medical records reviewed met the

inclusion criteria of 17-19 year old girls with an average age of 17.12 ($SD = .33$). Race distribution reflected the population as white 88.5% ($n = 23$), African American 3.8% ($n = 1$), Asian American 3.8% ($n = 1$), and other 3.8% ($n = 1$). Hispanic ethnicity was noted at 69.2% ($n = 18$). Parity remained consistent with no history of pregnancies reported (see Appendix G).

Baseline height for the study subjects ranged from 54 to 68 inches with a mean of 63.68 inches ($SD = 3.04$). Weight reflected a significant spread ranging from 102 to 240 pounds, with a mean of 146.63 pounds and the median of 143.50 ($SD = 36.27$). Three subjects initiated the study with baseline weights greater than 210 pounds (see Appendix H). A decision was made to include all data gathered due to limited population size.

This research study hypothesized that there would be a significant increase in contraceptive discontinuation for 17-19 year old girls who used DMPA if they experience a three-pound weight gain in three months. The data collected indicated that of those who gained greater than three pounds in three months 87.5% ($n = 7$) continued with DMPA use. The remaining 12.5% ($n = 1$) gained greater than three pounds in three months and discontinued DMPA use.

Of the 70.8% (n = 24) who continued with DMPA use after the second injection 94.4% (n = 17), did not gain greater than three-pounds in three months.

Table 1. Greater Than Three Pound Weight Gain in Three Months and Depot Medroxyprogesterone Acetate Discontinuation (Analysis Using Chi-Square)

		Continue DMPA at 3 Months		Total
		Yes	No	
Weight Gain > 3 Pounds In 3 Months (Yes)	Count	7	1	8
	Expected Count	7.4	0.6	8.0
	Percent	87.5%	12.5%	100%
Weight Gain > 3 Pounds In 3 Months (No)	Count	17	1	18
	Expected Count	16.6	1.4	18.0
	Percent	94.4%	5.6%	100%
Total	Count	24	2	26
	Expected Count	24.0	2.0	26.0

The Chi-square test performed did not provide conclusive statistical evidence that DMPA discontinuation would be significantly higher if greater than three pounds were gained in three months ($X^2 = .376$; $p = .540$). Although there were no significant statistical findings,

a trend toward method discontinuation was noted.

Percentages reveal a 12.5% discontinuation in girls who experienced a greater than three pound weight gain compared to 5.6% in those who did not gain weight.

On further analysis of data collected at the time of the third injection, six month follow-up appointment, the population subjects decreased to 22. These four subjects who discontinued family planning services reflected a 15.38% (n = 4) discontinuation rate of DMPA use. One of these four girls who discontinued services experienced a three pound or greater weight gain at the second injection 3.8% (n = 1).

The mean weight at the initiation of the study was 146.63 pounds (n = 26). At the second injection the mean weight was noted at 145.98 pounds (n = 26), which was a decrease of 0.65 pounds. At the time of the third injection the mean weight was 145.11 pounds (n = 22), with an overall weight gain of 1.41 pounds. The cumulative weight change experienced by these girls was a gain of 0.61 pounds.

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

This research study did not provide significant evidence to support DMPA discontinuation when a three-pound weight gain was experienced by 17-19 year old adolescent girls. Although this was the study finding, it is important to recognize that these girls did not discontinue DMPA use despite weight gain at three months. It was not possible to determine reasons for discontinuation of service at the third injection. However the overall population did not exhibit a significant weight gain.

Recommendations

There are several significant limitations of the findings in this research study. The sample size was small and from a specific setting, thus limiting the external validity of the results. With limited external validity it is not possible to generalize the findings or make conclusions outside of this study sample. Although weight gain was not determined to have a significant association with DMPA discontinuation there were other

findings of importance. The data suggest that despite weight gain, teens at school based clinics continued with a very safe and effective contraceptive method for six months.

In order to capture greater external validity, it is recommended that a larger sample of adolescent girls in a variety of settings be studied to determine the relationship of characteristics such as age, educational level and competence, socio-demographic status, race/ethnicity, provider education and support, to method adherence. By expanding the sample and collecting data from a variety of settings, knowledge on weight gain associated with DMPA discontinuation could be better understood, leading to specific areas for educational intervention.

In an effort to advance the practice of nursing it is important to develop educational programs to address the users understanding of the most common side effects of DMPA administration to benefit their decision making prior to initiating and during use of this contraceptive method. Through education adolescent girls would then have a better understanding and an enhanced ability to monitor and control weight gain through dietary

awareness, a regular pattern of exercise, and an overall understanding of maturation and the metabolic cycle.

Body image perception is a significant area of concern for adolescent girls that can effect overall self-esteem. The theoretical framework developed for this study predicted contraceptive discontinuation after girls' experience weight gain that they relate as a side effect to DMPA. In this setting girls did experience weight gain however at three months only one girl discontinued use. It would be beneficial to conduct a study to define characteristics of girls and providers that support management of side effects for contraceptive method compliance. Effective target areas for support and education may assist the girls in building and enhancing body and self esteem. Through confidence they may learn health-seeking behaviors that will benefit overall health and wellbeing.

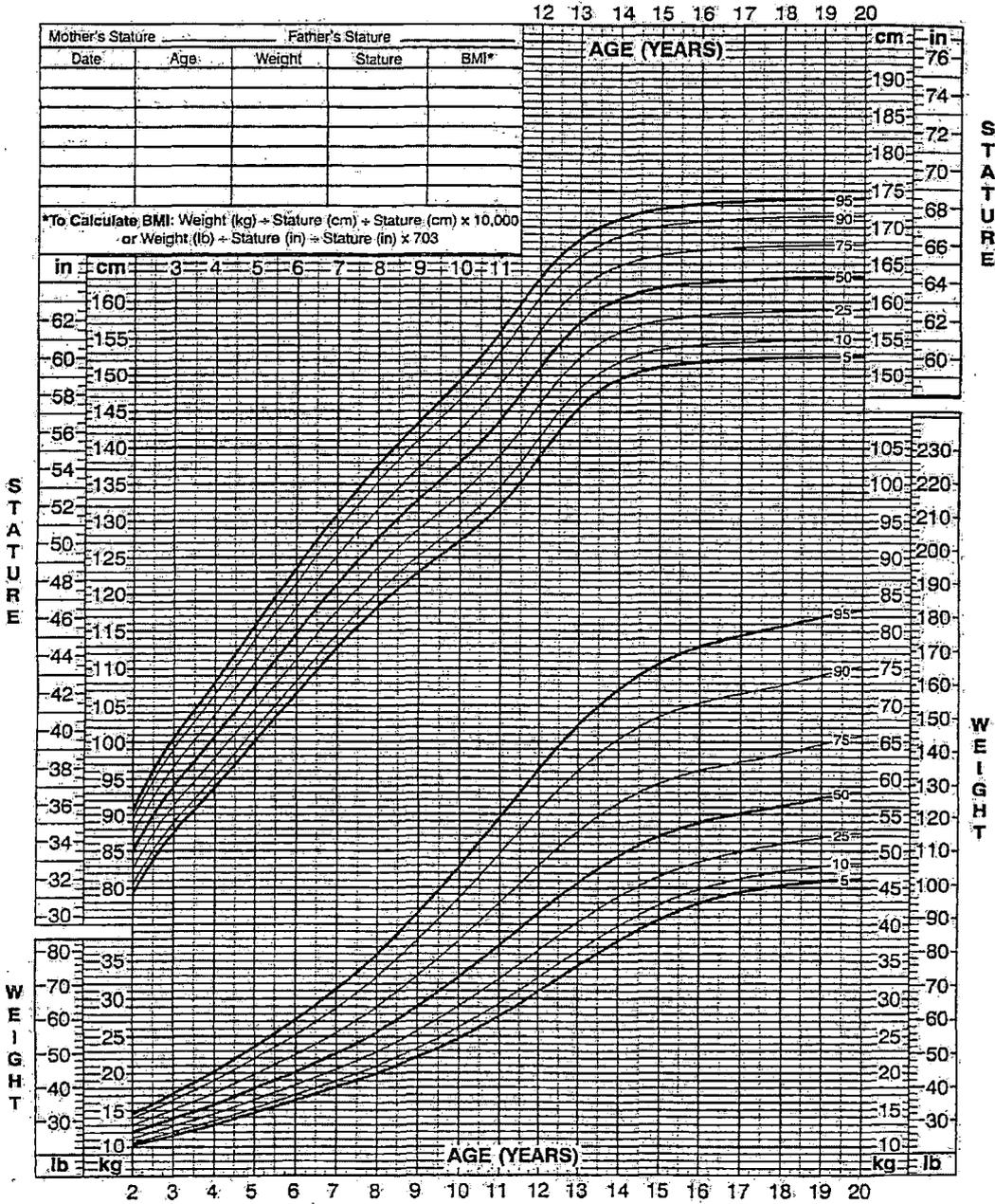
Further research should be conducted to not only study the weight variability in populations of other adolescent girls but also expand the length of the study for up to two years to understand the potential or probability of cumulative weight change. Through increased information on weight gain and other side

effects we may come to a better understanding of DMPA and develop effective management strategies for the adolescent population, thereby boosting overall adherence to this effective contraceptive method and thus reduce the overall teen pregnancy rate.

APPENDIX A
BODY MASS INDEX

2 to 20 years: Girls
Stature-for-age and Weight-for-age percentiles

NAME _____
 RECORD # _____



Revised and corrected November 28, 2000.
 SOURCE: Developed by the National Center for Health Statistics in collaboration with
 the National Center for Chronic Disease Prevention and Health Promotion (2000).
<http://www.cdc.gov/growthcharts>



APPENDIX B
TEEN HEALTH CENTER CONSENT
FORM

Fontana Unified School District
TEEN HEALTH CENTER
CONSENT FORM

The Teen Health Center(s) will have a physician and/or certified nurse practitioner available for comprehensive health services. These comprehensive services will address a wide range of adolescent health problems and concerns including but not limited to physical examinations, oral assessments, treatment for routine illness/minor injuries, health education, nutrition, weight control, smoking cessation, drug and alcohol referrals, prenatal and postnatal support, including birth control (which will be dispensed or provided by a physician), and sports exams. The center will encourage students to learn and develop skills related to health and wellness. The health center will provide confidentiality as mandated by California State law. I also give my permission for district personnel to transport my child to the appropriate clinic for such services.

If you wish your son or daughter to receive physician/certified nurse practitioner services or dentist/dental hygiene services, please sign, date, and return this form to your student's school.

.....
 has permission to be seen by a physician/nurse practitioner, or

LAST NAME FIRST NAME DATE OF BIRTH

dentist/dental hygiene for dental screening, dental cleaning and placement of dental sealants at the Teen Health Center.

This authorization shall remain in effect for the 19____-20____ school year. This consent shall remain in effect until revoked by you in writing and delivered to the principal:

YES	NO
_____ PARENT/GUARDIAN SIGNATURE	_____ PARENT/GUARDIAN SIGNATURE
_____ DATE	_____ DATE

Allergies (if any): _____

Chronic Medical Illness (past/present): _____

Current Medication (if any): _____

Date of Last Tetanus Shot: _____

Other Important Health History: _____

Family Doctor: _____ Family Dentist: _____

4/99

APPENDIX C
HEALTH ACCESS PROGRAMS

HEALTH ACCESS PROGRAMS FAMILY PACT PROGRAM CLIENT ELIGIBILITY CERTIFICATION (CEC)

Client identification number

This form is the property of the State of California, Department of Health Services, Office of Family Planning, and cannot be changed or altered.

Please print answers to all questions. The questions about your family size, income, and health care insurance are to determine if you are eligible for Family PACT Program services.

- Providers must keep a copy of this form in the client's medical record. (See PPBI, Client Eligibility Certification Form Completion Section for code determinations.)
- Code areas are for Provider use only.

Do you currently receive Medi-Cal benefits or services? Yes No

Do you have a Medi-Cal Benefits Identification Card (BIC)? Yes No

BIC number: _____ Issue date: _____

Do you have health care insurance for family planning services? (Private insurance, Health Maintenance Organization (HMO), Managed Care Plan, Student Health Insurance, etc.) Yes No

Do we need to keep your family planning services confidential from your partner, spouse, or parent? How may we contact you if we need to talk to you about something? Yes No
Confidentiality

Provider Use Only—CODE

First name: _____ Middle name: _____ Last name: _____ Suffix (Jr., Sr.): _____

Is your current name the same as your name at birth? If no, print your name at birth below. Yes No

First name at birth: _____ Middle name at birth: _____ Last name at birth: _____ Suffix (Jr., Sr.): _____

Number of live births: _____ County of residence: _____ Provider Use Only—CODE: _____ Nine-digit ZIP code: _____

Gender: Male Female Other
Social security number: _____ Mother's first name: _____

Date of birth (mm/dd/yyyy): _____ Place of birth (county, if California): _____ State (if not California): _____ Country (if not USA): _____

Race/ethnicity

1 Asian 2 Black 3 Filipino 4 Hispanic
5 Native American 6 Pacific Islander 7 White 8 Other

Primary Language

1 Armenian 2 Cantonese 3 English 4 Hmong 5 Khmer/Cambodian
6 Korean 7 Tagalog 8 Spanish 9 Vietnamese 0 Other

This information will be used to see if you are enrolled in any state health program. Information will also be used to monitor health outcomes and for program evaluation purposes. Your name will not be shared. Each individual has the right to review personal information maintained by the provider unless exempt under Article 8 of the Information Practices Act.

Complete eligibility information on reverse side.

APPENDIX D
PERMISSION LETTER



Fontana Unified School District

9680 Citrus Avenue P.O. Box 5090 Fontana CA 92334-5090 (909) 357-5000

July 13, 2001

To: Committee on the Protection of Human Subjects
California State University San Bernardino

Dear Sirs:

Please be advised that Donna Church has obtained permission to conduct her study of "Depot Medroxyprogesterone Acetate Discontinuation After Weight Gain In 17-19 Year Old Adolescent Girls". This retrospective chart review will consist of records from students receiving health services in the Fontana Unified School District during September 1999 to June 2001.

Sincerely,

Terry Paxton, RN, CPNP
Assistant Director
Comprehensive Health Services

KAREN J. HARSHMAN, Ed.D.
Superintendent of Schools
(909) 357-5000 ext. 7010 Fax: (909) 357-5012
EMMANUEL J. D'SOUZA
Associate Superintendent, Business Services
(909) 357-5000 ext. 7115 Fax: (909) 357-5287

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APPENDIX E
INSTITUTIONAL REVIEW BOARD
APPROVAL LETTER



CALIFORNIA STATE UNIVERSITY
SAN BERNARDINO

January 18, 2002

APPROVED
Full Board Review
IRB File #
01024
APPROVED

The California
State University

Ms. Donna Lea Church
Professor James E. Green
Department of Education
California State University
5500 University Parkway
San Bernardino, California 92407

Dear Ms. Church:

Your application to use human subjects, titled, "Depot Medroxyprogesterone Acetate Discontinuation Rates After Weight Gain in 17-19 Adolescent Girls" has been reviewed by the Institutional Review Board (IRB). Your informed consent statement should contain a statement that reads, "This research has been reviewed and approved by the Institutional Review Board of California State University, San Bernardino."

Please notify the IRB if any substantive changes are made in your research prospectus and/or any unanticipated risks to subjects arise. If your project lasts longer than one year, you must reapply for approval at the end of each year. You are required to keep copies of the informed consent forms and data for at least three years.

If you have any questions regarding the IRB decision, please contact Michael Gillespie, IRB Secretary. Mr. Gillespie can be reached by phone at (909) 880-5027, by fax at (909) 880-7028, or by email at mgillesp@csusb.edu. Please include your application identification number (above) in all correspondence.

Best of luck with your research.

Sincerely,

Joseph Lovett, Chair
Institutional Review Board

JL/mg

cc: Professor Ellen Daroszewski, Department of Nursing

APPENDIX F
RESEARCH STUDY DATA
COLLECTION TOOL

Research Study Data Collection Tool

Data of Medical record Review:		Code:
Age at Initial DMPA Injection: _____	Race: 1 = White 2 = African American 3 = Asian American 4 = Other	Ethnicity: 1 = Hispanic 2 = No Hispanic
Previous contraceptive use 1. Yes 2. No	Parity: 1. Pregnancies None 2. Abortions _____ 3. Miscarriages _____ 4. Live Births _____	Baseline Height (inches) and Weight (pounds) at DMPA initiation: Date _____ Height _____
Height, Weight, and Side Effects		
DMPA Initial Injection	DMPA #2	DMPA #3
Date _____	Date _____	Date _____
Weight _____	Weight _____	Weight _____
Height _____	Weight Change _____	Weight Change _____
Comments _____ _____	Comments _____ Weight gain > 3lbs 1. Yes 2. No Continues 1. Yes 2. No	Comments _____ Weight gain > 3lbs 1. Yes 2. No Continues 1. Yes 2. No
If students discontinues use at any time, reason for discontinuance: 		
Comments: 		
Reviewer:		

APPENDIX G
MEDICAL RECORD DEMOGRAPHIC
DATA

Medical Record Demographic Data Summary

Demographic Variables	Demographic Data
Age	17 year olds 88.5% 18 year olds 11.5% Mean Age 17.1154 Median Age 17.0000 Standard Deviation .3258
Race	White 88.5% African American 3.8% Asian American 3.8% Other 3.8%
Ethnicity	Hispanic 69.2% Non Hispanic 30.8%
Parity	None 100%

APPENDIX H
SUMMARY OF WEIGHT STATIC

Summary of Weight Status in Adolescent Girls Taking
 Depot Medroxyprogesterone Acetate as a Contraceptive Agent

Data Label	Mean	Median	Standard Deviation
Baseline Weight at DMPA Injection	146.6346	143.5000	36.2760
Weight at #2 DMPA Injection	145.9808	141.5000	35.7062
Weight Change at #2 DMPA Injection	-.6538	.0000	4.2586
Weight at #3 DMPA Injection	145.1136	139.0000	37.5246
Weight Change at #3 DMPA Injection	1.4091	1.0000	4.7199

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