HYPERTENSION IN BLACK WOMEN TAKING ORAL CONTRACEPTIVES

A THESIS

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF MASTER OF SCIENCE

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

COLLEGE OF NURSING

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AUGUST 1978

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July 21, 19 78

We hereby recommend that the Thesis prepared under our supervision by Beverly Harris Robinson entitled Hypertension in Black Women Taking Oral Contraceptives

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ACKNOWLEDGEMENTS

The committee who has assisted me in the preparation of this paper have been extremely supportive. I wish to thank Dr. Helen Gaevert, Ms. Donna Vokaty, and especially Mrs. Mary Elizabeth Benedict, the chairperson of the committee. Special thanks to Dr. Richard Bennett who generously assisted me in data analysis.

I would like to thank my family and friends for all the encouragement and support they have given during the preparation of this paper. When the task seemed insurmountable, they were always there to encourage me.

Thanks is also given to my typist, Norma Adams.

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CHAPTER I

INTRODUCTION

Since their introduction some 17 years ago, there has been an enormous growth in the use of oral contraceptives (OC). At the same time, there has been an increasing preoccupation and a growing awareness by health care professionals of the prevalence of hypertensive cardiovascular disease. The widening availability of blood pressure (BP) screening programs, the American Heart Association national campaign on the need for BP checks, and the educational warnings with regard to the danger of elevated BP have heightened public awareness of high BP. Such an elevation of arterial BP is called hypertension. Hypertension frequently has been referred to as "the silent killer" because it often has produced no noticeable symptoms before severe cardiovascular damage occurs. As a result of national awareness, the educated consumer has challenged health care professionals to search for answers to the problem of controlling hypertension and to provide high quality of care to those persons detected as hypertensive.

Of the reversible conditions attributed to the use of steroid contraceptives the most important is hypertension. There is general agreement that there is a significant relationship between OC use and hypertension. The side-effects of OC use are widespread problem receiving much attention. An elevation of BP above control levels has been recognized as one of the side-effects of OC therapy. By arbitrarily considering "elevated" BP as a systolic pressure greater than 140 millimeters of mercury (mm. Hg.) or diastolic greater than 90 mm. Hg., or both, the proportion of OC users among clients with elevated BP is significantly higher than the proportion of nonusers.

Current research shows that hypertension as a complicating factor of OC use appears not to be related to OC dose or components or duration of use. There is, however, clinical evidence suggesting that hypertension is related to the estrogen content of OC (Weinberger 1976). Other studies suggest that the women who have greater rises in BP while taking OC are those who would be more likely to develop hypertension spontaneously (Fregly & Fregly 1973; Weir 1976).

The Black population in the United States, including both males and females, appears to be at greater risk for the development of hypertension. Therefore, race

may exert a strong effect on elevated BP associated with OC use. Although the published material is scanty, the reported incidence of OC related elevated BP in Black females is frequent enough that more information is needed.

By documentation of the frequency of OC related high BP and description of the high-risk population group, the family planning nurse and other health care providers are then in a position to recognize these high-risk clients. In addition, the family planning providers could understand their role in the prevention and early detection of hypertension in OC users.

Although the added risk for the hypertensive individual taking OC may be considered small by some researchers, such risk can sum across the United States' population to a significant public health problem. Thus, the importance of recognizing the Black patient who is a high-risk candidate for this, as yet, unexplained hypertension has great significance for the family planning providers in their role in the prevention and early detection of hypertensive clients.

In summary, the effects of OC use on BP is a highly complicated problem. It does seem fitting then that research into the issue of hypertension among OC users with specific focus on Black females be done. The findings of a

study such as this should furnish data to determine whether or not health care providers should be more cautious in their decision to prescribe OC to Black clients. In addition, these research findings should furnish relevant data supporting the need for prevention of hypertension among a high risk population, Black women.

Statement of the Problem

The problem of this study was to determine if a significant relationship exists between oral contraceptive use and the development of hypertension in a select population of Black females between the ages of 18 to 35 years in a Southeast clinic.

Purposes

The purposes of the study were to investigate a select population of Black females, aged 18 thru 35 years:

1. To describe the incidence of hypertension in this group.

2. To determine if those clients with hypertension have ever received OC therapy.

3. To investigate the possible relationship between hypertension and OC use.

Background and Significance

Hypertension did not receive much mention in the health care literature until the early 1930's. Even then it was thought by physicians that to lower the BP was injurious to the patient. With the widespread introduction and use of the mercury manometer in the nineteenth century, experimental studies were carried out on BP, but limited applicability to the clinical situation existed. Since 1930, and particularly since the early 1960's when articles on the dangers of hypertension began appearing in lay literature, more emphasis has been placed on the important problem of hypertension. Today, hypertension is an increasingly common, complex health problem affecting many lives. Approximately 25 million Americans have hypertension (American Heart Association 1978). The rise in mortality associated with hypertension becomes significant at blood pressure readings greater than 130/90 (Weinberger 1976).

Traditionally, medical evaluation of the hypertensive patient has included a complete history, a physical examination, and laboratory studies. Recognizable and potentially curable causes of hypertension have been infrequent, comprising less than 5 percent of the patients displaying elevated BP (Vidt 1975). One cause of

potentially curable hypertension is OC use. Hypertension from OC administration was first confirmed in 1967 (Woods 1967). Since that time many additional studies and reports have appeared indicating that OC can initiate the full spectrum of hypertension, from mild to malignant, and also can worsen a pre-existing hypertension (Fish & Frank 1977; Weinberger 1976). Further studies implicated the estrogenic component of the contraceptive compounds as associated with the rise in BP (Weinberger 1976). It is especially important to ascertain the time period, whether weeks or months, between the client's beginning OC agent use and the development of hypertension. In most cases, a return to normal BP levels is noted on cessation of use of the OC. In a study conducted in 1970, investigators found that 7 percent (9 out of 120) of a random cluster of clients receiving OC developed hypertension for the first time ("Hypertension Affects Many" 1971). Nine of 98 patients in this study had pre-existing hypertension, which was aggravated by the OC.

The clinical implications of a mild, contraceptive-induced BP elevation remain unsettled but disturbing for both the health care provider and the consumer. The magnitude of risk entailed by this elevation continues to be a moot question. Despite the many studies

assessing the frequence of contraceptive - induced hypertension, the level for a clinically important BP elevation has not been established. Controversy mainly centers around the different definitions of hypertension and the diverse study designs used in researching the problem.

Since OC use has been associated with a rise in BP, albeit slight, serious thought and close surveillance should be given when prescribing OC agents to females already predisposed to the development of cardiovascular disease or stroke. The risk appears to be higher in women who are heavier or older or who have a history of hypertension in previous pregnancies or in their families. In other words, as stated in an editorial in the British Medical Journal, "those who are more likely to become hypertensive anyway" ("Pill And Raised" 1976, p. 58).

A family history of hypertension is important from 2 points of view. One, it suggests essential rather than secondary hypertension. Secondly, it may have prognostic implications. A history of a relatively early death in a parent or sibling from a hypertensive complication such as a stroke makes it more likely that the client with borderline or mild hypertension will eventually progress to a more severe stage.

Nevertheless, for any client receiving OC, periodic monitoring of BP is mandatory. If a woman is found to have OC induced hypertension, every effort should be made to avoid using anti-hypertensive drug therapy to treat disease by an OC drug.

When the mortality rates for hypertension at a significance level of 140/90 were subdivided in Blacks and Whites according to age, it became evident that in Blacks hypertension occurring at a relatively young age carried an extremely high risk (Laragh 1974). The National Health Survey conducted by the United States Public Health Service from 1960 to 1962 indicated that the prevalence of hypertension among Blacks was decidedly out of proportion to their percentage in the American population. With Blacks constituting an estimated 15 to 20 percent of the United States population, roughly 6 million Blacks were affected by abnormally elevated BP. Laragh (1974) concluded that the prevalence of hypertension in the United States was almost twice as high in Blacks as in Whites.

Hypertension was not only more prevalent among the Black population than among Whites, but had several substantially recognizable differences in its manifestations than that hypertension which affects Whites. Focusing upon the problem of hypertension in the Black American

population, it developed earlier in life, was frequently more severe, and resulted in a higher mortality at a younger age, more commonly from strokes than from coronary artery disease (Williams 1975). Thus, hypertension has become a common and serious health problem among Blacks.

All epidemiologic studies indicated that the prognosis in women with hypertensive disease was better than that for men. The Framingham study (Lowenstein 1975) revealed that Black women showed a definite increase of both systolic and diastolic BP after age 35. In addition, in the United States in 1960 - 1962, definitive and suspected hypertensive heart disease was between 2 and 5 times more prevalent in Black women at all ages than in White women. Mortality from hypertension was higher in Black females than in White females of the same age and socioeconomic level (Lowenstein 1975). Because BP is only one risk factor in a profile favoring development of arterial disease, it is possibly of great importance that even a slight rise not be allowed to occur in a person with other unfavorable characteristics.

Although the incidence of hypertension among women receiving OC therapy was recognized in current health care research and in clinical practice, a description of the high risk population among Black women was not avail-

able in the literature. For this reason, the assessment of the Black female patient with hypertension still requires further investigation.

A study conducted in a Family Planning Clinic in Washington, D. C. documented a history of elevated BP above 135/85 mm. Hg. in 48 percent (100 clients) of a random sample of Black clients attending that clinic ("Hypertension Affects Many" 1971). The average age of these women was 23 years. A Journal of the American Medical Association editorial further asserted that in Blacks even a history of hypertension could be detrimental ("Hypertension Is Different" 1971). Considering the small number of published reports specific to Black females taking OC who have developed hypertension, a survey of hypertension associated with Black female OC users, in the absence of other clinical causes, is indicated.

Hypertension, then, is a major challenge to the health care community. The health care professional has the opportunity to identify hypertensive patients early in the course of the disease. Only by a coordinated effort at recognition of the hypertensive client, appropriate evaluation, and thorough education can the well-recognized risks of hypertensive disease be controlled.

In summary, there was a need for further research focusing on the problem of hypertension in Black females. This study described the history and significance of hypertension in a select population of Black women ages 18 thru 35 years who took OC and was designed to furnish meaningful information and increase the understanding about the effects of hypertension on Black OC users.

Null Hypothesis

There was no significant relationship between oral contraceptive use and the development of hypertension among a select population of Black females aged 18 thru 35 years.

Definition of Terms

The following terms were defined for use in this study:

1. Blood pressure (BP) -- The pressure of the blood on the walls of the arteries, dependent on the energy of the heart action, the elasticity of the walls of the arteries, and the volume and viscosity of the blood. The maximum pressure occurs near the end of the stroke output of the left ventricle of the heart and is termed maximum or systolic pressure. The minimum pressure occurs late in ventricular diastole and is termed minimum or diastolic

pressure. (Dorland's Illustrated Medical Dictionary 1974, p. 1254).

2. Hypertension -- The level of BP at or above which evaluation and treatment do more good than harm. For the purpose of this study, "elevated" BP was hypertension arbitrarily defined in three ways:

(1) Systolic value greater than 140 millimeters of mercury (mm. Hg.).

(2) Diastolic value greater than 90 mm. Hg.

(3) Both of these criteria (Fisch & Frank 1977).

For the purpose of this study, the following arbitrary classification of hypertension was used:

Normal range -- systolic - below 140 mm. Hg.
diastolic - below 90 mm. Hg.

Borderline -- systolic - 140-149 mm. Hg.
diastolic - 90-94 mm. Hg.

Mild -- systolic - 150-159 mm. Hg.
diastolic - 95-104 mm. Hg.

Moderate -- systolic - 160-179 mm. Hg.
-- diastolic - 105-114 mm. Hg.

Severe -- systolic - 180 mm. Hg.
diastolic - 115 mm. Hg.
(Perez-Stable & Materson 1975, p. 111).

3. Current user -- a woman who was taking oral contraceptives (OC) at the time of her examination.

4. Never user -- a woman who never used OC.

5. Past user -- a woman who had taken OC but was not taking them at the time of her examination. (Fregly & Fregly 1973, p. 5).

6. Demographic data -- for purposes of this study was limited to the client's age, height, and weight.

7. Clinical data -- for purposes of this study was limited to client's BP, OC use, past history of elevated BP, and family history of elevated BP.

8. Procedure for obtaining BP as recommended by the American Heart Association and utilized by the agency under study (See Appendix A):

(1) Client rested 3 to 5 minutes before measurement in order to allow BP to stabilize.

(2) The BP was taken using the right arm of the seated individual.

(3) The right arm, unconstricted by clothing and slightly flexed, was placed on the table so that the brachial artery was approximately at heart level.

(4) Then findings were recorded on the client's record.

Limitations

The recognized limitations of this study were:

1. The investigator had no control over the completeness or accuracy of the data which was recorded on the client's record.

2. The small sample size limited generalization of findings.

3. Findings are limited to a description of the sample population.

4. A one-time survey of blood pressure (BP) made possible a designation only of suspect and not definite hypertension.

5. The sample population of oral contraceptive (OC) users was limited to those women taking OC for the purpose of contraception and not for specific medical reasons.

6. Hypertension does not exist as a discrete physiological variable. A vast array of features, sociocultural and others may induce stress and resultant hypertension. Such features have not been examined within the scope of this study.

7. Many persons had collected and recorded the factual data on the charts, including BP readings, and

variations in the accuracy of clinical data, demographic data and adherence to procedure for BP collection may have occurred.

7. BP readings at the clinical setting were collected and recorded by a family planning nursing assistant, licensed vocational nurse, or registered nurse.

Delimitations

The delimitations of this study were:

1. The population consisted of Black female clients aged 18 thru 35 years with BP 140/90 or greater who were seen in a family planning clinic in Houston, Texas during a 6-month period.

2. Demographic and clinical data was collected on a random sample of the Black female clients who met the above stated criteria.

3. Subjects participating in the study were between the ages of 18 and 35 years inclusive.

Assumptions

For the purpose of this study, it was assumed that:

1. Hypertension is a serious health problem resulting from multiple causes.

2. Oral contraceptive use alters the vascular functioning.

3. Data recorded on client records was reliable.

Summary

Significant hypertension frequently develops in clients taking OC. Although the complexities of the problem of hypertension among OC users are discussed frequently in the literature, there is a scarcity of information available that focuses on the Black client. For this reason, the assessment of the Black client taking OC requires further investigation. This study was designed to furnish meaningful information and to enhance the understanding about the effects of hypertension on Black clients who take OC.

The succeeding chapter, Chapter II, presents a review of the literature relative to the problem of hypertension with OC use, focusing on the related research, the causes, and the Black female as a susceptible population. Chapter III presents the procedure for the collection and treatment of data obtained from the client's records. Included is a discussion of the setting, the research population, and the instrument utilized in the study.

The analysis of data is discussed in Chapter IV. Chapter V includes a summary of the data derived from the study. Conclusions were drawn from data statistically significant. Implications and recommendations based on the data were made.

CHAPTER II

REVIEW OF LITERATURE

Introduction

A review of literature was completed in order to investigate the following areas: the problem of hypertension; the relationship between oral contraceptive (OC) use and hypertension; the mechanism causing OC induced hypertension; and the problem of hypertension in Black females taking OC. There was a limited amount of literature which spoke to the problem of hypertension in Black females who take OC. The review of literature begins with a discussion of hypertension, proceeds to a discussion and review of studies dealing with OC related hypertension, and then examines the theories on the mechanism causing OC related hypertension.

The Problem Of Hypertension

Hypertension is a health care problem of enormous magnitude. Current epidemiological studies indicate that the risk of cardiovascular complications is directly related to the level of blood pressure (BP), namely, that the higher the level of BP, the greater the risk of cardiovascular damage (Gordon 1974). No factor has been identified which more strongly than hypertension predisposes individuals to the development of stroke. Julius (1977)

recommended that the upper limit of normal BP in young clients (18 thru 35 years) be 140 mm. Hg. systolic, 90 mm. Hg. diastolic, or less. Clients with borderline hypertension are at a higher risk of developing future sustained hypertension and its consequences.

In prospective studies of adults, the baseline BP has the strongest relationship to the risk of subsequent development of higher pressures. Both within the "normal" range and in the narrow range of mild hypertension, the higher levels of initial BP are incrementally more likely to lead to later hypertension. (Harlan et al. 1962).

Clients screened and found to have an elevated BP should undergo further evaluation. A complete history and physical examination considering the epidemiological factors favoring essential hypertension should be undertaken. When elevated BP occurs, factors favoring a diagnosis of primary or essential hypertension are:

(1) Afro-American or Black racial heritage
(2) Onset of hypertension at a young age, not infrequent before age 30
(3) Onset of hypertension during pregnancy or as part of the toxemia syndrome
(4) Strong family history of hypertension
(5) Associated obesity.

When evaluating Black clients with hypertension, 95 percent of all cases are diagnosed as essential hypertension (Williams 1975). This essential hypertension may have its onset in childhood. If this is the case, it is important to identify prospective hypertensive clients at an early age because of the potential desirability of early intervention.

The prevalence of hypertension is greater among Blacks as is its tendency to be more severe. Mortality rate for stroke and hypertensive disease are 10 or more times greater in Blacks aged 25 to 44 years, than in Whites of similar age and sex groupings (Stamler et al. 1974; Smith 1977; Julius 1977). However, the most marked hypertensive differences between Blacks and Whites occur in the younger groups. Essential hypertension in a White teenager is rare, while it is not rare in young Black people. Finnerty (Stamler et al. 1974) reported a study in which 3,000 Blacks under age 20 were screened. The prevalence of hypertension in this group was 18 percent comparent with a hypertensive rate of 4 percent in inner city Whites. Among females a ratio difference of approximately 4 to 1 exists in the mortality rates of Black women to White women, the mortality rates being 58 per 100,000 in Black women (Laragh 1974).

The concept that genetic factors play an important role in BP regulation was well established in the literature, as was hypertension among relatives of hypertensives. The correlation of BP with obesity was established in observational and experimental studies (Smith 1977; Julius 1977). However, obesity is neither a necessary nor a sufficient cause for hypertension since many obese individuals, including some extremely fat persons, are not hypertensive. The association of obesity and hypertension is generally manifested in 3 different ways:

(1) Overweight is more prevalent in hypertensive than in normotensive individuals.

(2) Normotensive obese patients are more likely to become hypertensive.

(3) Hypertensive patients are at increased risk of becoming overweight compared to normotensive individuals (Smith 1977).

A further observation that strengthens the association between raised BP and obesity is that a change in BP over time is associated with a change in weight (Smith 1977).

Hypertension With Oral Contraceptive Use

Hypertension has emerged as the single most important chronic cardiovascular disorder, because it is the only one for which treatment has been shown to be effective (Perez-Stable & Materson 1975). One of the most common correctable conditions that cause hypertension is the use of OC. Weinberger (1975) reported that estrogen-induced hypertension was the most frequent identifiable form of hypertension and the easiest form to diagnose and treat.

When the OC pill became generally available in 1960, it was hailed as the first contraceptive in history that was safe, virtually 100 percent effective, simple to use, and reversible. OC use promised to release women from the fear of unwanted pregnancy. Experience, however, has tempered the initial enthusiasm. There is now evidence to support the facts that OC are not entirely safe for all women, their effects may not always be reversible, and OC use is not always effective. Consequently, as with every medication, the benefits of OC use must be weighed against its risks (Connell 1975). Today, over 10 million women in the United States are OC users (Fregly & Fregly 1977).

Despite the widespread use of OC, investigators are not in agreement regarding either the incidence of elevation of BP in OC users or the possible mechanisms by which an elevation may occur. Hypertension still appears as a rare side effect when one considers that millions of women are taking OC on a long-term basis. It should, however, be noted that there exist wide variations in the reported incidence of OC induced hypertension with very low incidences being counterbalanced by some extremely high estimates (Laragh 1974). Estimates of the incidence of hypertension due to OC use range in the various prospective and retrospective studies from 0 to 20 percent of clients in small studies (Weinberger 1976; Fregly & Fregly 1977; Perez-Stable & Materson 1975).

Variability in the range of occurring hypertension may result from client selection or reflect the different techniques used to measure BP and define hypertension. When care was taken to select only clients who did not have antecedent hypertension, an incidence of 0 to 7 percent was observed (Low 1975; Clezy 1972; Spellacy 1974; Weinberger 1969). In larger series, the incidence of frank hypertension was observed to be about 5 percent and hypertension was observed to occur in 2½ times more women taking OC than a control group of non-users (Weinberger

1976). Considering the large numbers of women taking OC, even a 5 percent incidence of hypertension becomes a health care problem of considerable significance.

There seems to be little doubt that chronic use of OC can elevate BP in certain susceptible women. Although the natural history and mechanisms of OC induced hypertension remain unknown, several facts concerning its management are known. Current epidemiological studies indicate that the risk of cardiovascular complications is directly related to the level of BP, namely, that the higher the level of BP, the greater risk of cardiovascular damage (Gordon 1974). OC induced hypertension may be serious, producing renal damage and probably serving as a risk factor for stroke and myocardial infarction (Corday 1977). Because hypertension may occur at any time after the OC is prescribed, no more than a 6-month's supply should be provided so that the client will return for a BP reading.

Overall, the OC is the best form of contraception for many women. Nevertheless, OC use may induce hypertension, and should hypertension occur, it must be dealt with appropriately. The time of onset and extent of this BP increase varies between individuals and only occasionally does the BP rise to levels which may be associated with clinical signs and symptoms (Harris 1969; Weir 1976).

The clinical picture of OC induced hypertension is indistinguishable from essential hypertension. Currently, the only means of making the diagnosis of OC hypertension is to stop the medication and note whether the hypertension remits, usually within 6 to 8 weeks (Weir 1976, Fregly & Fregly 1977). However, the population of women whose BP increased abnormally with OC pill therapy included some who are destined to become essential hypertensives (Low 1975). It may be difficult to separate OC hypertension from coincident, naturally occurring hypertension of any etiology. In fact, a number of investigators have suggested that pill hypertension may simply represent an unmasking or acceleration of underlying essential hypertension (Crane 1971; Laragh 1974; Woods 1967).

Those clients who are asymptomatic and have uncomplicated mild hypertension (BP $<$ 160/105) should be treated simply by discontinuation of the pill. If BP returns to normal, no specific diagnostic studies are necessary. These women are assumed to have pill-induced hypertension and should never receive OC again (Low 1975). Whether this small BP elevation observed in some OC users may become ultimately detrimental to them is not known. If, however, mild or moderate hypertension persists 6 months after stopping the OC, antihypertensive therapy

should be started and a complete evaluation for underlying hypertension undertaken.

Because of the relative infrequency of severe or symptomatic hypertension in association with OC therapy, these clients with severe hypertension should be evaluated for a secondary cause of hypertension (Low 1975). Woods (1967) observed that 50 percent of a group of women who became hypertensive during OC therapy later developed mild hypertension. However, most observers believe that true OC pill hypertension is reversible upon drug withdrawal although the return to normotension may require 3 months or more (Fregly & Fregly 1977; Crane 1971; Laragh 1974). Langer (1976) observed that hypertension was reversible after about 3 months of no medication but rapidly recurred if OC use was resumed.

Doll, in a review article by Mackay et al. (1973), suggested that the possibility exists for irreversible damage to occur in some circumstances of hypertension which would prevent the BP from returning to normal when OC therapy was discontinued. Manvais-Jarvis et al. in a Mackay et al. (1973) review article, stressed that a consistent elevation in BP in the initial months of OC use, even if moderate in degree, was an indication for cessation of its use. The rise of BP at the commencement of OC

treatment is less well-documented, but Weinberger (1976) observed that abnormal BP levels may not be reached for some months. Fairweather (1974) further stated that only when there was a consistent rise in BP maintained over a period of time could the change be considered important.

Some researchers believe that hypertension is not an absolute contraindication to the use of OC but stress that careful checks should be carried out to make sure there is no worsening of the condition. Should OC be prescribed for a woman known to be hypertensive, a full explanation to the client of the risks involved and a commitment to frequent monitoring of BP should be made. However, it is generally agreed that if there is significant BP rise either in the hypertensive client or in the client with a previously normal BP, the medication should be stopped and an alternative contraceptive prescribed.

While it is generally acknowledged that the estrogen component in OC is responsible for elevation of BP, a duration-related phenomenon and the dose-related aspects are less clear. Hypertension, however, has been observed to occur with all known contraceptive formulations, including the minipill compounds (Weinberger 1976; Fregly & Fregly 1977). Therefore, the importance of checking the medical and reproductive history of the patient

cannot be over-emphasized. It should be noted that in famale clients, the antihypertensive evaluation may be inaccurate in the presence of OC use (Gordon 1974).

Attempts have been made to relate OC causally to the development of hypertension by measuring BP in women before and after starting OC (Crane 1971; Laragh et al. 1967; Spellacy 1974). The evidence obtained from studies of this type gives strong support to the fact that OC use does indeed produce an increase in systolic and to a less extent diastolic pressure in some women (Fregly & Fregly 1973). While these changes in BP may on an individual basis seem clinically trivial, it should be recognized that the impact on a whole population of women could be substantial.

Factors protecting against an elevation of BP in most OC users is incompletely understood. In addition, Laragh (1976) believes that the possible impact of a five- to ten-year period of a woman's life in which the BP is even slightly elevated over its natural baseline is to be worried about, even without hard data. Laragh (1976), one of the first physicians to report the association between hypertension and OC, has reviewed recent research develop ments. He estimated that about 5 percent of women who use OC for 5 years or more become frankly hypertensive, though very many develop minor increases in BP.

Data from a massive 5 year study of Royal College of General Practitioners of England showed that in 5 years of OC use, 5 percent of women will develop hypertension (Corday 1977). Their risk is 2.6 times greater than women who do not take OC (Corday 1977). The Royal College of General Practitioners of England (1974) suggested that development of hypertension is related to the duration of medication. This study, reported in 1974, indicated that 5 percent of women taking OC for 5 years or longer will develop hypertension and added that these women cannot be reliably identified in advance. Corday (1977) also noted that not all cases of hypertension occurring while the woman is using OC will disappear when the pill is stopped, and commented that OC use may be uncovering at an earlier time what was going to happen spontaneously rather than actually causing new hypertension.

Prior to 1967, there were only 2 case reports in the literature relating hypertension to the use of OC. In 1962, Brownrigg described a single case in which the BP of a 37 year old client rose from 120/80 mm. Hg. to 200/110 mm. Hg. after 6 months of OC use. Her BP returned to 110/80 mm. Hg. 4 months after discontinuing use. Four years later, after Owen (1966) reported a similar case, Swaab (1966) suggested the possibility that hypertension may be a sequel to OC use.

Nevertheless, the causal nature of the relationship between hypertension and OC use was not established until 1967 when 14 more cases were reported in the literature (Woods 1967; Laragh 1967; Mackay et al. 1973). Mackay et al. (1973) and others attribute this delay to failure by health care providers to include BP recordings as part of the evaluation of clients receiving OC (Fregly & Fregly 1973). Of the 14 clients experiencing elevated BP while using OC, Laragh et al. (1967) and Woods (1967) reported improvement or return to normalcy in 12 cases.

Since 1967, further reports have been published implicating OC use as one cause of hypertension. In a study of 66 clients, Weir et al. (1971) observed only a rise in the systolic, but not the diastolic pressure in those clients who experienced elevated BP. Other researchers (Laragh et al. 1967; Woods et al. 1967; Newton et al. 1968) confirmed a return of BP to normal after OC therapy was discontinued. Laragh et al. (1974) noted that re-introduction of the OC caused a re-appearance of the rise in BP.

Some confusion arose in the early prospective studies undertaken in an attempt to establish the effect of OC use on the incidence of hypertension because of small

samples and inconsistent definitions for hypertension. Mackay et al. (1973) reviewed several epidemiologic studies that were reported by family planning clinics and other special units. Most of these studies were retrospective in nature or lacked a control group. One such study involved a random retrospective chart study of 120 clients who had been taking 8 brands of OC and 100 control clients. Only a small difference in mean change between the 9 groups was noted and no consistent pattern was observed.

Research by Chermik (1968) compared 303 clients on OC with 55 who were using an intrauterine device. No significant difference in the incidence of elevated BP in the 2 groups was established after 10 cycles of OC therapy.

An British study observed that 99 of 9,000 OC users had a BP level greater than 140/90 mm. Hg. Thirty-seven of these clients were already using OC when the hypertension was discovered and 31 were previously normotensive. After discontinuation of OC use, the BP fell in 27 of the 32 clients followed by the researchers (Chidell 1970).

In a research review by Mackay et al. (1973), 4 other studies reported high incidences of elevated BP as did Chidell. Tyson reported an elevation in BP in

16 percent of 45 clients on OC, while Spellacy and Birk (1974) found that 9 of 57 clients (16 percent) developed hypertension after 6 or more cycles of treatment.

In 1972, several carefully conducted trials were published. Smith (1972) reported findings from a prospective study of a special hypertensive clinic covering a large family planning clinic program at a municipal hospital. Hypertension was observed in about 1 percent of the clients. Of 60 hypertensive clients evaluated, 21 discontinued OC use without the addition of antihypertensive medication and were followed for 200 days. The researcher reported that significant declines in BP were not seen in the group as a whole until about 100 days had elapsed.

Mahran and Fadel (1972) investigated for 6 months 100 clients on low dose OC who attended a family planning clinic. One hundred women wearing intrauterine devices comprised their control group. All clients had their BP measured under the same clinic conditions. Sixty-eight women (61.8 percent) among the OC users had a systolic pressure higher than that recorded at the onset of the study. In 51 of these women, this rise in BP took place during the first 3 months of OC use. No BP changes were recorded in the 100 control women who were being followed simultaneously. Despite the reported rise

in BP, the researchers concluded that in general, the low dose contraceptive pills used in their study did not cause hypertension.

In 1962, after 2 years of planning, the Royal College of General Practitioners of Great Britain began a large scale, controlled prospective study of the health of OC users involving 1,400 physicians, 23,611 OC users, and 22,766 controls. An interim report of the first 5 years of this study, published in 1974, evaluated various metabolic alterations and clinical changes associated with OC use. This British study estimated the incidence of hypertension in the first year of OC use to be less than 1 percent, but showed that there was a relation between the duration of OC use and the development of hypertension. Data from this study, as previously noted, indicated that about 5 percent of OC users develop hypertension after 5 years of use, an incidence about 2.6 times greater than controls (Royal College of General Practitioners 1974).

In 1969 the Walnut Creek Contraceptive Drug Study, involving the largest group of women thus far studied, determined BP for 7,605 women aged 18 to 60 during a 3 year period. The subjects included 1,941 current users of OC, 2,189 never users, and 1,593 past users, as well as 682 women taking other estrogenic hormones, 953

pregnant, and 247 post-partum women (Ramcharan 1974). The purpose of this prospective study was to monitor the non-contraceptive effects of OC. BP were recorded with clients in a supine position. By defining elevated BP as a systolic pressure greater than 140 mm. Hg., or diastolic greater than 90 mm. Hg., or both, the proportion of OC users among clients with elevated BP was significantly higher than the proportion of nonusers at every age level. The study concluded that OC were associated with a modest yet definite increase in BP. The study also found no significant association between BP and total months of OC use for past and current users. In addition, no association was found between BP and OC formulation or dose. According to this study, if a woman is selected at random, she is 1.76 times as likely to have a systolic BP 140 mm. Hg. or higher and diastolic pressure 90 mm. Hg. or over if she is an OC user than if she is a nonuser (Ramcharan 1974).

This 1974 report from the Kaiser Permamente Contraceptive Drug Study at Walnut Creek further indicated that OC users have nearly 7 times the likelihood of developing hypertension as women who never took OC, and nearly 6 times the risk as former OC users. These findings were, however, based on data gathered during multipha-

sic health screening of women who were members of the Kaiser Foundation Health Plan in the Walnut Creek, California area. All data was standardized for age, since current users tended to be somewhat younger than the never users and past users. The average length of observation in each group was almost identical - slightly more than 19 months for each woman. Based on an age-adjusted rate, these approximate incidence rates of new cases of hypertension were determined:

6.2 new cases per 1,000 current users,

1.1 new cases per 1,000 former users, and

0.9 new cases per 1,000 never users (Ramcharan 1974).

These incidence rates, however, cannot necessarily apply to the entire United States population, since the study population was largely white and middle class, and hypertension is much less prevalent among this group than among Blacks and poor persons. As a consequence, based on this study no comments can be made on race as a variable in hypertension associated with OC use.

Spellacy and Birk (1974) studied the effect of OC on the BP of 415 normotensive women over a 2 year period. Women wearing intrauterine devices served as the control group and had no significant change in either their weight

or BP during the 24-month study period. The women taking OC had a significant weight increase for 6 months, but it later decreased. This group also demonstrated a significant rise in both systolic and diastolic BP at 6 months, while only the diastolic pressure was elevated at 12 months. By 24 months neither the systolic nor diastolic pressures of the women taking OC were significantly different from those women wearing an intrauterine device.

Weir (1976) in a 5 year prospective study begun in 1969 in Glasgow, Scotland, compared BP changes in a group of 186 women taking OC with those of a control group of 60 women using diaphragms or intrauterine devices. The results of this survey suggested that the increase in BP among OC users generally occured within the first 2 years of their administration although the BP of some women continued to rise progressively for at least 5 years. This Glasgow study does not support the concept of a subgroup of women who are more sensitive than the general female population to the pressor effects of OC.

Epidemiologic information on factors determining individual susceptibility to the hypertension stimulating effects of estrogen are scarce and inconclusive. As a result, one cannot designate with certainty those women prone to develop OC induced hypertension. Despite these

conflicting research reports, there appears to be a definite risk of hypertension developing in certain clients receiving OC. Although, this susceptible client is as yet not well-defined, there is, nevertheless, evidence from the literature that there may be a special at-risk group of women. Those factors which appear to have the strongest association with arterial BP are heredity, age, race, and obesity (Smith 1977; Royal College of General Practitioners 1974). Such associations may or may not be causally related and are not necessarily predictive.

The Walnut Creek Contraceptive Study (Fregly & Fregly 1977) the study by the Royal College of General Practitioners (1974), and numerous independent researchers (Clezy et al. 1972; Laragh et al. 1967; Fisch et al. 1972) strongly correlated the development of hypertension in an OC user with the woman's age. The incidence of development of hypertension during OC use increased with increasing age of the woman. Women using OC in the age range 40 to 44 years were at approximately 5 times the risk of developing hypertension as those using OC in the age range 30 to 34 years; 10 times the risk as OC users in the 25 to 29 year age range (Fregly & Fregly 1977; Ramcharan 1974). This finding confirmed the findings of Fisch et al. (1972), Rosenberg (1969), and Laragh et al. (1967), that age may be a significant cofactor in elevated BP with OC use.

Data shows a positive correlation between hypertension and increased weight for height in adults (Report of the Task Force 1977). Laragh (1976) reported similar data implicating weight as a cofactor in the development of hypertension in some women on OC. He noted that a weight gain was one of the surest and earliest indications of sodium and water retention in a woman taking OC.

Relative weight accounts for about 10 percent of the variations in BP among the population in the United States (Report of the Task Force 1977). Whether increased BP is related simply to increased body weight or only to excess body fat has not been determined. Many obese people including some extremely fat persons are not hypertensive (Kannel et al. 1976). To date, there have been relatively few longitudinal studies relating obesity to the risk of developing hypertension. Nevertheless, hypertension does develop more frequently in overweight adults and there is a strong relationship to the rate of increase of body weight (Kannel et al. 1976; Chiang, et al. 1969). Chiang et al. (1969) reports that overweight women generally have more hypertension than do overweight males. Loss of weight has been reported to lead to a decrease in BP, but the relationship is not consistent nor is it clear whether or not this decrease depends on dietary modifications.

Laragh (1976) further suggested that 2 groups in whom OC are contraindicated may include younger women in whom a longer term contraceptive commitment is likely and members of ethnic groups such as Blacks who are especially susceptible to the development of hypertension. Fairweather (1974) also reported some evidence of ethnic differences in BP changes, but noted that these had not been studied in depth. Low (1975) concurred, stressing that caution must be exercised when prescribing OC for women from populations which manifest high incidences of hypertension. In the United States today, Blacks are so afflicted.

Few researchers have investigated in the incidence of hypertension occurring in Black women who take OC. The major studies done in the United States have focused on White, middle-class females (Fregly & Fregly 1977; Ramcharan 1974).

A study by Saruta et al. (1970) reported one of the highest percentages (10 of 56) of initially normotensive women who when on OC developed hypertension. This study included 17.8 percent (10 of 56) Black women, the largest percentage of Black women reported in any study reviewed. Reports by Fregly and Fregly (1977) agreed with Saruta's findings, that when compared, Black women have

higher BP than White women when compared at similar age ranges.

Genetic characteristics as a cofactor may play a part in the increased susceptibility to hypertension during OC therapy (Clezy et al. 1972; Weinberger 1969). A prospective study done by Clezy et al. (1972) on women with a familial history of essential hypertension noted that these women had increased tendencies to develop hypertension from OC. These observations further serve to implicate the use of OC by Black women as a factor in the development of hypertension. However, the magnitude of the problem of hypertension occurring in Black females taking OC is still uncertain.

Mechanism

The mechanisms by which OC may induce hypertension in certain susceptible women are not clearly understood. It does, however, seem clear that a single mechanism for the production of hypertension in those certain susceptible women ingesting OC cannot be cited. Multiple physiologic changes occur. Consequently, whether hypertension develops in a given individual depends on the magnitude of the increase in cardiac output, the degree of change in peripheral resistance, body water, and the interaction of the renal and adrenal cortical systems, all these

factors being implicated in various theories to be discussed (Laragh et al. 1974; Vidt 1975; Weir 1976; Laragh 1976).

Although no uniform abnormality has been identified to explain the mechanisms whereby estrogens induce hypertension, 3 possible mechanisms have been proposed in this syndrome of hypertension during OC use:

(1) an effect on the renin-angiotensin-aldosterone system,

(2) an indirect vascular effect whereby the smooth muscle of vessels is sensitized to a vasoconstrictor agent, e.g., angiotensin II,

(3) a more direct estrogen effect in promoting salt and water retention.

To date, none of them provides a complete answer.

Presiding over BP is that complex of hormones and enzymes known as the renin-angiotensin-aldosterone (RAA) system, located along the biochemical axis between the kidney and the adrenal cortex. Fluid and electrolyte balance is at the same time the purpose of this system, its agent, and its medium. As a result of investigations into the cause of hypertension that develops in some women taking OC, notable changes have been uncovered in the renin-angiotensin system.

The influence of OC on the RAA system in individuals with all inherent or acquired susceptibility has been amply documented. Relevant reviews of this theory have been given by Brown (1966), Laragh et al. (1967), Skinner et al. (1969), and Vidt (1975). The system is a complex one, and the methodology is equally so. Because very similar biochemical abnormalities are apparent in normotensive women using OC, it can, therefore, be postulated that women who develop hypertension while taking OC are more sensitive to these changes than those who do not.

In the RAA system, renin produced by the juxtaglomerular apparatus of the kidney, combines in the blood with renin substrate to form angiotensin I, a decapeptide. Angiotensin I is converted to angiotensin II, an octapeptide, largely by a converting enzyme present in the lung. When compared on an equimolar basis, angiotensin II is the most potent vasoconstrictor produced by the body. It also stimulates the adrenal cortex to secrete the mineralocorticoid hormone, aldosterone.

Production of renin by the kidney is stimulated when either BP or blood volume is reduced and when either plasma sodium or potassium concentration falls. Stimulation of B-adrenergic receptors in the kidney can stimulate

secretion of renin by the juxtaglomerular cells. The system appears to be influenced by several feedback control loops. An increased blood concentration of angiotensin II can decrease production of renin by the kidney (short feedback loop), while increased sodium and water retention induced by increased blood concentration of aldosterone as a consequence of increased blood angiotensin II concentrations can stimulate the juxtaglomerular cells to reduce renin secretion. This is designated as the long feedback loop. If an increase in plasma renin concentration is initiated by a fall in BP, the peripheral vasoconstriction induced by angiotensin II would serve as feedback loop to redice renin secretion. Consequently, both feedback loops are directly related to BP.

A number of investigators have shown that women chronically ingesting OC containing estrogens have measurable increases in plasma renin substrate concentration, plasma renin activity, and plasma aldosterone concentration while plasma renin concentration is decreased. These observations led Saruta et al. (1970) to suggest that those women who become hypertensive during ingestion of an OC agent may have a defective short feedback loop which when functioning properly, would decrease renin secretion as angiotensin II levels of the blood increased and conse-

quently would reduce angiotensin II levels of the blood (negative feedback). Those women with defective feedback mechanisms would have an elevated blood renin concentration in addition to elevated levels of renin substrate, angiotensin II, and aldosterone. Theoretically then, the hypertension developing in these women could be attributed to elevated plasma levels of angiotensin II and aldosterone.

This appealing notion has been difficult to prove. It is interesting and a little puzzling that both normotensive and hypertensive women on OC show increases in plasma renin substrate, plasma renin activity and aldosterone secretion (Fregly & Fregly 1977). Beckerhoff et al. (1973) and Catt et al. (1971), similarly have shown that women who did not become hypertensive on OC agents and who had a 50 percent reduction in plasma renin concentration still had a 3-fold increase in plasma renin activity and plasma aldosterone concentration. Thus, a 3-fold rise in plasma renin activity and plasma aldosterone concentration can be consistent with normotension. Other possibilities have been suggested to account for these facts. An increase in the rate of metabolism of angiotensin II by angiotensinases in the blood may occur in those women who do not become hypertensive while ingesting

OCs. This would serve the function of decreasing the biological half-life of angiotensin II. However, a defective angiotensin metabolism in women who become hypertensive while ingesting OC agents has yet to be documented. The Royal College of General Practitioners (1974) reported that their intensive investigation of OC users showed substantial change in the RAA system.

The most important of the changes in the RAA system appears to be the increase in plasma renin substrate. Laragh (1976) believes that there is a buffer feedback mechanism operating in response to this increase in renin substrate. Those individual OC users who show an elevated BP are the ones who cannot adequately supress renal renin secretion or compensate for this increase in renin activity. Consequently, in the presence of raised substrate reservoir even normal increments in renin secretion as a response to physiological stimuli could lead to exaggerated angiotensin production and hypertension. Saruta et al. (1970) have extended this research and supported the general concept of a diminished feedback suppression of renin release. Saruta et al. (1970), in their prospective study, evaluated 56 normotensive and 6 hypertensive clients receiving OC therapy. They reported a consistent and significant rise in plasma renin in those

patients who became hypertensive. These findings cannot, however, be considered conclusive because abnormal levels of angiotensin and aldosterone may be found in clients who do not develop hypertension and also the converse may also be true (Mackay 1973; Fairweather 1974). Mackay (1973) reported the findings of Rosenberg which suggested that a deficiency in renal function renders some patients sensitive to the aldosterone-stimulating effect of OC. Craig (1975) suggested that these changes in aldosterone secretion and renin activity are usually transitory. He found that a client on OC may have rather markedly induced changes in these moieties and yet may be normotensive. Despite the transient nature of the changes in the serum constituents, the hypertension may persist as long as 12 weeks or more after the serum levels return to normal and continue until the OC is discontinued (Craig 1975; Laragh 1976; Perez-Stable & Materson 1975). Once the OC are withdrawn plasma renin acitivty generally returns to normal or subnormal within 4 weeks (Laragh 1976).

Whether they develop hypertension or not, most women using OC have increased levels of renin substrate and high plasma renin activity (Perez-Stable & Materson 1975). Therefore, women using OC should have BP readings taken every 6 months and discontinue use of OC should hypertension be detected.

Because OC induced activation of the RAA system does not necessarily lead to hypertension, it appears that additional unknown factors are operative in the development of increased BP in women taking OC. It is now clear that the original hope of many investigators that the RAA system might be useful as a screening device for predicting those women who would develop hypertension on OC has limited usefulness.

In researching the causes of hypertension in women taking OC, it has been suggested that most women using OC can compensate for the increased levels of angiotensin II and aldosterone either by decreased sensitivity or by increased catabolism of these substances while those clients with familial predisposition, obesity, and other as yet, unknown factors cannot (Weindling & Henry 1974). Angiotensin II causes sodium and water retention by stimulating the adrenal cortex to secrete aldosterone. Further, angiotensin II elevates BP by stimulating arteriolar smooth muscle to contract (Low 1975). Saruta et al. (1970) found that normotensive OC users showed no change in plasma renin concentration from pre-OC levels, while women who developed hypertension on OC showed an increase in plasma renin concentration.

Other investigators (Beckerhoff et al. 1973; Catt et al. 1971; Laragh 1974; Vorherr 1973; Mackat et al. 1973; Weir et al. 1975) have found that administration of OC was associated with either no change or a small decrease in plasma renin concentration whether or not hypertension appeared. Since angiotensin II is the dominant pressor substance in the renin-angiotensin system, its concentration is thought to be a critical determinant of BP. Because plasma renin substrate and plasma renin activity have been shown to be increased to the same extent in normotensive and hypertensive pill users and angiotensin II concentration does not always increase in pill-related hypertension because of negative feedback regulation of renin release, it is again difficult to explain OC induced hypertension on the basis of changes in the RAA system alone.

A rise in plasma angiotensin II concentration may occur in some women while taking OC, but no relationship has been found between BP and concurrent circulating levels of angiotensin II in the same women. Nor, is the rise in BP completely related to the plasma concentration of aldosterone or to the total exchangeable sodium (Weir 1976). Other studies suggest that changes in plasma renin substrate rather than in plasma renin activity may play a

critical role in the development of hypertension (Fregly & Fregly 1973).

Of the various hypotheses advanced to explain the effects of increases in BP with OC use, Laragh (1976) rejects the view that all can be explained by increased plasma renin substrate, and, therefore, increased angiotensin II formation. Clients with hypertension associated with OC use do not always demonstrate increased plasma activity. In fact, it is sometimes reduced.

Hypertensive clients with low plasma renin are believed to have fewer cardiovascular complications than those with high renin values. Yet, renin values are significantly lower in hypertensive Blacks than in hypertensive Whites (Stamler et al. 1974).

A third theory relating OC use to hypertension involves the direct effects estrogen has on salt and fluid retention. Laragh (1976) suggests that volume overload is a major factor when women taking OC develop hypertension. The kidney plays an important role in BP control by regulating sodium and water excretion. Aberrations in renal sodium and water handling have been proposed as an alternative explanation for the hypertension observed with OC use. Estrogen is known to depress urinary sodium excretion

in normal patients (Low 1975). Enhanced aldosterone secretion in some women taking OC has been implicated as the mechanism of estrogen-induced sodium retention.

This estrogenic component is the major causative factor in the observed changes in the RAA system. Thus, the well-recognized tendency of some women to retain water when using OC may have its origin in the deviations of this feedback system (Craig 1975). Although the mechanism of the rise in BP is not entirely clear, it is thought to be due to an estrogen-induced increase in renin substrate (Langer 1976). Susceptible women appear to be unable to implement the normal feedback mechanism.

The hypertensive client, then, might be explained as that suceptible one whose buffer capacity for this compensation has either failed or is inadequate and whose renin activity even when somewhat depressed is either inappropriately high for the level of plasma renin substrate present or is set to yield inappropriately large responses to various physiologic stimuli (Fregly & Fregly 1973; Crane 1971). It is also clear that a great deal of study is needed to understand the mechanisms by which estrogenic hormones may elevate BP and to devise reliable tests to determine the susceptibility of women ingesting OC to elevations in BP.

Summary

A review of the literature available on hypertension as a complicating factor in OC use was presented. Although the exact etiology of the hypertension which develops in women taking OC is not known, several theories regarding the mechanism were reviewed. Studies done to determine the relationshp between OC use and hypertension were presented. The observations relating race and relative weight, as associated variables in the development of hypertension, were discussed.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

The purposes of this study were to investigate a select population of Black females, aged 18 thru 35 years: (1) to describe the incidence of hypertension in this group, (2) to determine if those clients with hypertension had ever received OC therapy, and (3) to investigate the possible relationship between hypertension and OC use. The study was retrospective in nature and conducted using the explanatory, non-experimental design (Abdellah & Levine 1965).

Abdellah and Levine stated:

> Many hypothesis tested in non-experimental studies express associative rather than causal relationships. Associative relationships are characterized by the fact that the variables being considered are related to the same individuals composing the study population (Abdellah & Levine 1965, p. 130 - 131).

Demographic and clinical data was collected using the data collection instrument on the family planning records of a randomized sample selected from all clients who met the criteria of the study. Abdellah and Levine (1965) suggest that one way of enhancing the comparability of groups in non-experimental explanatory research is to restrict the target population to homogenous subjects.

However, such restrictions of the target population limit the scope of generalization of the findings of the study. Despite the restrictions that such a limitation would put on the generalization of study findings, only Black females aged 18 to 35 years, with a BP of 140/90 mm. Hg. or higher were used in this study.

The setting for this study and the description of the population for this study are presented. In addition, the research instrument used and the procedure for collection and treatment of data are discussed.

Setting

The setting for this investigation was the Acres Home Health Center of Harris County Health Department in Houston, Texas. Written permission was obtained from the Medical Director of the agency to use this health center as the setting for the study (Appendix B). This health center conducts 3 family planning clinics per week, each clinic attendance averaging 30 clients. This family planning clinic was established 7 years ago and is supported through the use of State and Federal funds. It offers services to all clients without cost.

Population

The population for this study consisted of the clients attending family planning clinic. During a 6-month period, 1,567 clients were seen in this family planning clinic. Fourteen hundred sixty-eight of these clients were Black. The total population of this family planning clinic was 100 percent female, 94 percent being Black females. The age range of the total population was 13 to 46 years, the average age being 25 years. During the specified study period, 20 clients were 15 years or younger; 5 clients, 40 years or older. All clients fitted into the middle and low socioeconomic groups. The return rate for this female planning clinic was 80 percent.

The target population for the study was derived from the total number of Black female clients attending the family planning clinic during a 6-month period. These women were between the ages of 18 to 35 years and had hypertension at the time of examination.

Of the sample population found to meet the stated racial, age, and BP criteria, 30 records were selected for study using a random sampling method, a table of random numbers. After data collection was completed, the sample of study clients was divided for purposes of statistical analysis on the basis of OC use into 3 groups, OC users,

past users, and never users. The client characteristics of the sample were tabulated.

Instrument

The instrument used for the collection of data from the sample population was developed by the investigator and considered adequate by the members of the thesis committee and the statistician. The researcher was the only investigator for the study. Data collection consisted of transferring recorded data from the family planning record to simple columnar data collection instrument (Appendix C). Demographic and clinical data was collected from the charts of the randomly selected sample population of clients who met the criteria of the study and included BP, OC contraceptive use, age, family history of elevated BP, personal history of elevated BP, weight, and height.

Data Collection

Before the study was implemented, agency permission for use of the family planning charts of all clients meeting the stated criteria during a specified 6-month time period was obtained in writing (Appendix D). The purpose of the study design, methodology, and collection of data was explained to the Medical Director and Nursing Section Chief of the agency. Client anonymity was guaranteed.

The clients' medical records were reviewed then. Demographic and clinical data were collected on a random sample of 30 clients who met the stated criteria for this study.

Treatment of Data

After all data were collected using the instrument, tables were contructed showing the number of clients in the group categories: OC users, past users, and never users. There are descriptive tables showing the results of the study.

All data were tabulated by the investigator and were analyzed, using 2 methods, which reflect frequency and significance. The first method of analysis, used for the demographic and clinical data, was the chi-square test for independence, a non-parametric statistical test of significance. This test was used to analyze the significance of differences between the OC users, past user, and never user groups as compared in terms of qualitative variables, BP levels, personal history of hypertension, family history of hypertension, and obesity.

Frequency distributions consisted of counts of the number of clients in each group found to possess each of the demographic variables measured. The chi-square test was performed by calculating theoretical frequencies for

each scale value, subtracting the theoretical from the actual frequencies, squaring the difference, dividing by the theoretical frequency, and then summing all the quotients. This sum was the computed value of chi-square for the sample data. The larger the computed value of chi-square, the smaller was the probability that the difference in the frequency distributions compared were due to random sampling. The variables present in this study were analyzed independently, in groups, and totally for a test of chi-square significance (Bruning & Kintz 1977).

Comparison of the distribution of the variables between the current user, past user, and never user groups was undertaken in an attempt to determine which factors or group of factors might cause hypertension and which factors did not appear to be related to the hypertension. The level of significance selected was 0.05. Chi-square contingency table analyses were used for the purpose of comparing distribution and frequency.

The second statistical method used to treat the data was a one-way analysis of variance. The systolic and diastolic BP for the 3 groups, OC users, past users, and never users, were compared by an analysis of variance to compare the variance due to the independent variable of OC use with variance due to error or randomness.

The investigation attempted to examine the correlation between OC use and elevated BP. If elevated BP had no relationship to OC use then the proportion of women with hypertension taking OC would be the same as the proportion of women with hypertension not using OC.

Summary

This retrospective, non-experimental study was proposed as an effort to determine if a relationship existed between OC use and the development of hypertension in a selected population of Black females, ages 18 to 35 years in a family planning clinic during a 6-month period. Hypertension was specifically defined. The instrument utilized in this study was a data collection instrument developed by the investigator. The instrument was considered valid for purposes of this study. The study was implemented using 30 randomly selected client records from the total population of family planning clients meeting the designated criteria for the study.

Demographic and clinical data were described and statistically analyzed by the use of the chi-square test for independence and a one-way analysis of variance. The following chapter will give the analysis of the data and present tables of the data collected.

CHAPTER IV

ANALYSIS OF DATA

The purpose of this study was to investigate a select population of Black females, aged 18 to 35 years: (1) to describe the incidence of hypertension in this group, (2) to determine if those clients with hypertension had ever received OC therapy, and (3) to investigate the possible relationship between hypertension and OC use. The data obtained by the methods previously described were analyzed by utilization of the chi-square (X^2) test for independence and a one-way analysis of variance.

The sample consisted of 30 randomly selected client family planning records of Black females, ages 18 to 35 years with hypertension. The clinical and demographic data obtained from these records was described in Tables 1 thru 8. Due to the limited sample, no statistical test was performed on the ages of clients. The data obtained for the study sample compares the similiarities and differences of the OC user, past user, and never user groups.

Table 1 describes the women in the study by age and present OC use status. This table shows the number and percentage of women by age in each of the 3 categories. There were equal numbers of women in the past user and

never user groups. The current OC user group had 4 times as many subjects in comparison to either of the other 2 groups. Current OC users tended to be younger than the never users.

The specified age range for study subjects was 18 to 35 years old. The mean age of the 30 study subjects was 26½ years old. The median age was also 26½ years. The greatest percentage of subjects currently using OC fell in the 27 to 29 year old group. Among never OC users, the 18 to 20 year old and 24 to 26 year old groups shared an equal percentage, 40 percent each. Forty percent of past users, a total of 2 subjects, fell in the 21 to 23 year old category.

TABLE 1

WOMEN IN STUDY BY AGE AND ORAL CONTRACEPTIVE USE

AGE (YEARS OLD)	CURRENT USERS NUMBER	CURRENT USERS PERCENT	PAST USERS NUMBER	PAST USERS PERCENT	NEVER USERS NUMBER	NEVER USERS PERCENT
18 - 20	4	20%	0	---	2	40%
21 - 23	4	20%	2	40%	1	20%
24 - 26	2	10%	1	20%	2	40%
27 - 29	5	25%	0	---	0	---
30 - 32	3	15%	1	20%	0	---
33 - 35	2	10%	1	20%	0	---
ALL AGES	20	100%	5	100%	5	100%

$X^2 = 15$ range 18 - 35 years

df = 2 mean 26½ years

p = <.05 median 26½ years

On the assumption that group membership would occur through chance alone, a chi-square test of goodness of fit indicated no significant difference at the .05 level based on what appears to be an unusual case distribution, with the large number current OC users creating a noticeable disproportion (Table 1). It should be noted that an estimated 80 percent of the total family planning clientele in this clinic use OC as the method of choice. Consequently, a random sample of cases with a distribution

of 20 OC users, 5 past users, and 5 never users meets the expectations. Considering the small sample of Black females used in this study, such a case distribution can be considered relevant to the study findings. Studies reproted in the literature deal with much larger samples and almost exclusively with White, middle-class females.

Table 2 compares the systolic and diastolic BP ranges with the 3 categories of users. A comparison of user group specific median BP levels with the median BP levels of the other 2 groups showed that past user and never user groups did not differ appreciably in either the systolic or diastolic components. The median systolic BP level of current OC users was 2 mm. Hg. higher than that of the other 2 groups. A 10 mm. Hg. range existed between the diastolic median BP of current users and never users. There is no evidence from inspection of these distributions to support the idea that the use of OC significantly affects some women's BP levels more strongly than it does women using another contraceptive method.

TABLE 2

A COMPARISON OF BLOOD PRESSURE RANGE WITH ORAL CONTRACEPTIVE USE

		Blood Pressure in mm. Hg.			
		Systolic		Diastolic	
Status	Number	Range	Median	Range	Median
Current Users	20	140-200	142	90-100	100
Past Users	5	140-150	140	90-102	100
Never Users	5	140-150	140	90-100	90
Total	30				

As shown in Table 3, the mean systolic BP levels among current users were not significantly higher than the mean systolic BP levels among past users and never users at every age level, except within the current user 33 to 35 year old age group. This age category had a mean systolic BP of 170 mm. Hg., while all other current user age groups averaged systolic means ranging from 144 mm. Hg. to 147 mm. Hg. Mean diastolic BP levels in the past user group were higher in the 18 to 23 year old age groups than those of current users and never users of similar ages. In the current user group, women aged 30 to 35 years accounted for the highest diastolic BP levels.

TABLE 3

MEAN SYSTOLIC AND DIASTOLIC BLOOD PRESSURES* OF STUDY SUBJECTS BY AGE AND ORAL CONTRACEPTIVE USE

AGE (YEARS OLD)	CURRENT USERS		PAST USERS		NEVER USERS	
	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC	SYSTOLIC	DIASTOLIC
18 - 20	144	96	140	100	150	90
21 - 23	147	93	149	101	140	90
24 - 26	144	92	144	92	145	97
27 - 29	145	97	-		-	
30 - 32	144	100	140	100	-	
33 - 35	170	103	-		-	

Total: 20

*Blood pressures in mm. Hg.

The null hypothesis, that there is no significant relationship between OC use and the development of hypertension among a select population of Black females between the ages of 18 and 35 years, was tested using a one-way analysis of variance on the diastolic and systolic BP of the 3 user classifications, current OC user, past users, and never users. The diastolic BP averages obtained in the calculation of the one-way analysis of variance indicated that past users, with a diastolic BP average of 99 mm. Hg., were 2 mm. Hg. higher than current users and 6 mm. Hg. higher than the subjects in the never user group. Past users, in contrast to the diastolic BP averages, had an average systolic pressure of 144 mm. Hg., 4 mm. Hg. less than the current user group and 2 mm. Hg. less than the never user group (see Appendices E and F). The difference among group means was found to be non-significant at the .05 level for both systolic and diastolic BP measurements (Tables 4 and 5). Consequently, the null hypothesis must be accepted.

TABLE 4

RESULTS OF ANALYSIS OF VARIANCE OF
SYSTOLIC BLOOD PRESSURES BY ORAL CONTRACEPTIVE USE

Source	SS	df	ms	F	P
Total	4150	29	-	-	-
Between groups	47	2	23.5	0.155	NS
Within groups	4103	27	152	-	-

TABLE 5

RESULTS OF ANALYSIS OF VARIANCE OF
DIASTOLIC BLOOD PRESSURES BY ORAL CONTRACEPTIVE USE

Source	SS	df	ms	F	P
Total	1088	29	-	-	-
Between groups	98	2	49	1.34	NS
Within groups	990	27	36.6	-	-

Using data collected from each subject's chart, a comparison of the personal history of hypertension with OC use status was completed (Table 6). Ninety percent (27 of 30) of all clients denied any history of hypertension. In the past OC user and never user categories, all subjects denied any personal history of hypertension. Statistical analysis using chi-square to evaluate the variables indicated no significance ($p > .05$). The null hypothesis must be accepted.

TABLE 6

COMPARISON OF PERSONAL HISTORY OF HYPERTENSION WITH ORAL CONTRACEPTIVE USE STATUS

STATUS	NUMBER	PERSONAL HISTORY HYPERTENSION	
		YES	NO
Current Users	20	3	17
Past Users	5	0	5
Never Users	5	0	5
Total:	30	3	27
Percent:	100%	10%	90%

$X^2 = 0.639$

$df = 2$

$p = >.05$

In an attempt to determine whether or not family history had an influence on the incidence of hypertension, the reported incidence of family history of hypertension was obtained from each subject's chart. A statistical analysis using chi-square was not significant at the .05 level. It is important to note that a family history does appear to be related to the development of high BP. However, family history of hypertension does not appear to be affected by OC use or non-use. Fifty-three percent (16 of 30) of the subjects indicated a positive family history of hypertension (Table 7).

TABLE 7

COMPARISON OF FAMILY HISTORY OF HYPERTENSION WITH ORAL CONTRACEPTIVE USE STATUS

STATUS	NUMBER	FAMILY HISTORY HYPERTENSION	
		YES	NO
Current Users	20	10	10
Past Users	5	4	1
Never Users	5	2	3
Total:	30	16	14
Percent:	100%	53%	47%

$X^2 = .443$ df = 2 p = >.05

Table 8 compares the body weight of all study subjects with OC use. Determination of obese or non-obese categories was obtained using the tables of desired height-weight ratios as constructed by the Metropolitan Life Insurance Company (1969). The degree of association between relative body weight and elevated BP was assessed by means of chi-square. Using 2 degrees of freedom, chi-square was not significant at the .05 level. Sixty percent (18 of 30) of all subjects were considered obese as defined by Metropolitan Life Insurance Company height-weight ratio charts. This finding coincides with available scientific evidence linking hypertension and obesity.

TABLE 8

COMPARISON OF WEIGHTS OF HYPERTENSIVE SUBJECTS WITH ORAL CONTRACEPTIVE USE

STATUS	NUMBER	OBESE	NOT OBESE
Current Users	20	13	7
Past Users	5	4	1
Never Users	5	1	4
Total:	30	18	12
Percent:	100%	60%	40%

$X^2 = 2.135$

df = 2

p = >.05

Summary

In this chapter are analyses of data reflecting frequency and significance. The data is presented with analysis of each of the 3 groups of hypertensive subjects; current OC users, past users, and never users. The chi-square test of independence and a one-way analysis of variance were performed for the factors of BP, personal history of hypertension, family history of hypertension, and obesity. A series of chi-square analyses of data were employed in each discriminant category of current OC user, past user, and never user to identify variable association. No association was found at the .05 level of significance. The one-way analyses of variance indicated that no significant relationship could be noted between systolic and diastolic BP of the 3 user categories.

The results support the null hypothesis that there is no significant relationship between OC use and development of hypertension among this population of Black females, age 18 to 35 years. The following chapter summarizes the study, and its conclusions, implications and recommendations for further study.

CHAPTER V

SUMMARY, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

This study was conducted in an effort to evaluate the relationship between OC use and hypertension. This chapter presents a summary of the research study. Conclusions based on the analysis of data collected in this study are discussed. In addition, the implications of this study are provided. Finally, recommendations for future research studies are offered.

Summary

Although the incidence of hypertension is recognized, a description of the high risk population has not been available. This study was undertaken in an effort to describe hypertensive Black females, ages 18 thru 35 years, who take OC and to investigate for a relationship between hypertension and OC use. Hypertension was defined for the purposes of this study.

The literature reviewed showed several studies regarding the development of hypertension as a complicating factor in OC use, but few studies were found to have focused on Black females. Few studies related body weight to hypertension. The exact etiology of the hypertension

which develops with OC use is no known, although there are several clinical states which, by themselves, might produce hypertension. These clinical states have been reviewed in Chapter II and the pathophysiology involved has been presented.

The overall framework for this study was a retrospective, non-experimental research design. Permission to conduct the study was obtained from the Director of Harris County Health Department. The total number of family planning clients seen at the Acres Home Health Center, Houston, Texas, during the specified 6 month period who developed hypertension and met other criteria for the study was 102. Of this number, a sample of 30 client records were randomly selected for use in this study. Of the sample group, 20 belonged to the current user group; 5, the past user group; and 5, the never user group. Categorical data was collected using an instrument developed by the investigator (Appendix C).

Analysis of the data was performed using the chi-square test of independence and a one-way analysis of variance. The data were presented with analysis of each of the 3 populations: current OC users, past users, and

never users. The one-way analysis of variance of diastolic and systolic BP indicated no significant relationship existed between OC use or non-use and BP measurements.

In evaluating data involving personal history of hypertension and obesity, the chi-square was not significant at the .05 level with 2 degrees of freedom. There was no difference in the frequency of a family history of hypertension between current OC users, past users, and never users. Nor was there a definite correlation between personal history of hypertension and contraceptive use. Although the size of the sample and the time length of the study are limited, enough data was accumulated to provide a baseline for expansion of the study and use of an equivalent collection instrument.

Conclusions

Based on the findings of this study, the following conclusions were made:

1. Current OC users, aged 27 years and above were most likely to have the highest systolic and diastolic BP measurements.

2. There was no significant correlation between contraceptive use and personal history of hypertension.

3. There was no significant correlation between contraceptive use and family history of hypertension.

4. There was no significant correlation between current OC user and obesity.

Implications

The following implications were identified as a result of this study:

1. The study was retrospective in nature, involving the use of previously recorded one-time BP measurements, which may have weakened the reliability of the study.

2. The limited time span used in the study may not have been long enough to demonstrate a relationship between hypertension and OC use.

3. Although no significant relationship between hypertension and OC use was demonstrated in this study, the possibility of such a relationship cannot be ignored.

4. The sample size imbalance of OC users to past users and never users was relevant to study findings.

5. Obesity among current OC users as a co-factor in hypertension may present a significant long-term risk.

6. Current OC users, aged 27 years and older, were potentially the group most susceptible to cardiovascular disease.

Recommendations

As a result of the findings of this study, the following recommendations were made:

1. Replication of this study utilizing a larger sample and more balanced subgroups than were used in this study.

2. Initiation of a mass education program urging all women to have their BP measured semi-annually as part of their continuing health care.

3. Incorporation of a hypertension detection program into a woman's total health care regimen.

4. Nurses should teach all women to measure their own BP.

5. Educate nurses to use their knowledge and clinical skills to assist clients in understanding the dangers of hypertension and the need to control it.

6. Women with sustained elevated BP should participate in a systematic long-term follow-up program, which may include hygienic counseling covering weight control, salt intake, exercise, smoking, lessening of psychological stress, and antihypertensive pharmacotherapy when indicated.

7. Initiation of federally funded research in the field of BP control in Black females, an at risk group for the development of hypertension.

8. Plan a hypertensive information workshop for family planning clinic personnel to expand their knowledge and meet learning needs in the area of contraception for at risk clients.

9. Challenge nurses to learn how to understand a client in order to help the client make the necessary lifestyle adaptations required by the hypertensive treatment program.

10. Nurses should conduct a 3 year prospective study at Acres Home Health Center of Black females, ages 18 to 35 years, monitoring the client's BP from OC therapy initiation through a 3 year period to determine if there is a correlation between OC use and the development of hypertension.

11. Challenge physiological pharmocologists to make an OC pill, specifically designed for the woman susceptible to hypertension.

Summary

The study was conducted using data obtained from 30 family planning records of clients with hypertension as it was defined for this study. For purposes of data analysis, clients were separated according to OC use into 3 groups: current users, past users, and never users. Systolic and diastolic BP measurements were analyzed using

a one-way analysis of variance. Chi-square test for independence at the .05 significance level was used to evaluate personal history of hypertension, family history of hypertension and obesity as each category related to OC use or non-use. The null hypothesis, that there was no significant relationship between OC use and the development of hypertension among a select population of Black females between the ages of 18 and 35 years, was accepted.

Implications for nurses and other health care professionals included being aware of the problem of hypertension and complications involving in OC use, especially for the Black female. Recommendations included a suggestion for replicating this study using a larger sample and more balanced subgroups, extensive education for health professionals and the public regarding hypertension, and a challenge to improve available contraceptives for susceptible women.

APPENDIX A

AMERICAN HEART ASSOCIATION - BLOOD PRESSURE SCREENING INSTRUCTIONS

APPENDIX A

AMERICAN HEART ASSOCIATION
Texas Affiliate, Inc.

HIGH BLOOD PRESSURE SCREENING INSTRUCTIONS

I. Procedure

A. Let the individual rest 3 to 5 minutes in order to allow blood pressure to stabilize.

B. Take the blood pressure of the seated individual, then record where indicated on the right side of form. Also record on upper left side of form. In this screening program, the diastolic reading should be the point of disappearance of sound (not fading of sound).

II. A. If blood pressure is normal (below 140/90 for individuals under 40; upper limit for individuals over 40 is 160/95):

1. Tell the individual his/her blood pressure is normal today.

2. Check "not referred" on the form.

3. Separate the two halves of the referral form and give the right portion to the individual. Left portion of form should be turned in to local Heart Association office for follow-up of those persons found to have elevated pressures.

B. If blood pressure is elevated (systolic 140 or above and/or diastolic 90 or above, or above 160/95 if over 40 years old):

1. Tell the individual that right now his/her blood pressure is elevated. (DO NOT MAKE A DIAGNOSIS. Merely report your findings according to our criteria.)

2. Have a second screener take an independent reading. If both readings are within the same elevated range, encourage the individual to visit a physician for further evaluation, and stress the significance of further evaluation.

3. Check "referred" on the form.

4. Distribute literature on high blood pressure only to those found to be suspect.

Guidelines for Answering Questions About Hypertension

Drugs — Do not discuss hypertensive medications with suspect hypertensives; refer them to their physicians for information.

Diet — Tell the suspect that many physicians do recommend a low salt diet.

Physiology — Be able to tell the person what his/her blood pressure represents, e.g. the upper number = the maximum force with which the blood is pumped from the heart; the bottom number = the amount of pressure remaining in the arteries when the heart is resting between beats.

Risk Factors — Emphasize that the vessels, the heart, the brain and the kidney are all affected by an elevated pressure.

Risk of hypertensive complications can be decreased by not smoking, losing weight, moderate use of salt and avoidance of foods high in saturated fats.

To obtain additional literature on diet, high blood pressure, smoking, have the individual call the nearest American Heart Association office.

APPENDIX B

AGENCY PERMISSION FOR CONDUCTING STUDY

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING
DENTON, TEXAS 76204

DALLAS CENTER
1810 INWOOD ROAD
DALLAS, TEXAS 75235

HOUSTON CENTER
1130 M. D. ANDERSON BLVD.
HOUSTON, TEXAS 77025

AGENCY PERMISSION FOR CONDUCTING STUDY*

THE HARRIS COUNTY HEALTH DEPARTMENT

GRANTS TO BEVERLY CLAIRE HARRIS ROBINSON, R.N.
a student enrolled in a program of nursing leading to a Master's Degree at Texas Woman's University, the privilege of its facilities in order to study the following problem:

HYPERTENSION IN BLACK WOMEN TAKING ORAL CONTRACEPTIVES

The conditions mutually agreed upon are as follows:

1. The agency (may) (~~may not~~) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (may) (~~may not~~) be identified in the final report.
3. The agency (~~wants~~) (does not want) a conference with the student when the report is completed.
4. The agency is (willing) (~~unwilling~~) to allow the completed report to be circulated through interlibrary loan.
5. Other _____

Date: May 16, 1978

Janice Jones, M.D.
Signature of Agency Personnel

Beverly H. Robinson
Signature of Student

Mary E. Benedict
Signature of Faculty Advisor

* Fill out and sign three copies to be distributed as follows: Original-Student; First copy - agency; Second copy - TWU College of Nursing.

GP:GEN 13
07026074 cd

APPENDIX C

INSTRUMENT

APPENDIX C

SURVEY OF BLACK FEMALE FAMILY PLANNING PATIENTS AGES 18 - 35 WITH ELEVATED B/P (140/90 OR ↑)

DATE	PATIENT NUMBER	BLOOD PRESSURE	CURRENT USER	PAST USER	NEVER USER	AGE	FAMILY HX ↑ B/P	PAST HX ↑ B/P	WEIGHT	HEIGHT

APPENDIX D

HUMAN RIGHTS FORMS

TEXAS WOMAN'S UNIVERSITY

HOUSTON CAMPUS

HUMAN RESEARCH REVIEW COMMITTEE REPORT

STUDENT'S NAME Beverly Robinson
BEVERLY H. ROBINSON

PROPOSAL TITLE HYPERTENSION IN BLACK WOMEN TAKING ORAL CONTRACEPTIVES

COMMENTS:

DATE: 4/7/78

Vera Harmon
~~Disapprove~~ Approve

Irene L Robertson
~~Disapprove~~ Approve

James McLeod
~~Disapprove~~ Approve

~~Disapprove~~ Approve

GP: PME 24
05020075
BAB:cd

APPLICATION TO HUMAN RESEARCH COMMITTEE

Subject: Research and Investigation Involving Humans

Statement by Program Director and Approved by Department Chairman

This abbreviated form is designed for describing proposed programs in which the investigators consider there will be justifiable minimal risk to human participants. If any member of the Human Research Review Committee should require additional information, the investigator will be so notified.

Five copies of this Statement and a specimen Statement of Informed consent should be submitted at least two weeks before the planned starting date to the chairman or vice chairmen on the appropriate campus.

Title of Study: HYPERTENSION IN BLACK FEMALES TAKING ORAL CONTRACEPTIVES

Program Director(s): Mrs. Mary Elizabeth Benedict

Graduate Student: Beverly Claire Harris Robinson

Estimated beginning date of study: March 27, 1978

Estimated duration: four weeks

Address where approval letter is to be sent:

3315 High Pine Drive

Missouri City, Texas 77459

OK

1. Brief description of the study (use additional pages or attachments, if desired, and include the approximate number and ages of participants, and where they will be obtained).

2. What are the potential risks to the human subjects involved in this research or investigation? "Risk" includes the possibility of public embarrassment and improper release of data. Even seemingly nonsignificant risks should be stated and the protective procedures described in 3. below. In addition state the potential benefits, if any, to the subjects.
3. Outline the steps to be taken to protect the rights and welfare of the individuals involved.

4. Outline the method for obtaining informed consent from the subjects or from the person legally responsible for the subjects. Attach documents, i.e., a specimen informed consent form. These may be properly executed through completion of either (a) the written description form, or (b) the oral description form. Specimen copies are available from departmental chairmen. Other forms which provide the same information may be acceptable. A written description of what is orally told to the subject must accompany the oral form.

5. If the proposed study includes the administration of personality tests, inventories, or questionnaires, indicate how the subjects are given the opportunity to express their willingness to participate. If the subjects are less than the age of legal consent, or mentally incapacitated, indicate how consent of parents, guardians, or other qualified representatives will be obtained.

Signature of Approval _____ Date _____
Program Director

Signature of Approval Beverly H. Robinson Date April 12, 1978
Graduate Student

Signature of Approval Francis Jones, M.D. Date April 12, 1978
~~Dean, Department Head~~ Director
Harris County Health Department

Date received by committee Chairman: _____

011011077
DV:cs

TEXAS WOMAN'S UNIVERSITY

Form A -- Written presentation to subject)

Consent to Act as a Subject for Research and Investigation:

(The following information is to be read to or read by the subject):

1. I hereby authorize Beverly Claire Harris Robinson
(Name of person(s) who will perform procedure(s) or investigation(s)

to perform the following procedure(s) or investigation(s):
(Describe in detail)

To conduct a survey of the family planning records (Form 7I23 and Family Planning Follow-up Record) using the data collection instrument (see attachment) to obtain data on selected characteristics of those patients under investigation.

2. The procedure or investigation listed in Paragraph 1 has been explained to me by Beverly Claire Harris Robinson.
(Name)

3.(a) I understand that the procedures or investigations described in Paragraph 1 involve the following possible risks or discomforts:
(Describe in detail) The family planning records of patients will be th
urce of data for this study. The filing system of this agency is a patient
bering system. Therefore, the use of client names is unnecessary. Although
re is the possible risk that the client's name may inadvertently be revealed,
ry effort will be made to avoid such an incident. The results of the survey c
ords will be reported in the form of statistical totals from which no individua
be identified. As a result, anonymity of the clients will be maintained.

TEXAS WOMAN'S UNIVERSITY

(Form A - Continuation)

3.(b) I understand that the procedures and investigations described in Paragraph 1 have the following potential benefits to myself and/or others:

The study findings will provide information which will be useful to my agency's Nursing and Family Planning sections in the screening, evaluation, and counseling of potentially hypertensive Black female clients. Specifically, the findings will provide additional information that will be useful in the county-wide hypertension screening program, of which Black clients are a target group.

4. An offer to answer all of my questions regarding the study has been made. If alternative procedures are more advantageous to me, they have been explained. I understand that I may terminate my participation in the study at any time.

Francine Jones, M. D. — April 14, 1978

Subject's signature — Date

(If the subject is a minor, or otherwise unable to sign, complete the following):

Subject is a minor (age____), or is unable to sign because:

N/A

Signatures (one required)

_____ _____

Father — Date

_____ _____

Mother — Date

_____ _____

Guardian — Date

APPENDIX E

ANALYSIS OF VARIANCE OF INDIVIDUAL SYSTOLIC BLOOD PRESSURES BY ORAL CONTRACEPTIVE USE

APPENDIX E

ANALYSIS OF VARIANCE OF INDIVIDUAL SYSTOLIC BLOOD PRESSURES BY ORAL CONTRACEPTIVE USE

GROUP 1 CURRENT USERS		GROUP 2 PAST USERS		GROUP 3 NEVER USERS	
Subject	Blood Pressure	Subject	Blood Pressure	Subject	Blood Pressure
S_1	142	S_{21}	144	S_{26}	150
S_2	150	S_{22}	148	S_{27}	150
S_3	166	S_{23}	150	S_{28}	140
S_4	200	S_{24}	140	S_{29}	140
S_5	150	S_{25}	140	S_{30}	150
S_6	160				
S_7	140				
S_8	146				
S_9	142				
S_{10}	140				
S_{11}	140				
S_{12}	150				
S_{13}	140				
S_{14}	148				
S_{15}	140				
S_{16}	140				
S_{17}	140				
S_{18}	140				
S_{19}	140				
S_{20}	140				
Sums:	2954		722		730
Average:	148		144		146

APPENDIX F

ANALYSIS OF VARIANCE OF INDIVIDUAL DIASTOLIC BLOOD PRESSURES BY ORAL CONTRACEPTIVE USE

APPENDIX F

ANALYSIS OF VARIANCE OF INDIVIDUAL DIASTOLIC BLOOD PRESSURES BY ORAL CONTRACEPTIVE USE

GROUP 1 CURRENT USERS		GROUP 2 PAST USERS		GROUP 3 NEVER USERS	
Subject	Blood Pressure	Subject	Blood Pressure	Subject	Blood Pressure
S_1	90	S_{21}	92	S_{26}	94
S_2	92	S_{22}	102	S_{27}	90
S_3	100	S_{23}	100	S_{28}	90
S_4	110	S_{24}	100	S_{29}	100
S_5	108	S_{25}	100	S_{30}	90
S_6	110				
S_7	90				
S_8	00				
S_9	94				
S_{10}	90				
S_{11}	92				
S_{12}	90				
S_{13}	100				
S_{14}	100				
S_{15}	94				
S_{16}	100				
S_{17}	90				
S_{18}	92				
S_{19}	96				
S_{20}	100				
Sums:	1938		494		464
Average B/P:	97		99		93

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