# A STUDY OF CLIENTS' PERCEPTIONS OF REASONS FOR CHOOSING OR NOT CHOOSING 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

by
LINDA S. BYERS, R.N., B.S.

DENTON, TEXAS

MAY, 1977

## The Graduate School

## Texas Woman's University

Denton, Texas

|   | December 9      | 19_76          |
|---|-----------------|----------------|
|   |                 |                |
| We hereby recommend that the            | thesis          | prepared under |
| our supervision by Linda S              | S. Byers        |                |
| entitled A Study of Clie                | ents' Perceptio | ns of          |
| Reasons for Choosing                    | Or Not Choosin  | g Oral         |
| Contraceptives                          | . ,             |                |
|   |                 | * ,            |
|   | ,               |                |
| *************************************** |                 |                |
| Committe                                | Pana M. Cour    | k R.W. M.D.    |
| au                                      | Chairman O. Jes | nen 24D        |
| Can                                     | ole a Thom      | seon, R.N., M. |
|   |                 |                |
|   |                 |                |
|   |                 |                |
| Accepted                                |                 |                |
| Accepted:                               |                 |                |
| The Clis Ondges                         | 001             |                |

#### DEDICATION

To my husband, Ron, for all his love and support

#### ACKNOWLEDGMENTS

A special thanks to my committee:

Dr. Mona Counts, for convincing me I could do it, and pushing me until I did;

Dr. Andy Jensen, for his quiet encouragement; and

Carole Thompson, for her infectious enthusiasm for maternity nursing and family planning.

Thanks to others who helped make this thesis possible:

Dr. Donald S. Myers, Director, Bell County Health
Department, and his staff, who
graciously allowed me the use of
their facilities;

Dr. John Counts, who guided me in statistical computations;

Penney Huggins, who edited the final draft;

Juanita Malina, my typist, who kept me in line at all times; and

All my classmates, without whose encouragement I would never have finished.

Linda S. Byers

#### TABLE OF CONTENTS

|                                      |  | Page         |
|--------------------------------------|--|--------------|
| DEDICATION<br>ACKNOWLEDO<br>TABLE OF |  | iii<br>iv    |
| LIST OF T                            | ABLES  | vii          |
|                                      |  |              |
| CHAPTER                              |  |              |
|                                      |  |              |
| I                                    | INTRODUCTION                                   | 1            |
|                                      | Statement of the Problem Statement of Purposes | 3            |
|                                      | Background and Significance                    | 4            |
|                                      | Questions                                      | 9<br>9<br>10 |
|                                      | Delimitations                                  | 11           |
|                                      | Assumption                                     | 11<br>11     |
| II                                   | REVIEW OF THE LITERATURE                       | 13           |
|                                      |  | 13<br>13     |
|                                      | 3  | 14           |
|                                      |  | 17           |
|                                      |  | 18<br>19     |
|                                      |  | 30           |
|                                      | Summary  | 31           |
| III                                  | DROGEDURE FOR COLLEGETON AND EDEATHERM         |              |
| 111                                  | PROCEDURE FOR COLLECTION AND TREATMENT OF DATA | 33           |
|                                      | Introduction                                   | 33           |
|                                      | Setting  | 34<br>35     |
|                                      | Methodology                                    | 35           |
|                                      | Tool   | 36           |
|                                      | Data Collection                                | 37           |
|                                      | Treatment of Data                              | 38<br>39     |
|                                      | Summary  | 37           |

## TABLE OF CONTENTS (continued)

|          |                                    |                      |      |    |    |    |    |    |     |   |   |   |   |   |   | Page           |
|----------|------------------------------------|----------------------|------|----|----|----|----|----|-----|---|---|---|---|---|---|----------------|
|          |                                    |                      |      |    |    |    |    |    |     | * |   |   |   |   |   |                |
| CHAPTER  |                                    |                      |      |    |    |    |    |    |     |   |   |   |   |   |   | *              |
| IV       | ANALYSIS                           | OF DATA              | A .  | •  | •  | •  |    |    | • . | • | • | • | • | • | • | 40             |
|          | Introduc                           | tion                 |      |    |    |    |    |    |     |   |   |   |   |   |   | 40             |
|          | Results                            |                      |      |    |    |    |    |    |     | • | • | • | • | • | • | 40             |
|          | Patterns                           |                      |      | -  |    |    |    |    |     |   |   |   |   |   |   | 42             |
|          | Package :                          |                      |      |    |    |    |    |    |     |   |   |   |   |   |   | 46             |
| > '      | Knowledge                          |                      |      |    |    |    |    |    |     |   |   |   |   |   |   | 47             |
|          | Importan                           |                      | es c | f  | In | fo | rm | at | io  | n |   |   |   |   |   | 53             |
|          | Attitude                           |                      |      |    | •  | •  |    | •  |     | • |   | • | • | • |   | 53             |
|          | Summary                            |                      |      | •  | •  | •  | •  | •  | •   | • | • | • | • | • | • | 55             |
| V        | RECOMMENT<br>Summary<br>Conclusion | DATIONS<br><br>ons . |      |    |    |    |    |    |     |   |   |   |   |   |   | 56<br>56<br>57 |
|          | Implicat                           |                      |      | •  | •  |    |    |    |     |   |   |   |   | • | • | 58             |
|          | Recommen                           | dations              | •    | •  | •  | •  | •  | •  | •   | • | • | • | • | • | • | 59             |
| REFERENC | ES                                 |                      |      | •  | •  | •  | •  | •  | •   | • | • | • | • | • | • | 60             |
| BIBLIOGR | APHY                               | • • •                |      | •  | •  | •  | •  | •  | •   | • | • | • | • | • | • | 64             |
| APPENDIC | ES                                 |                      |      |    |    |    |    |    |     |   |   |   |   |   |   |                |
| A -      | PERMISSI                           | ON FOR               | THE  | ST | UĽ | Y  | •  | •  | •   | • | • |   | • | • | • | 66             |
| В -      | QUESTION                           | NAIRE                |      | •  | •  | •  | •  | •  | •   | • | • | • | • | • | • | 70             |
| C -      | TEACHING                           | METHOD               | OLO  | ΞY |    |    |    |    |     |   |   |   |   | _ | _ | 77             |

## LIST OF TABLES

|  | Page   |
|--|--|
| DEMOGRAPHIC DATA FOR PARTICIPANTS  | 41   |
| PATTERNS OF ORAL CONTRACEPTIVE USE   | 43   |
| QUESTIONS ABOUT THE PACKAGE INSERT   | 46   |
| QUESTIONS USED TO ASSESS KNOWLEDGE   | 48   |
| CORRELATION OF CATEGORIES OF DEMO-<br>GRAPHIC VARIABLES WITH KNOWLEDGE<br>SCORES | 52   |
| IMPORTANT SOURCES OF INFORMATION   | 53   |
| ATTITUDES ABOUT SAFETY AND EFFICACY OF ORAL CONTRACEPTIVES                       | 54   |
|  | PATTERNS OF ORAL CONTRACEPTIVE USE  QUESTIONS ABOUT THE PACKAGE INSERT  QUESTIONS USED TO ASSESS KNOWLEDGE  CORRELATION OF CATEGORIES OF DEMOGRAPHIC VARIABLES WITH KNOWLEDGE  SCORES  IMPORTANT SOURCES OF INFORMATION  ATTITUDES ABOUT SAFETY AND EFFICACY |

#### CHAPTER I

#### INTRODUCTION

For the past several years, consumers have become more active in the distribution of goods and services. Many consumer groups, including "Nader's Raiders" and the woman's movement, have spurred people to take a more active role in their own affairs. This also has been true in medical care. Consumers have been demanding more information about their medical treatment and a greater voice in what their treatment will be. The increasing demand for knowledge has underscored the issues of informed consent and patient's rights.

The American Hospital Association published a patient's bill of rights in 1973. One of these rights states: "The patient has the right to obtain from her physician complete current information concerning her diagnosis, treatment, and prognosis in terms the patient can be reasonably expected to understand" (Hospitals, 1973, p. 41).

Applying this right would include giving the patient information about oral contraceptives. The use of oral contraceptives is generally a long-term treatment prescribed for well clients. During their treatment, clients may be followed by several practitioners or clinics. Under these

circumstances, client awareness of advantages, side effects, and symptoms to report is one way of providing for continuity of care.

When oral contraceptives were first marketed in 1960, they were hailed as the perfect contraceptive. Marketing information related that they were safe, almost 100 percent effective, completely reversible, and simple to use. Almost immediately, large numbers of women began using the "pill." Women, for the first time, felt they were able to control fertility completely. In a short time, other advantages became apparent. The "pill" frequently caused an improvement in acne; it decreased menstrual bleeding, and subsequent anemias; and it regulated previously irregular menstrual periods. Indeed, in 1960, the birth control pill seemed to be the "perfect contraceptive."

In recent literature, however, disadvantages related to oral contraceptives are in the spotlight. Complications to the "pill" are constantly being illuminated in popular and professional literature. Research shows that, in addition to the medical problems the "pill" may cause, it is not always effective. Neither is it always completely reversible, nor is it simple for all women to use. So, the realization has come that oral contraceptives, like other potent medications, have benefits and risks, both of which must be considered.

In contraceptive practice, various alternative treatments are available. There are risks and benefits for the client from each treatment method. Whether or not clients are aware of the risks and benefits of oral contraceptives is not known. Nurses and family planners have researched many aspects of fertility control. However, client knowledge and attitudes about oral contraceptives and client perceptions of reasons for choosing or not choosing them have received little attention. Therefore, the following problems were studied.

#### Statement of the Problem

The problems were:

- 1. Do client attitudes and knowledge reflect published information about oral contraceptives?
- 2. Can a methodology be developed to expedite assimilation of the information clients can use in choosing or not choosing oral contraceptives?

#### Statement of Purposes

Five purposes were served by this study. They are:

1. To determine client attitudes toward oral contraceptives

- 2. To determine client perceptions of knowledge regarding oral contraceptives
- 3. To determine client perceptions of reasons for choosing or not choosing oral contraceptives
- 4. To determine how client responses to the above three purposes relate to published information about oral contraceptives
- 5. If client attitudes and knowledge are extremely diverse from published information, to develop a methodology to expedite assimilation of the information clients can use in choosing or not choosing oral contraceptives.

#### Background and Significance

The consumer and the woman's movements have produced a greater awareness of patient's rights to information and to participation in the decision making concerning their health care. Consumers of health care have defined their perceptions of quality care as humanistic. Quality care begins with scientific medicine, but that care should be delivered in a respectful and dignified manner at a price the consumer can afford; she wants to know what is going on and why (Quinn and Somers, 1974, p. 240). Health professionals have begun to respond to patient needs for information. Patient education is receiving greater emphasis in health care.

Quinn and Somers (1974, p. 240) relate that "an informed patient is a more receptive patient who tends to respond better and more quickly to the treatment program outlined for her." Although users of oral contraceptives are not sick people, they are consumers of health care. Whether oral contraceptive users are informed and are following their treatment regimen is not known.

There is a relative dearth of research regarding client use of information about oral contraceptives or attitudes which affect their use of the drugs. One of the few studies conducted in this area reported factors which influence continuance in a family planning program (Ager, Werle, and Shea 1973, p. 15). The results showed that women who dropped the program had significant fears of side effects. Otherwise, no factors were different between those who continued and those who did not. How a client's self-concept affects her use of family planning methods has been pursued (Meleis 1971, p. 229). Meleis' study found that women with a high self-concept and a good husband-wife relationship were better contraceptive users.

One study (Fleckenstein et al. 1976, p. 1331) has been published dealing with patient's attitudes, knowledge, and preferred information sources for oral contraceptives. The results of 828 questionnaires were analyzed. Women between 20 and 29 who were well educated and had a high

family income were found to be the most knowledgeable about oral contraceptives (Fleckenstein et al. 1976, p. 1334).

Sixty-eight percent of all respondents considered the information about oral contraceptives available to them from all sources to be inadequate (Fleckenstein et al. 1976, p. 1334).

Many of the women, including users, did not feel that the benefits of preventing unwanted pregnancy outweighed the risks to their health (Fleckenstein et al. 1976, p. 1335).

Medical research has dealt with many aspects of oral contraceptive use, but advantages are seldom studied. Fleckenstein attributes many of clients' negative attitudes to this fact (Fleckenstein et al. 1976, p. 1336). Pills are known to reduce premenstrual tension, menstrual cramps, menstrual blood loss, iron deficiency anemia, acne, and ovarian cysts (Hatcher et al. 1976, p. 55), but these are seldom publicized. In contrast to the paucity of information on advantages, complications and risks have received much attention.

Thromboembolic disease is a risk associated with oral contraceptives and often reported in medical literature (Inman and Vessey 1968, p. 193; Vessey and Doll 1969, p. 651; Alkjarsig, Fletcher, and Burstein 1975, p. 199). The potential risk is serious and is higher in pill users than in nonusers (Vessey and Doll 1969, p. 651). However, the absolute number of women involved is quite small. Only one

in 2,000 pill users will be hospitalized for venous disease each year (Alkjarsig, Fletcher, and Burstein 1975, p. 199). Pill users are also more prone to hypertension (Heyman and Hurtz 1975, p. 13). In women who are otherwise normal, no laboratory data can yet identify the women at risk for vascular problems.

Recently, benign hepatic adenomas have been reported which seem to be linked with oral contraceptives (Baum et al. 1973, p. 926; Antoniades et al. 1975, p. 638; Edmondson, Henderson, and Benton 1976, p. 470). In a review of forty-two reported cases, Edmondson and associates (Edmondson, Henderson, and Benton 1976, p. 470) reported that only five had never used oral contraceptives, and none had a history of using agents toxic to the liver. Although the rare tumors are benign, rupture and massive hemorrhage can occur, often leading to death. In a study with matched controls (Edmondson, Henderson, and Benton 1976, p. 472), it was found that the risk of liver tumors increased after five years of oral contraceptive use. In addition, oral contraceptives containing the estrogen, mestranol, which is metabolized in the liver, were used by a significantly larger number of patients with liver tumors than by controls.

Metabolic changes in pill users have been reported, especially in carbohydrate and lipid metabolism (Weindling and Henry 1974, p. 1767). There is also an increased need

for Vitamins C,  $B_6$ , and  $B_{12}$  (Luke 1976, p. 33). Many annoying, but less serious adverse effects have been enumerated. Nausea, vomiting, weight gain or loss, breast tenderness, chloasma, and vaginitis are known to occur in many women on oral contraceptives (Hatcher et al. 1976, p. 54).

Amenorrhea and infertility after discontinuance of oral contraceptives have been linked to suppressed pituitary-ovarian function (Rifkin, Nachtigall, and Beckman 1972, p. 429). Although most pill users promptly revert to their normal menstrual cycle, approximately 1 percent remain amenor-rheic at the end of one year (Good and Kempers 1974, p. 864). Rifkin and associates have suggested that women with irregular periods before beginning oral contraceptives may be at greater risk of subsequent amenorrhea (Rifkin, Nachtigall, and Beckman 1972, p. 431).

All of the preceding problems may seem relatively minor to the person prescribing oral contraceptives. Compared to the risk of an unwanted pregnancy, the problems are minor.

However, clients who use oral contraceptives are generally well people. Since various methods of contraception are available, clients have the right to make an informed choice to use or not to use oral contraceptives. Whether or not the client uses the available information led to this study.

#### Questions

The questions proposed in this study were:

- 1. What attitudes do clients have concerning oral contraceptives?
- 2. What are clients' perceptions of knowledge regarding oral contraceptives?
- 3. What are clients' perceptions of reasons for choosing or not choosing oral contraceptives?
- 4. How do clients' responses to the above three questions relate to published information about oral contraceptives?
- 5. If clients' attitudes and knowledge are extremely diverse from published information, can a teaching methodology be developed to expedite assimilation of the information clients can use in choosing or not choosing oral contraceptives?

#### Definition of Terms

For the purposes of this study, the following definitions were utilized:

1. <u>Clients</u>. Females who are currently using or are interested in using a contraceptive methodology.

- 2. <u>Perceptions</u>. Conscious integration of sensory input
- 3. Attitudes. A set of beliefs held by a person which predisposes him to act in a certain way toward an object or idea
- 4. Oral contraceptives. A hormone pill of estrogen and progestin singularly or in combination which prevents ovulation
- 5. <u>Published information about oral contraceptives</u>. That information in the popular and professional literature which describes currently known advantages and disadvantages associated with oral contraceptive use.

#### Limitations

Variables which were not controlled, but may have influenced the results were:

- 1. Collection of data in one geographic area
- 2. One nurse-investigator with limited time and funds

#### **Delimitations**

Certain variables which could have influenced results were controlled. They were:

- 1. All clients spoke and understood English
- 2. Time limit for the interview was fifteen minutes

#### Assumption

It was assumed that all responses were truthful.

#### Summary

Consumers are becoming more involved in health care, especially where alternatives to care are available. Many alternatives are available in family planning. Risks and benefits of oral contraceptive use are discussed in the literature. Whether or not clients were aware of them led to this study. Clients' attitudes toward oral contraceptives, their perceptions of knowledge about oral contraceptives, and their perceptions of reasons for choosing or not choosing oral contraceptives were studied. These were related to published information about oral contraceptives to determine if a teaching tool were necessary.

Chapter II is a review of literature concerning consumer interest in health care and patients' rights.

Previous studies of family planning, patient knowledge and attitudes about birth control pills are reviewed. Last, medical and popular literature are reviewed for discussion of risks and benefits of oral contraceptive use. Chapter III is a presentation of the methodology used in the study. Results of the sixty structured interviews are presented in Chapter IV. Knowledge scores, attitudes, and perceptions of reasons for choosing or not choosing oral contraceptives are discussed. Chapter V includes a summary, conclusions, implications, and recommendations for further study.

#### CHAPTER II

#### REVIEW OF LITERATURE

#### Introduction

For the purposes of this study, literature concerning consumer interest in health care and patients' rights to information was reviewed. Patient knowledge about and attitudes toward oral contraceptives as presented in published studies was reviewed. Finally, research on the advantages, disadvantages, and risks of oral contraceptives was discussed.

#### Patients' Rights

Patients' rights is a topic those in the medical and nursing professions have become more concerned with in the past few years. People are demanding some of the same rights as consumers of medical care as they do as consumers of other goods and services. The American Hospital Association has responded to these changes by publishing its patients' bill of rights in 1973. One of the rights states: "The patient has the right to obtain from her physician complete current information concerning her diagnosis,

treatment, and prognosis in terms the patient can be reasonably expected to understand" (Hospitals 1973, p. 41).

The role of the nurse as a consumer advocate is discussed in two articles concerning patients' rights (Quinn and Somers 1974, p. 240; Annas and Healey 1974, p. 25). Annas and Healey relate that the goal of a patients' rights advocate is to get the doctor and the patient to make decisions about care together, with the patient having the final word (Annas and Healey 1974, p. 31). With the growth of consumerism has come an increased emphasis on patient education. Health care deliverers have become accustomed to consumers being aware of and concerned about the quality and cost of their care. Consumers are more satisfied with their care when they have control.

The success or failure in a particular situation, measured by increased patient satisfaction and improved quality of care, is linked more closely with the degree of control exercised by the consumers than with the particular method of participation (Medical Malpractice 1973, p. 80).

Consumers must have accurate information on which to base their decisions.

#### Knowledge and Attitude

Very few studies have looked at attitudes about or knowledge of oral contraceptives and how they affect an

individual's use of the pill. In 1974, a study was undertaken in New Orleans to follow up patients who had chosen oral contraceptives as their method of contraception (Sear and Turner 1974, p. 230). Ninety percent of the patients were found and interviewed one to two months after being given the "pill." The investigators found that 5.2 percent did not start the pills, and that 6.1 percent quit before beginning the second cycle (Sear and Turner 1974, p. 231). Of the latter, 62 percent gave side effects, especially bleeding, as their reason for stopping. These authors discourage pressure recruitment techniques and recommend careful attention to bleeding or spotting problems. Possibly this would prevent many patients from discontinuing oral contraceptives (Sear and Turner 1974, p. 233).

In 1973, a study was done of factors which influence continuance in a family planning program (Ager, Werle, and Shea 1973, p. 15). Some of these factors were reactions to the pill, length of use of effective contraception, availability of clinic services, and various demographic factors. They found that women who dropped the program had significant fears of side effects from the "pill." Other than that, there were no differences between those who continued and those who did not.

Fleckenstein's study published after this thesis was initiated, is the one study found which directly

addresses patients' attitudes and knowledge about oral contraceptives (Fleckenstein et al., 1976, p. 1331). The 828-participant study included a cross section of women in the Rochester, New York area. Women in their twenties who were well educated and who had a high family income were found to be the most knowledgeable about the "pill." Less than one third of the respondents answered 70 percent of the knowledge questions correctly. Most respondents considered oral contraceptives fairly safe and very effective. Fortyfour percent did not believe that the benefits of oral contraceptive use outweighed the risk to their personal health. Many of these were presently using oral contraceptives.

Over half of the respondents in Fleckenstein's study considered the information about oral contraceptives available to them from all sources to be inadequate. The conclusion of the Royal College of General Practitioners

Oral Contraceptive Study (1974, p. 83) states, "The estimated risk at the present time of using the pill is one that the properly informed woman would be happy to take." The feelings of the medical profession and of the lay public do not appear to be the same. Fleckenstein et al. (1974, p. 1335) attributed this to lack of publicity of the non-contraceptive advantages of the pill.

#### Medical Research

Much of the medical research on oral contraceptives has been conducted in Great Britain. Researchers there have been studying oral contraceptives in depth since the early 1960's. The most comprehensive study to be reported was published in 1974 by the Royal College of General Practition-In 1968, they set up a nationwide study using 1,400 ers. general practitioners and 46,000 women, half of whom were taking oral contraceptives, and half of whom never had. Each general practitioner recorded for the study any complaint of a patient or a control who was under his care. Reports were sent in each six months. The interim report, published in 1974, covered four years. The study is continuing, and more valuable results especially in terms of the effects of long-term usage, are expected in the next few years. Specific findings from this study will be presented as each area is discussed in the following paragraphs. Advantages of oral contraceptive use other than contraception will be discussed. Possible complications of thromboembolism, hypertension, liver disorders, decreased fertility, and several other adverse effects will then be presented.

#### Advantages

Advantages of oral contraceptive use have received little discussion in the recent literature. However, several potential medical problems are found less frequently among pill users. There is a decreased incidence of benign cystic breast disease in pill users (Royal College 1974, p. 26). This becomes apparent after about two years of use. This protective effect is significant in that many observers believe that cystic breast tumors may be precursors of breast cancer (Lake 1975, p. 76).

Pills minimize menstrual cramps, decrease the number of days of menstrual flow, and decrease blood loss (Hatcher et al. 1976, p. 54). Due to the decreased blood loss, iron deficiency anemia is seen less frequently in pill users (Royal College 1974, p. 27). Premenstrual tension is reportedly reduced in pill users although the Royal College study attributes most of that to bias of underreporting and not specifically to pharmacologic properties of the pill (Royal College 1974, p. 29). An increase in breast size is noted by many women currently using oral contraceptives (Hatcher et al. 1976, p. 54).

There is a decreased incidence of functional ovarian cysts in pill users which is attributed to the suppression of ovulation (Royal College 1974, p. 27). Acne

is also often improved with oral contraceptive use (Hatcher 1974, p. 54). The Royal College study (1974, p. 25) found no increase in malignant neoplasms in pill users. However, observations are needed for ten years before concluding that the pill has no carcinogenic properties. As reported in these studies, there are some significant non-contraceptive benefits of oral contraceptive use.

#### Adverse Effects

#### Thromboembolic Disease

Adverse effects of oral contraceptives have been discussed in detail in the literature and in medical research. Thromboembolic disease is one adverse effect that was noted early in the use of oral contraceptives (Vessey and Doll 1968, p. 199). Several studies were done in England to follow women who were hospitalized with ideopathic thromboembolism (Inman and Vessey 1968, p. 193; Inman et al. 1970, p. 203; Badaracco and Vessey 1974, p. 215). These studies as well as the Royal College Study (1974, p. 43) cite a five to six times increased incidence of deep vein thrombosis in pill users. However, even with the increased incidence, the actual rate of thrombosis severe enough for hospitalization is one in 2,000 pill users per year (Vessey and Doll 1968, p. 205).

The increased risk of thrombosis is associated with the estrogen dosage in oral contraceptives (Inman et al. 1970, p. 209; British Medical Journal 1970, p. 232; Royal College 1974, p. 43). The Royal College study found that the risk of deep vein thrombosis decreased by 25 percent when an estrogen dose of 50 micrograms or less was used (Royal College 1974, p. 43). Inman's study (1970, p. 203) found a positive correlation between estrogen dose and pulmonary embolism, cerebral thrombosis, and coronary thrombosis as well as deep vein thrombosis. These conditions are rare, but are life-threatening when they occur. The Royal College study (1974, p. 43) found no correlation between incidence of thromboembolism and duration of pill use. For women who develop thrombosis while on the pill, and who subsequently discontinue it, the risk of recurrence is extremely low (Badaracco and Vessey 1974, p. 217).

Heart attacks and clotting disorders are greatly increased in the woman over forty who is on the pill (Hatcher et al. 1976, p. 51), while the risk of deep vein thrombosis, pulmonary embolism, cerebral thrombosis, or cardiac thrombosis is minimal in the woman under forty. Because of these findings, it has been recommended that women over forty use some other form of birth control (Hatcher et al. 1976, p. 51). Oliver (1970, p. 212) recommends that screening be done before pill use to test serum lipid content and to

evaluate the patient's blood pressure. He also recommends measuring serum cholesterol during the first year of pill use (Oliver 1970, p. 213). Alkjarsig and associates published results of a study using plasma fibrinogen chromatography. Although the numbers in the study were small, they believe that by detecting even clinically silent thrombithey may be able to better identify which pill users are at greatest risk of symptomatic thrombi (Alkjarsig, Fletcher, Burstein 1975, p. 211).

#### Hypertension

An increase in blood pressure has been found in women using oral contraceptives (Royal College 1974, p. 37; Weir et al. 1974, p. 533; Mason, Oakley, Wynn 1973, p. 317). Many possible explanations have been given. The Royal College (1974, p. 37) study concluded that women taking oral contraceptives have their blood pressure taken more often than do controls. Therefore, some of the increase may be the result of closer supervision.

Mason and associates found that metabolic changes known to be pill-induced, such as impaired glucose tolerance, increased blood pyruvate levels, and increased serum lipid concentration were found to be exaggerated in a matched group of hypertensive pill users (Mason, Oakley, Wynn 1973, p. 317). They also found that women who developed severe

hypertension were older, more obese, and of higher parity than those with mild hypertension or normal blood pressure (Mason, Oakley, Wynn 1973, p. 320). Weir and associates (1974, p. 533), however, found no correlation between increased blood pressure and weight, renal disease, family history of hypertension, parity, social class, or smoking. The Royal College study (1974, p. 37) found a positive correlation only to age. These authors all advocate a detailed history before beginning a woman on pills, but pills are contraindicated for a woman with severe hypertension.

Results from the Royal College study (1974, p. 37) confirm that the increase in blood pressure in the first year of pill use is very slight. The incidence of hypertension increases steadily with continued use. Although the exact mechanism is unknown, it seems to be related to the estrogen component (Weir et al. 1974, p. 533). Weir's study also found that when pill use was discontinued, blood pressure returned to normal within three months (Weir et al. 1974, p. 534). Although blood pressure can increase with duration of pill use, the possibility of hypertension still does not justify withdrawing all users for a break periodically (Royal College 1974, p. 37).

#### Benign Hepatic Adenomas

During the past several years, many cases of benign hepatic adenomas have been reported in medical literature (Nissen and Kent 1975, p. 460; Edmondson, Henderson, and Benton 1976, p. 470). Primary liver tumors are extremely rare. In their review of all reported cases, Edmondson and associates found that only five of the thirty-six for whom medical history was available had never taken oral contraceptives (Edmondson, Henderson, and Benton 1976, p. 470). The marked increase in liver tumors in the past five years suggests a cause and effect relationship with oral contraceptives (Nissen and Kent 1975, p. 460).

Why are problems showing up in the liver? It is known that the sex steroids are metabolized in the liver (Nissen and Kent 1975, p. 466). Estrogens, and possibly some progestins slow liver function (Ockner and Davidson 1967, p. 331). Cholestasis is produced by estrogens, and some researchers suggest this is due to a direct inhibitory effect on the hepatocyte (Metreau, Dhumeaux, and Berthelot 1972, p. 325). In most pill users, the cholestasis is not symptomatic, but some cases of jaundice have been reported (Metreau, Dhumeaux, and Berthelot 1972, p. 325). Liver changes seen in oral contraceptive use are similar to those seen in pregnancy; therefore, women who had jaundice during

pregnancy are found to have jaundice while using oral contraceptives (Metreau, Dhumeaux, and Berthelot 1972, p. 321).

The cells in benign primary liver tumors vary little from normal hepatocytes (Baum et al. 1973, p. 926).

They do not affect liver function, nor do they become malignant if left in situ (Nissen and Kent 1975, p. 466). Often, however, the tumor bleeds into a sinus separating it from normal liver tissue. This may rupture causing massive hemorrhage (Nissen and Kent 1975, p. 460). Resection of the tumor is dangerous due to the high vascularity of hepatic tissue, but this has been necessary in most of the reported cases (Nissen and Kent 1975, p. 461).

Edmondson and associates studied all reported cases to find some similarity of presenting symptoms. None of the reported cases had a past history of liver disease, alcoholism, or ingestion of hepatotoxic drugs. In retrospect, they were able to define symptoms of mass in the region of the liver, right upper quadrant pain, massive intraperitoneal hemorrhage, or no symptoms (Edmondson, Henderson, and Benton 1976, p. 470). All these symptoms are nonspecific and thus make diagnosis difficult. Routine x-rays and laboratory work are not helpful (Baum et al. 1973, p. 928). Liver function tests are totally nondiagnostic (Stauffer et al. 1975, p. 301). For symptomatic patients in nonemergency situations, liver scans and arteriograms are helpful in localizing the

tumor (Baum et al. 1973, p. 928). Needle biopsy is contraindicated (O'Sullivan and Wilding 1974, p. 10).

So far, no routine laboratory work has been helpful in identifying which pill users are at risk. One study has identified that there is a significant increase in risk with use of oral contraceptives longer than five years, and with use of mestranol-containing compounds (Edmondson, Henderson, and Benton 1976, p. 472). A study is underway now to determine what chemical structure in the pills might increase risk of benign liver tumor (Reese 1976).

Pre-existing liver malfunction is a relatively strong contraindication to pill use. Various authors have cited situations in which pill use should be highly questioned: active liver disease, gallbladder disease, mononucleosis, hepatitis, or any patient who had recurrent jaundice of pregnancy (Hatcher et al. 1976, p. 41; Metreau, Dhumeaux, and Berthelot 1972, p. 330; Ockner and Davidson 1967, p. 331).

On yearly return visits, physical examination of the liver in pill users should be done (Antoniades et al. 1975, p. 629). Screening should again be done for medical problems which could increase risk of liver tumors. Patients should be taught to report at once a mass in the right upper quadrant or severe pain in that area. "Early identification of women with liver lesions within a group

of 20 million pill users awaits a precise diagnostic method" (Nissen and Kent 1975, p. 466).

#### Gallbladder dysfunction

Due to the previously documented slowing of liver function by oral contraceptives, gall bladder problems are increased in pill users. The Royal College study (1974, p. 51) reported an increase in gallstones, cholecystitis, and pruritis. The development of gallstones was related to duration of pill use, but cholecystitis was not. Pruritis was increased after five years of pill use. Cholestasis is documented to occur within a few months of beginning pill use. Pruritis is thought to be due to cholestasis. Therefore, it is considered strange that pruritis developed only after five years of use (Royal College 1974, p. 51).

#### Other Adverse Effects

Metabolic changes caused by oral contraceptives can cause thromboembolic disease, hypertension, and hepatic disorders. These were discussed previously in this chapter.

Other metabolic changes have been documented although their long-term significance is not known. Fisch and Freeman (1975, p. 500) found an elevated white blood cell count in oral contraceptive users who were obese and who smoked more than one pack of cigarettes per day. Weindling and Henry

(1974, p. 1967) published a list of common laboratory values which are altered in pill users. They are:

| Test                     | Value     |  |  |  |  |  |
|--------------------------|-----------|--|--|--|--|--|
|                          |           |  |  |  |  |  |
| Albumin                  | Decreased |  |  |  |  |  |
| Glucose at 1 hour        | Increased |  |  |  |  |  |
| Serum Triglycerides      | Increased |  |  |  |  |  |
| Serum Thyroid binding    |           |  |  |  |  |  |
| globulin                 | Increased |  |  |  |  |  |
| Serum Thyroxine          | Increased |  |  |  |  |  |
| Platlets                 | Increased |  |  |  |  |  |
| Blood procoagulants      | Increased |  |  |  |  |  |
| Serum Iron               | Increased |  |  |  |  |  |
| Total iron binding capa- |           |  |  |  |  |  |
| city                     | Increased |  |  |  |  |  |

Serum vitamin levels are decreased in most pill users (Luke 1976, p. 33). Vitamins C,  $B_6$ ,  $B_{12}$ , and folic acid deficiencies are seen along with clinical symptoms corresponding with those deficiencies (Luke 1976, p. 33).

There is an increased reporting of headaches and migraines in pill users. The Royal College study (1974, p. 31) reported an increase, but they believed that all increased reports could be due to bias. Hatcher et al. (1976, p. 52) believes there is a pharmacologic basis for headaches. They could be attributed to an excess of estrogen or progesterone, or if severe, could be symptoms of hypertension. The brand of pills may be changed to minimize this problem.

Many annoying but relatively minor side effects are attributed to pill use. There is an increased incidence of urinary tract infections. This is possibly related to the estrogen dose (Royal College 1974, p. 61). Nausea is often reported in pill users. Cyclic weight gain and breast tenderness are also reported. All of these can be attributed to the estrogen dose and are worse within the first three months of use (Hatcher et al. 1976, p. 52).

Chloasma, or mask of pregnancy, may be seen in pill users. This will be intensified by sunlight and may be irreversible (Hatcher et al. 1976, p. 52). Vaginal discharge, cervicitis, and monilial vaginitis may be increased (Hatcher et al. 1976, p. 52). Data in the Royal College study (1974, p. 63) showed twice the vaginitis in pill users than in nonusers. However, the study concludes that the incidence of vaginitis among pill users is far lower than most physicians expect. There is a reported increase in depression (mood swings) in pill users. Much of this can be attributed to bias, but there is some real increase in mild forms of depression (Royal College 1974, p. 31).

#### Amenorrhea and Infertility

Amenorrhea and infertility after pill use have received much attention in medical reports (Good and Kempers 1974, p. 861; Golditch 1972, p. 903; Rifkin, Nachtigall, and

Beckman 1972, p. 420). After discontinuing oral contraceptives, most women resume their normal menstrual cycles within a few months. Prolonged amenorrhea one year after discontinuing pills occurs in less than one percent of users (Golditch 1972, p. 906). The continued amenorrhea is speculated to be due to oversuppression of the ovarian-hypothalamic-pituitary axis which controls the menstrual cycle (Beaconsfield et al. 1974, p. 575). The response to treatment depends on the degree of suppression.

Any patient presenting with post-pill amenorrhea should be tested for medical abnormalities which could be contributory. Radiologic films of the sella turcica are taken to rule out pituitary tumors. Tests of thyroid and adrenal function are done (Halbert and Christian 1969, p. 161). Treatment of choice is clomiphene citrate (Clomid) which helps to stimulate ovulation (Rifkin, Nachtigall, and Beckman 1972, p. 429). Clomiphene has successfully stimulated ovulation in about half the cases, but many of these patients did not conceive (Beaconsfield et al. 1974, p. 574). Other types of treatment are being explored, including attempts to produce Leutinizing Hormone releasing hormone on a large scale (Good and Kempers 1974, p. 865).

It is difficult to predict which patient will be a candidate for post-oral contraceptive amenorrhea and infertility. Duration of pill use past three cycles is not a

significant factor (Halbert and Christian 1969, p. 162; Gambrell, Greenblatt, and Mahesh 1971, p. 846). Prior menstrual history has not been statistically proven to be a factor although the general feeling is that it is. several reports, many of the patients had had irregular periods before beginning oral contraceptives (Halbert and Christian 1969, p. 162; Beaconsfield et al. 1974, p. 572; Good and Kempers 1974, p. 862). Some patients had been put on oral contraceptives to regulate their menstrual cycles. It seems that steroid hormones are a poor choice since they depress an already malfunctioning hypothalamic-pituitaryovarian cycling system (Gambrell, Greenblatt, and Mahesh 1971, p. 847). Drugs which suppress the hypothalamus such as morphine and phenothiazines predispose their users to post-pill amenorrhea (Rifkin, Nachtigall, and Beckman 1972, p. 431). It is recommended that women with late menarche, previous amenorrhea, or irregular periods greater than 35 days not be given pills (Steele, Mason, and Brett 1973, p. 344).

Post-pill amenorrhea is distressing because of the infertility associated with it. Many of these patients used oral contraceptives in order to plan their family. Now, they want a pregnancy very badly. The Royal College study (1974, p. 71) discussed this problem. Rates of amenorrhea and infertility are available for their pill takers, but

there is no way of comparing them with controls. They conclude that infertility is not greatly increased but that conception is delayed in the first three months after pill use. In their results, 85 percent of the nulliparous, and 93 percent of parous women conceived within two years of discontinuing oral contraceptives (Royal College 1974, p. 77). They believe that this is not significantly different from women who never used the pill, and that fertility postpill is just delayed, not decreased. Since figures for controls are not available, this information is difficult to evaluate.

# Popular Literature

Medical facts were accurately reported in popular literature from 1975 and 1976; however, these facts were often distorted (Gallagher 1976, p. 91; Lake 1975, p. 75; Masters and Johnson 1975, p. 42). In some cases, very rare, but serious, side effects were emphasized making the risks seem far greater than they are. The Gallagher article stated that the risk of death was seven and one-half times greater for oral contraceptive users than for non-users (1976, p. 91). This is true, but the actual numbers of deaths directly attributed to oral contraceptives are not stated. An article in Newsweek (1976, p. 60) reported factual information about new research regarding oral

contraceptives in women over forty. The most balanced article was in <u>Reader's Digest</u> (Lake 1975, p. 75). Lake presents risks and benefits in a readable form which corresponds with facts in medical research.

## Summary

Consumer interest in health care is growing. Information about consumer knowledge and attitudes can help care providers to meet patient needs. In the area of family planning, risks and benefits are important. Oral contraceptives have both risks and benefits which must be presented and given priority. Several minor side effects may be experienced by many users. More severe side effects such as thromboembolic disease and liver disorders are experienced by only a very few. Non-contraceptive benefits may pertain to a majority of users. These are shorter periods, decreased blood loss, decreased frequency of anemia, decreased risk of breast or ovarian tumors. After comparing risks and benefits, women with no medical problems which contraindicate pill use should be good candidates for oral contraceptives.

#### CHAPTER III

### PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

## Introduction

In order to ascertain whether clients' attitudes and knowledge reflect published information about oral contraceptives, a descriptive survey was done. According to Leedy, the researcher does two things in using descriptive research:

First, he observes with close scrutiny the population of his research parameter; second, he makes a careful record of what he observes, so that, having made his observations, he can come back to the record that he has made of them and can study that record carefully in order to discover the meaning of what he has observed (Leedy 1974, p. 80).

Chapter III is a presentation of the procedure used for collection and treatment of data. The setting for the study is described. Population and sample selection are presented. Selection of the tool and modifications made are described. The chapter concludes with a description of data collection and the statistics used for analysis of the data.

## Setting

The setting of this investigation was all the family planning clinics of the Bell County Health Department in Central Texas. Clinics are held in two towns within the county. Temple has a population of approximately 45,000 and is a self-supporting industrial-farming community. The family planning clinic draws clients from the town itself, from many nearby farming communities, and from Belton, the county seat, which has no clinic. Clinics are held three times per week. This clinic is staffed by the county family planning nurse and at least one other registered nurse from the health department's staff of seven. Health care is provided by obstetric-gynecologic residents from a large teaching hospital in the area.

The second family planning clinic in the county is held in Killeen, a town of 50,000 adjacent to a large military installation. Most of the clients are civilians, although a small number are military dependents. Clinics are held once or twice per week. The clinic is staffed by the county family planning nurse, one other registered nurse, and a family planning nurse practitioner. Health care is provided alternately by the nurse practitioner and an obstetric-gynecologic resident from the same large teaching hospital.

### <u>Population</u>

The sample was selected from clients who presented themselves to the family planning clinics in November 1976. The following criteria were used for selection:

- 1. Those who spoke and understood English
- 2. Those who were currently using or wanted to use contraceptive methodology

All eligible participants were admitted to the study population until the sample size (N) equalled 60.

## Methodology

An in-depth review of literature was conducted at the beginning of the study. Professional literature in family planning, nursing, and medicine was reviewed. Topics reviewed were client attitudes and knowledge of family planning methods, reasons clients gave for using or discontinuing any method, and consumer's interest in health care. Also surveyed were advantages, disadvantages, and risks of oral contraceptive use.

Popular literature was surveyed. Newsweek, Redbook, and Reader's Digest were chosen for their readibility and wide circulation. All articles pertaining to oral contraceptives between January 1975 and September 1976 were reviewed.

A tool was located and modified according to information found in the literature.

#### Tool

A questionnaire to measure clients' knowledge of and attitudes about oral contraceptives was developed by Fleckenstein et al. (1976). The tool assessed: 1) demographic data, 2) prior use or nonuse of oral contraceptives, and 3) perceptions of present knowledge and attitudes regarding oral contraceptives. The questionnaire was used once in a study of 828 subjects in the Rochester, New York area. Other research using the tool is not available.

Permission to use the questionnaire was obtained from Dr. Lawrence Fleckenstein. The questionnaire was modified slightly and used in this study as a guide for the structured interviews (Appendix B). Three possible oral contraceptive side effects were added. Also added was a question regarding present use of any contraception and reasons for choosing that method. An open-ended question regarding advantages of oral contraceptive use was included.

Content validity was established by a panel of experts who have advanced preparation in family planning methodology. The first panel member, a registered nurse, is presently a full-time graduate student in maternal-child

health. She has extended practice in obstetrics and family planning and prior teaching experience in a baccalaureate nursing program. She has completed a graduate level course in family planning. The course provided in-depth coverage of risks, benefits, and contraindications for each contraceptive method. Counseling needs of clients and counseling methodologies were included. Clinical practice time was provided.

The second panel member, also a registered nurse, is a graduate student in maternal-child health. She is a part-time instructor in maternal-child health in an associate degree nursing program and has extensive clinical experience in obstetrics and family planning. She also has completed the previously described graduate course in family planning.

## Data Collection

Formal permission for the study was first obtained from the Texas Woman's University (Appendix A) and the Bell County Health Department (Appendix A). Informal discussions regarding the purpose of the study were held with various staff members of the health department before and during data collection. Data were collected during November 1976.

Charts were reviewed for clients who attended the family planning clinics during the study. All clients who met the stated criteria were approached in the clinic waiting room. The purpose of the study was explained, as well as the fact that participation was voluntary. If clients expressed a willingness to participate, written permission was obtained on the Texas Woman's University Oral Permission form (Appendix A).

Interviews were then conducted in a private room.

Interviews were tape-recorded to ensure accuracy in marking the questionnaire. Permission for this was also obtained from each client. Items from the modified Fleckenstein questionnaire were read to the participants and responses elicited. Items were read in order to control for bias which could have been introduced by the varying educational and reading levels of the clients. No information was given by the investigator during data collection. Interviews were limited to fifteen minutes. Clients were given time to ask questions at the end of the interview.

## Treatment of Data

Demographic data were tabulated, categorized, and described. Patterns of oral contraceptive use were presented by descriptive statistics. One-way analysis of variance was done to compare categories of demographic data to total

knowledge scores. Perceptions of reasons for choosing or not choosing oral contraceptives were presented by descriptive statistics. Attitudes were tabulated and described.

## Summary

A descriptive survey was done in order to determine whether clients' attitudes and knowledge reflect published information about oral contraceptives. Clients, selected according to stated criteria, were obtained from the family planning clinics of the Bell County Health Department.

Data were collected in structured interviews using the modified Fleckenstein questionnaire as a guide. Data on demographic variables, various patterns of oral contraceptive use, knowledge, attitudes, and preferred sources of information were analyzed by descriptive statistics. Analysis of variance was done to compare demographic categories and use of oral contraceptives to total knowledge scores. Chapter IV is a presentation of these results.

#### CHAPTER IV

#### ANALYSIS OF DATA

### Introduction

Results of the study are presented in the following chapter. Scheduled interviews were conducted with sixty family planning patients. Demographic data, oral contraceptive use patterns, knowledge scores, and attitude results are presented. Results of one-way analysis of variance between demographic variables and knowledge scores are presented.

# Results of Data Analysis

Demographic data are presented in Table 1. The respondents under age twenty-five made up 78.4 percent of the sample. Marital status varied widely. Women with no children made up 28.3 percent of the sample. Forty percent had one child, and 16.7 percent had two. Respondents expressed religious preference of Protestant, Catholic, or no present affiliation, with 30 percent in the latter category. Ethnic groupings showed a larger percentage of blacks

Table 1. DEMOGRAPHIC DATA FOR PARTICIPANTS

|                        | Number of |                                       |
|------------------------|-----------|---------------------------------------|
| Data                   | Subjects  | Percentage                            |
| Age, years             | y         |                                       |
| <20                    | 22        | (36.7)                                |
| 20-24                  | 25        | (41.7)                                |
| 25 or more             | 13        | (21.7)                                |
| Marital status         |           |                                       |
| Married                | 24        | (40.0)                                |
| Single                 | 21        | (35.0)                                |
| Divorced               | 7         | (11.7)                                |
| Separated              | 8         | (13.3)                                |
| Number of children     |           |                                       |
| 0                      | 17        | (28.3)                                |
| 1                      | 24        | (40.0)                                |
| 2                      | 10        | (16.7)                                |
| 3                      | 5         | (8.3)                                 |
| 4                      | 2         | (3.3)                                 |
| 5 or more              | 2         | (3.3)                                 |
| Occupation             |           |                                       |
| Student                | 6         | (10.0)                                |
| Housewife              | 20        | (33.3)                                |
| Employed, Blue collar  | 24        | (40.0)                                |
| Unemployed             | 10        | (16.7)                                |
| Religious preference   |           |                                       |
| Protestant             | 31        | (51.7)                                |
| Catholic               | 11        | (18.3)                                |
| No present affiliation | 18        | (30.0)                                |
| Ethnic group           |           |                                       |
| Caucasian              | 33        | (55.0)                                |
| Mexican-American       | 10        | (16.7)                                |
| Black                  | 17        | (28.3)                                |
| Education              |           |                                       |
| Less than high school  | 36        | (60.0)                                |
| Finished high school   | 10        | (16.7)                                |
| More than high school  | 14        | (23.3)                                |
| Total family income    |           |                                       |
| <\$3,000               | 19        | (32.8)                                |
| \$3,000 - \$6,999      | 22        | (37.9)                                |
| \$7,000 - \$11,999     | 14        | (24.1)                                |
| \$12,000 - \$19,999    | 3         | (5.2)                                 |
| 722,000 - 713,535      | 5         | * * * * * * * * * * * * * * * * * * * |

and Mexican-Americans, 28.3 and 16.7, respectively, than does the general population. Sixty percent of the sample had less than high school education. Only 5.2 percent lived in a family with greater than \$12,000 yearly income, and 32.8 percent had less than \$3,000 yearly income.

# Patterns of Use

Table 2 presents patterns of oral contraceptive use. In this sample, 10 percent had never used oral contraceptives. Years of oral contraceptive use varied widely. The majority, 55.6 percent, had used pills less than three years, but 14.8 percent had used pills five or more years. Present users were asked why they chose the pill. Over 40 percent cited convenience and effectiveness of the pill, and unacceptability of other methods as reasons.

In response to the question of which brand of oral contraceptives they had used most recently, most (57.5 percent) could name the brand. Several more (18.5 percent) could describe the package sufficiently to make identification possible.

The number of brands taken varied. Results showed that 42.6 percent had taken only one brand of oral contraceptives. The other 57.4 percent were almost evenly spaced over two, three, and four or more brands. The number of brands taken by past users was higher than the average for

Table 2. PATTERNS OF ORAL CONTRACEPTIVE USE

|  | Number                           | Percentage  |
|--|----------------------------------|---|
| Oral contraceptive use Present user Past user Non-user   | 37<br>17<br>6                    | (61.7)<br>(28.3)<br>(10.0)                              |
| Reason(s) oral contraceptives chosen - Convenience Other methods unacceptable More effective than other methods Recommended by someone | present u<br>18<br>16<br>15<br>9 | (48.6)<br>(43.2)<br>(40.5)<br>(24.3)                    |
| Years oral contraceptives taken* <1 1 2 3 4 5 or more  | 5<br>17<br>8<br>10<br>6<br>8     | (9.3)<br>(31.5)<br>(14.8)<br>(18.5)<br>(11.1)<br>(14.8) |
| "Do you remember (without checking) the recently been using?"*  No  Could describe package  Yes - could name                           | 13<br>10<br>31                   | (24.0)<br>(18.5)<br>(57.5)                              |
| Number of brands taken*  1 2 3 4 or more   | 23<br>10<br>11<br>10             | (42.6)<br>(18.5)<br>(20.4)<br>(18.5)                    |
| Number of brands taken by past users  1 2 3 4 or more  | 6<br>2<br>5<br>4                 | (35.3)<br>(11.8)<br>(29.4)<br>(23.5)                    |
| Times stopped using oral contraceptive  1 2 3 4 or more  | 23<br>6<br>6<br>1                | (63.9)<br>(16.7)<br>(16.7)<br>(2.7)                     |

Table 2. PATTERNS OF ORAL CONTRACEPTIVE USE (continued)

| Reason(s) stopped oral contraceptive use Wanted children No longer needed contraception Doctor's advice Undesirable side effects Fear of side effects Other                                  | 5 (29.4)<br>2 (11.8)<br>4 (23.5)<br>10 (58.8)<br>5 (29.4)<br>8 (35.3) |
|--|---|
| Reason(s) stopped oral contraceptive use<br>(interrupted use) *** Wanted children No longer needed contraception Doctor's advice Undesirable side effects Fear of side effects Other         | 6 (31.6)<br>2 (10.5)<br>1 (5.3)<br>5 (26.3)<br>3 (15.8)<br>8 (42.1)   |
| Reason(s) oral contraceptives never used Never desired contraception Used another form of contraception Doctor's advice Against religious beliefs Pills are too dangerous to my health Other | 4 (66.7)<br>1 (16.7)<br>0 (0.0)<br>1 (16.7)                           |

<sup>\*</sup> Statistics include present and past users

<sup>\*\*</sup> Statistics include present (interrupted use) and past users

<sup>\*\*\*</sup> Respondents could choose more than one reason

all users. Of past users, 52.9 percent had taken three or more brands, while present users had only 38.9 in that category.

Actual side effects or fear of side effects were reported frequently as reasons for discontinuing pill use. Actual side effects were cited by 58.8 percent of past users as a reason for stopping the pills. Fear of side effects was listed by 29.4 percent of the same group. Of present users with interrupted use, 26.3 percent cited actual side effects, and 15.8 percent gave fear of side effects as reasons for discontinuing the pill. Other reasons given were use of a different method, and unwillingness or lack of transportation to come for a physical exam. desire for children was cited by 29.4 and 31.6 percent of past users and present users, respectively, as a reason for discontinuing the pill. The majority of those who had never used oral contraceptives (66.7 percent) stated that they had not needed anything for contraception. Two of the six in this group believed that oral contraceptives were too dangerous to their health.

# Package Insert

All packages of oral contraceptives have an information folder inserted into the package. Questions related to this package insert received a favorable response (Table 3). An overwhelming majority (88.9 percent) of oral contraceptive users were aware of the package insert. A high percentage (91.7) of those aware of the insert had read it. Most (77.3 percent) of those who had read it, found it helpful. These results would seem to indicate that women readily accept this information source.

Table 3. QUESTIONS ABOUT THE PACKAGE INSERT

| "Is there an informational folder     |          |        |   | 1    |
|---------------------------------------|----------|--------|---|------|
| (package insert) inside your brand?"  |          |        |   |      |
| Yes                                   | 48       | (88.9) |   |      |
| No                                    | 5        | (9.2)  | 1 |      |
| Not sure                              | i i      | (1.9)  |   |      |
| "Have you read it?" (Asked only of    |          |        |   | _    |
| those who specified "yes" above.)     |          |        |   |      |
| Yes                                   | 44       | (91.7) |   |      |
| No                                    | 4        | (8.3)  |   |      |
| "Did you find it helpful for you?"    |          |        |   | _    |
| Yes                                   | 34       | (77.3) |   |      |
| No                                    | 10       | (22.7) |   | _    |
| Responses of those who said they read |          |        | * |      |
| the insert to "Can pills cause blood  |          |        |   |      |
| clots?"                               | 1.       |        |   |      |
| Yes                                   | 24       | (54.5) |   |      |
| No, or Don't Know                     | 20       | (45.4) |   | . 4, |
| Note: Numbers in parentheses are perc |          |        |   |      |
| rampers in barencheses are ber        | -circuge | -      |   |      |

## Knowledge

Patient knowledge was determined from a score derived from questions related to use and possible side effects of oral contraceptives. The questions and responses are presented in Table 4. One point was given for each correct response (underlined in Table 4). The sum represents the total knowledge score. One question regarding benefits of oral contraceptives was asked. Results are presented in Table 4, but are not taken into account in the total knowledge scores.

The highest possible score was 21. There were eleven possible side effects of oral contraceptive use. Eight complaints could not be caused by the pill, and two questions concerned proper use. The mean score for this sample was 10.77, with a range from 4 to 16. Six, or 10 percent, scored in the bottom third between 0 - 7. The middle third, from 8 through 14, contained 50, or 83 percent. The upper third from 15 - 21 contained 4, or 7 percent. These scores are extremely low. Since correct answers to all of the knowledge questions except two are contained in the package insert, clients might be expected to score very high. Clients might also be expected to score very high since 89 percent were aware of the package insert, and 91 percent of those had read it (Table 3).

Table 4. QUESTIONS USED TO ASSESS KNOWLEDGE

|    |   | Yes(%)  | No (%)   | Don't<br>Know(%)   |
|----|---|---|--|--|
| Α. | Side effects questions "Can birth control pills ever cause any of the following complaints?"  |   |  |  |
|    | Weight gain Diarrhea Loss of vision Bad breath Depression Nausea Lumps in the breast Abnormal vaginal bleeding Tender or sore breasts | 40(66.7)* 3(5.0) 9(15.0) 1(1.7) 34(56.7) 36(60.0) 9(15.0) 33(55.0) 17(28.3)                             | 12(20.0)<br>40(66.7)<br>34(56.7)<br>46(76.7)<br>18(30.0)<br>21(35.0)<br>30(50.0)<br>22(36.7)<br>27(45.0) | 8(13.3)<br>17(28.3)<br>17(28.3)<br>13(21.6)<br>8(13.3)<br>3(5.0)<br>21(35.0)<br>5(8.3)<br>16(26.7) |
|    | "Can birth control pills ev cause?"   | ver .   |  |  |
|    | High blood pressure Ulcers Pneumonia Cancer Blood clots Arthritis Jaundice Headaches Sore throat                                      | 21 (35.0)<br>4 (6.7)<br>0 (0.0)<br>31 (51.7)<br>32 (53.3)<br>2 (3.3)<br>1 (1.7)<br>44 (73.3)<br>2 (3.3) | 12(20.0)<br>28(46.7)<br>43(71.7)<br>7(11.7)<br>14(23.3)<br>44(73.3)<br>34(56.7)<br>13(21.6)<br>50(83.3)  | 14(23.3<br>14(23.3<br>25(41.6<br>3(5.0   |
|    | Difficulty getting pregnandater you guit taking the   | t<br>m 16(26.7)   | 29(48.3)   | 15(25.0  |

Table 4. QUESTIONS USED TO ASSESS KNOWLEDGE (continued)

| *  |  | Number             | Percent                        |
|----|--|--------------------|--------------------------------|
| В. | Correct use questions "What do you do when you remember Thursday morning that you have forgotten to take Wednesday's pill?"  |                    |                                |
|    | Take both Wednesday's and Thursday's pill on Thursday Skip Wednesday's pill and continue with Thursday's pill Don't know Other   | 53<br>4<br>2<br>1  | (88.3)<br>6.7<br>3.3<br>1.7    |
|    | "How many menstrual periods can you miss before you should stop taking the pill and call your doctor?"   |                    |                                |
|    | One<br>Two<br>Three<br>Four  | 34<br>22<br>3<br>1 | (56.7)<br>(36.7)<br>5.0<br>1.7 |
| c. | Response(s) to "What are some advantages of pill use?"   |                    |                                |
|    | Not getting pregnant Not worrying about pregnancy Regulation of menses, decrease in amount and duration of flow Increase in body image due to increased breast size or diminished acne Other | 34<br>15           | (56.7)<br>(25.0)               |
|    |  | 28                 | (46.7)                         |
|    |  | 3<br>16            | (5.0)<br>(26.7)                |

<sup>\*</sup>Correct responses are underlined.

At least 60 percent of the respondents were aware of the association between pill use and weight gain, nausea, and headaches. At least 50 percent were aware of the association with depression, abnormal vaginal bleeding, and blood clots. Of the possible side effects listed, only jaundice and decreased or delayed fertility after discontinuing pill use are not listed on the package insert. The results show that many clients are not aware of many of the possible side effects of oral contraceptive use.

The majority of clients (51.7 percent) thought the pills could cause cancer. Another 36.7 percent did not know. The Royal College study (1974, p. 25) confirmed that the risk of cancer was not increased in pill users. Clients' responses do not reflect this association. Recent news reports linking high doses of estrogen to uterine carcinoma could have affected the responses.

Respondents were well informed as to how to use the pills. Of all respondents, including those who had never taken oral contraceptives, 53, or 88.3 percent, correctly identified what to do if they missed a pill. Although it is recommended that users who have not missed any pills wait to contact their doctor until their second missed period (Hatcher 1976, p. 47), only 36.7 were willing to wait that long. More patients (56.7 percent) stated they would call after missing one period.

Responses to the question of advantages of oral contraceptive use fell into five categories. These categories with results were: 1) Not getting pregnant was listed most frequently (56.7 percent). 2) Not worrying about pregnancy was listed by 25 percent of the respondents. 3) Regulation of menses with decreased amount and duration of flow was listed by 46.7 percent of the respondents. 4) Increased body image was listed by 5 percent. 5) Other responses included population concerns, being able to space children as desired, and being able to make long-term family plans without interruptions for unplanned childbearing. None of the respondents mentioned the decreased incidence of benign breast disease, ovarian tumors, or premenstrual tension known to be associated with pill use (Royal College 1974, p. 26).

Analysis of variance was done between each category of demographic data and total knowledge scores. Results are presented in Table 5. No significant correlation was found between age, marital status, number of children, occupation, religious affiliation, ethnic group, education, or total family income and total knowledge scores. A significant difference was found between present users, past users, and those who had never used oral contraceptives and their knowledge scores (p <.05).

Table 5. CORRELATION OF CATEGORIES OF DEMOGRAPHIC VARIABLES WITH KNOWLEDGE SCORES

| Variable                  | F    | đf   | F ∝.05 |   |
|---------------------------|------|------|--------|---|
| 1                         |      |      |        | : |
| Age                       | .97  | 2/57 | NS     |   |
| Marital status            | .72  | 3/56 | NS     |   |
| Number of children        | .81  | 5/54 | NS     |   |
| Occupation                | .29  | 3/56 | NS     |   |
| Religious preference      | .32  | 2/57 | NS     |   |
| Ethnic group              | .86  | 2/57 | NS     |   |
| Education                 | .72  | 2/57 | NS     |   |
| Family Income             | .45  | 3/54 | NS     |   |
| Users or nonusers of oral |      |      | 4.     |   |
| contraceptives            | .12  | 1/58 | NS     |   |
| Present, past, or never   |      | 7, 3 |        |   |
| users of oral contra-     |      |      |        |   |
| ceptives                  | 3.13 | 2/57 | Sig.   |   |
| 00202100                  | 0.10 | 2/3/ | 9      |   |

On the patient-oriented package insert, a special box warns of the association of abnormal blood clotting with oral contraceptive use. Signs and symptoms to report to a physician are given. Only 53.3 percent of all respondents were aware of this association. Of those who had taken pills, and who had read the package insert, 54.5 percent were aware that pill use could cause clotting (See Table 3). Most of the respondents (58.3 percent) considered the information available to them about oral contraceptives to be adequate. However, a large percentage (41.7) did not.

## Important Sources of Information

Important sources of information about oral contraceptives are listed in Table 6. The percentage of respondents who listed each source as very important is given.

The doctor was listed as very important most often (85 percent). Printed materials were preferred next often. Professionals (doctor, nurse, pharmacist) were preferred over nonprofessionals (family and friends).

Table 6. IMPORTANT SOURCES OF INFORMATION

| Source  | Number   | Percent*   |
|---|--|--|
| Doctor Booklet about the pill Package insert Nurse Magazine and newspaper articles Pharmacist Family Friends Television | 51<br>45<br>40<br>39<br>17<br>15<br>13<br>8<br>7 | (85)<br>(75)<br>(66.7)<br>(65)<br>(28.3)<br>(25)<br>(21.7)<br>(13.3)<br>(11.7) |

<sup>\*</sup>Percent listed as "very important."

# <u>Attitudes</u>

Attitudes about the safety and efficacy of oral contraceptives are presented in Table 7. Respondents to this study had favorable attitudes. A large majority (91.7 percent) believed that the pill is safe. Even more (93.3

percent) believed that it is effective. When asked if the benefits of pill use outweighed the risk to their health, the majority of respondents (76.7 percent) answered positively.

Table 7. ATTITUDES ABOUT SAFETY AND EFFICACY OF ORAL CONTRACEPTIVES

| Attitudes  | Number             | Percent                          |
|--|--------------------|----------------------------------|
| Oral contraceptive safety Completely safe Fairly safe Fairly dangerous Very dangerous  | 9<br>46<br>5<br>0  | (15)<br>(76.7)<br>(8.3)<br>(0)   |
| Oral contraceptive efficacy Very effective Moderately effective Slightly effective Not effective   | 32<br>24<br>2<br>2 | (53.3)<br>(40)<br>(3.3)<br>(3.3) |
| "I believe that the benefits of preventing pregnancy by taking the pill outweigh the risk the pill might be to my health."  Agree Disagree | 46<br>14           | (76.7)<br>(23.3)                 |

Question 5 in this study was: "If clients' attitudes and knowledge are extremely diverse from published information, can a teaching methodology be developed to expedite assimilation of the information clients can use in choosing or not choosing oral contraceptives?" The maximum possible score was 21. The clients' mean score was 10.77.

This is sufficiently diverse as to suggest that a teaching methodology might be of some value in increasing knowledge. Therefore, a teaching methodology has been developed (Appendix C). Data from this study show that clients in this area have a low educational level. Clients stated they read printed materials; however, their knowledge scores did not reflect that information. Therefore, teaching must be done verbally. The teaching methodology developed for this study is designed as a small group discussion. A minimum of twenty minutes is needed.

### Summary

Chapter IV has presented the results of the study.

Demographic variables of respondents and their patterns of oral contraceptive use were presented. Clients' reasons for using, not using, or discontinuing oral contraceptives were discussed. Clients' knowledge as measured by responses to side effects and use questions, and clients' attitudes were listed. Knowledge scores were generally low, and attitudes were very positive. Chapter V presents conclusions which can be drawn from the study. Implications for nurses caring for family planning patients are discussed.

#### CHAPTER V

SUMMARY, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

This chapter contains a summary of the entire study.

Several conclusions suggested by the data are presented.

Implications for nurses are enumerated, followed by recommendations.

#### Summary

This descriptive study was designed and implemented to ascertain the following: 1) Do clients' attitudes and knowledge reflect published information regarding oral contraceptives? and 2) If clients' attitudes and knowledge are extremely diverse from published information, can a methodology be developed to expedite assimilation of the information clients can use in choosing or not choosing oral contraceptives?

A review of professional and popular literature regarding oral contraceptives was done. Permission was granted to use the Knowledge and Attitude questionnaire developed by Fleckenstein and associates. The questionnaire was modified and used as a basis for structured interviews

with family planning patients. Data were collected at the Bell County Health Department during family planning clinics. Interviews were continued until sixty clients had been interviewed.

Results showed a sample that was very young (78 percent under age 25), had a low educational level (60 percent had less than high school education), and a low family income (70 percent had less than \$7,000 per annum). Pill users stated that they chose the "pill" for its convenience and effectiveness, and stated that other methods were not acceptable. The mean knowledge score was 10.77, out of a possible 21. Attitudes toward the pill were favorable.

## Conclusions

The conclusions which could be made from the study are as follows:

- Clients in this area were poorly informed of the side effects and risks of oral contraceptives. The lack of information extended to all groups of clients.
- 2) Clients' attitudes were highly favorable to the pill.
- 3) Clients considered professionals very important as sources of information about oral contraceptives.

- 4) Clients stated that they read printed material about the "pill." However, total knowledge scores did not reflect that clients assimilated what they read.
- 5) A teaching methodology could be developed to increase clients' knowledge about oral contraceptives. This must be presented orally due to clients' low educational levels and poor comprehension of printed materials.
- 6) Conclusions derived from this study cannot be generalized to populations other than the sample group who were clients using the family planning services of the Bell County Health Department.

## <u>Implications</u>

Several implications can be made for nurses as a result of this study. Clients in this study were poorly informed as to the possible effects of oral contraceptive use. They considered a nurse to be an important source of information. This suggests that clients would be receptive to formal teaching in a clinic setting. It is recommended that professional nurses be used in such roles. Nursing education should include content on teaching methods with specific attention to clients' levels of understanding. Inservice education can provide this content for nurses who are employed.

Most clients stated that they had read the package insert and booklets on the "pill." However, this was not demonstrated in their knowledge scores. Subjective responses from several clients were that package inserts and booklets contained language they could not understand. This would indicate that printed materials cannot be relied on as the method of teaching. Information should be presented orally with clients having time to discuss questions and clarify ideas.

## Recommendations

- The study should be replicated using a larger sample from various areas.
- 2) A similar study should be done after the teaching methodology has been implemented and results compared and contrasted with this study.
- 3) Printed material should be developed that corresponds with the reading level of the clients served.
- 4) Studies should be done to further explore the teaching role of the professional nurse in family planning.

#### REFERENCES

- Ager, J.W.; Werley, H.H.; and Shea, F.P. 1973. Correlates of continuance in a family planning program. Journal of Obstetric, Gynecologic, and Neonatal Nursing. 2(6):15-23.
- Alkjarsig, N.; Fletcher, A.; and Burstein, R. 1975. Association between oral contraceptive use and thromboembolism: A new approach to its investigation based on plasma fibrinogen chromatography. American Journal of Obstetrics and Gynecology. 122:199-211.
- Annas, G.J. and Healey, J. 1974. The patient's rights advocate. Journal of Nursing Administration. 4 (May/June):25-31.
- Antoniades, K.; Campbell, W.N.; Hecksher, R.H.; Kessler, W.B.; and McCarthy, G.E. 1975. Liver cell adenoma and oral contraceptives. Journal of the American Medical Association. 234:628-629.
- Badaracco, M.A. and Vessey, M.P. 1974. Recurrence of venous thromboembolic disease and use of oral contraceptives. British Medical Journal. 1:215-217.
- Baum, J.K.; Holtz, F.; Bookstein, J.J.; and Klein, E.W. 1973. Possible association between benign hepatomas and oral contraceptives. The Lancet. 2:926-929.
- Beaconsfield, P.; Dick, R.; Ginsburg, J.; and Lewis, P. 1974. Amenorrhea and infertility after the use of oral contraceptives. Surgery Gynecology and Obstetrics. 138:571-575.
- British Medical Journal. 1970. Combined oral contraceptives: A statement by the Committee on Safety of Drugs. 2:231-232.
- Edmondson, H.A.; Henderson, B.; and Benton, B. 1976. Liver-cell adenomas associated with use of oral contraceptives. The New England Journal of Medicine. 294:470-472.
- Fisch, I.R. and Freedman, S.H. 1975. Smoking, oral contraceptives, and obesity: effect on white blood cell count. Journal of the American Medical Association. 234:500-506.

- Fleckenstein, L.; Joubert, P.; Lawrence, R.; Patsner, B.; Mazzullo, J.M.; and Lasagna, L. 1976. Oral contraceptive patient information. Journal of the American Medical Association. 235:1331-1336.
- Gallagher, D. 1976. Is your contraceptive safe for you? Redbook. 147(May):91.
- Gambrell, R.D.; Greenblatt, R.B.; and Mahesh, V.B. 1971.

  Post-pill and pill-related amenorrhea galactorrhea.

  American Journal of Obstetrics and Gynecology.

  110:838-848.
- Golditch, I.M. 1972. Postcontraceptive amenorrhea.
  Obstetrics and Gynecology. 39:903-908.
- Good, A.E. and Kempers, R.D. 1974. Prlonged over-suppression syndrome. Medical Clinics of North America. 58:861-868.
- Halbert, D.R. and Christian, C.D. 1969. Amenorrhea following oral contraceptives. Obstetrics and Gynecology. 34:161-167.
- Hatcher, R.A.; Stewart, G.K.; Guest, F.; Finkelstein, R.; and Godwin, C. 1976. Contraceptive Technology 1976-1977. Irvington Publishers, Inc., New York, New York.
- Heyman, A. and Hurtz, H.I. 1975. Clinical complications of oral contraceptives. Disease a Month. August 1975, 1-34.
- Hospitals. 1973. Statement on a patient's bill of rights. 47:41.
- Inman, W.H.W.; Vessey, M.P.; Westerholm, B.; and Engelund, A. 1970. Thromboembolic disease and the steroidal content of oral contraceptives. British Medical Journal. 2:203-209.
- Inman, W.H.W. and Vessey, M.P. 1968. Investigation of deaths from pulmonary, coronary, and cerebral thrombosis and embolism in women of childbearing age. British Medical Journal. 2:193-199.
- Lake, A. 1975. What we now know about the pill. Readers Digest. 106(March):75-78.

- Leedy, P.D. 1974. Practical Research: Planning and Design. New York: MacMillan.
- Luke, Barbara. 1973. Think "nutrition" is she's on the pill. RN. 39:33-37.
- Mason, B.; Oakley, N.; and Wynn, V. 1973. Studies of carbohydrate and lipid metabolism in women developing hypertension on oral contraceptives. British Medical Journal. 3:317-320.
- Masters, W.H. and Johnson, V.E. 1975. Contraception and sexual pleasure. Redbook. 145(May):42-47.
- Medical Malpractice. 1973. Report of the Secretary's Commission on Medical Malpractice. Washington, D.C.
- Meleis, A.I. 1971. Self concept and family planning. Nursing Research. 20:229-236.
- Metreau, J.M.; Dhumeaux, D.; and Berthelot, P. 1972. Oral contraceptives and the liver. Digestion. 7:318-335.
- Mills, Stephanie. 1975. The Joy of Birth Control. Emory University Family Planning Program, Atlanta, Ga.
- Newsweek. 1976. Birth-control deaths. 87(March 1):60.
- Nissen, E.D. and Kent, D.R. 1975. Liver tumors and oral contraceptives. Obstetrics and Gynecology. 46: 460-467.
- Ockner, R.K. and Davidson, C.S. 1967. Hepatic effects of oral contraceptives. The New England Journal of Medicine. 276:331-334.
- Oliver, M.F. 1970. Oral contraceptives and myocardial infarction. British Medical Journal. 2:210-213.
- O'Sullivan, J.P. and Wilding, R.P. 1974. Liver hamartomas in patients on oral contraceptives. British Medical Journal. 3:7-10.
- Quinn, N. and Somers, A.R. 1974. The patient's bill of rights: A significant aspect of the consumer revolution. Nursing Outlook. 22:240-244.

- Reese, Gloria. Unpublished Master's Thesis. Texas Woman's University, Denton, Texas.
- Rifkin, I.; Nachtigall, L.E.; and Beckman, E.M. 1972.

  Amenorrhea following the use of oral contraceptives.

  American Journal of Obstetrics and Gynecology.

  113:420-432.
- Royal College of General Practitioners: Oral Contraceptives and Health. 1974. Pitman Medical. New York.
- Sear, A.M. and Turner, M.N. 1974. Factors associated with short-term oral contraceptive discontinuation. Family Planning Perspectives. 6:230-233.
- Stauffer, J.Q.; Lapinski, M.W.; Honold, D.J.; and Myers, J.K. 1975. Focal nodular hyperplasia of the liver and intrahepatic hemorrhage in young women on oral contraceptives. Annals of Internal Medicine. 83: 301-306.
- Steele, S.J.; Mason, B.; and Brett, A. 1973. Amenorrhoea after discontinuing combined oestrogen-progestogen oral contraceptives. British Medical Journal. 4:343-345.
- Vessey, M.P. and Doll, R. 1968. Investigation of relation between use of oral contraceptives and thrombo-embolic disease. British Medical Journal. 2:199-205.
- \_\_\_\_\_. 1969. Investigation of relation between use of oral contraceptives and thromboembolic disease.

  A further report. British Medical Journal.

  2:651-657.
- Weindling, H. and Henry, J.B. 1974. Laboratory test results altered by "the pill." Journal of the American Medical Association. 229:1762-1768.
- Weir, R.J.; Briggs, E.; Mack, A.; Naismith, L.; Taylor, L.; and Wilson, E. 1974. Blood pressure in women taking oral contraceptives. British Medical Journal. 1:533-535.

### BIBLIOGRAPHY

- Arrata, W.S.M. and de Alvarez, R.R. 1972. The oversuppression syndrome. American Journal of Obstetrics and Gynecology. 112:1025-1030.
- Astedt, Birger. 1975. New aspects of the thrombogenic effect of oral contraceptives. American Heart Journal. 90:1-3.
- Carnegie, M.E. 1974. The patient's bill of rights and the nurse. Nursing Clinics of North America. 9:557-562.
- Christopherson, W.M.; Mays, E.T.; and Barrows, G.H. 1975. Liver tumors in women on contraceptive steroids. Obstetrics and Gynecology. 46:221-223.
- Connell, Elizabeth. 1971. The pill and the problems.

  American Journal of Nursing. 71:326-332.
- \_\_\_\_\_. 1975. The pill revisited. Family Planning Perspectives. 7:62-71.
- Contostavlos, D.L. 1973. Benign hepatomas and oral contraceptives. The Lancet. 2:1200.
- Friedman, S. and Goldfien, A. 1969. Amenorrhea and galactorrhea following oral contraceptive therapy.

  Journal of the American Medical Association.
  210:1888-1891.
- Horowitz, B.J.; Solomkin, M.; and Edelstein, S.W. 1968. The oversuppression syndrome. Obstetrics and Gynecology. 31:387-389.
- Jequier, A.M.; O'Shea, A.; and Jacobs, H.S. 1975. Functional and post oral contraceptive amenorrhea:
  Response to luteinizing hormone releasing hormone.
  British Journal of Obstetrics and Gynaecology.
  82:333-336.
- Keerdoj, E. 1976. Father of the pill. Newsweek. 88(Aug. 30):8-9.

- Kelso, D.R. 1974. Benign hepatomas and oral contraceptives. The Lancet. 1:315-316.
- Knapp, W.A. 1974. Liver hamartomas in patients on oral contraceptives. The Lancet. 1:270-271.
- Muller, C.F. 1974. Feminism, society, and fertility control. Family Planning Perspectives. 6(2):68-72.
- Ory, H.; Cole, P.; MacMahon, B.; and Hoover, P. 1976. Oral contraceptives and reduced risk of benign breast diseases. New England Journal of Medicine. 294: 419-422.
- Schweitzer, I.L; Weiner, J.M.; McPeak, C.M.; and Thursby, M.W. 1975. Oral contraceptives in acute viral hepatitis. Journal of the American Medical Association. 233:979-980.
- Slavinsky, A.T. and Romoff, V. 1972. Consumer participation. Journal of Nursing Administration. 2(May/June):14-18.
- Tountas, C.; Paraskevas, G.; and Deligeorgi, H. 1974.

  Benign hepatoma and oral contraceptives. The

  Lancet. 1:1351-1352.

#### APPENDIX A

PERMISSION FOR THE STUDY

# TEXAS WOMAN'S UNIVERSITY RESEARCH INSTITUTE

DENTON, TEXAS 76204



BONE METABOLISM LABORATORY BOX 23546, TWU STATION PHONE (817) 387-5305

November 8, 1976

Ms. Linda S. Byers, R.N., B.S.N. Texas Woman's University Dallas Campus Dallas, Texas

Dear Ms. Byers:

The Human Research Review Committee has revied and approved your amended program plan, "A study of clients" perceptions of reasons for choosing or not choosing oral contraceptives".

You are reminded that documentation of informed consent should be retained in your files in regard to the above-referenced project.

Sincerely yours,

George P. Vose, Chairman

Human Research Review Committee

cc Dr. Bridges Ms. Goosen

# TEXAS WOMAN'S UNIVERSITY COLLEGE OF NURSING DENION, TEXAS

DALLAS CENTER 1810 Inwood Road Dallas, Texas 75235

HOUSTON CENTER 1130 M.D. Anderson **Blvd**. Houston, Texas 77025

# AGENCY PERMISSION FOR CONDUCTING STUDY\*

| THE     | Bell County Health Department   |
|---------|---|
| CRANTS  | TO Linda Byers, R.N.  |
| Texas ' | ent enrolled in a program of nursing leading to a Master's Degree at Woman's University, the privilege of its facilities in order to study llowing problem: |
|         | dy of Clients' Perceptions of Reasons For Choosing or Not<br>ing Oral Contraceptives  |
|         |   |
|         |   |
| The co  | nditions 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 .  | Citation 5, 1976 Signature of Agency Personnel  |
| Lina    | la S. Byers, R.N. BSN.  Signature of Faculty Advisor  |

<sup>\*</sup>Will out and sign three copies to be distributed as follows: Original — Student; first copy — agency; second copy — T.W.U. College of Nursing.

# TEXAS WOMAN'S UNIVERSITY COLLEGE OF NURSING

# Consent to Act as a Subject for Research and Investigation:

I have received an oral description of this study, including a fair explanation of the procedures and their purpose, any associated discomforts or risks, and a description of the possible benefits. An offer has been made to me to answer all questions about the study. I understand that my name will not be used in any release of the data and that I am free to withdraw at any time.

| Signature           | Date  |
|---------------------|---|
|                     |   |
|                     |   |
|                     |   |
| Witness             | Date  |
|                     |   |
|                     |   |
|                     |   |
| olaining the Study: |   |
|                     |   |
| Signature           | Date  |
|                     |   |
|                     |   |
| Position            |   |
|                     |   |
|                     | plaining the Study:  t I have fully inform description of the |

APPENDIX B

QUESTIONNAIRE

### KNOWLEDGE AND ATTITUDE QUESTIONNAIRE

This questionnaire is designed to evaluate your knowledge about birth control pills. Please either check the appropriate box or fill in the information in the blanks provided.

| 1.5 | Age                            |                              |
|-----|--------------------------------|------------------------------|
|     | -                              |                              |
|     | Marital Status:                |                              |
|     | (1) // Married (2) // Single ( | 3) //Divorced (4) // Widowed |
| 3.  | Number of children:            |                              |
| 4.  | Occupation:                    |                              |
|     | (1) //Student (2) //Housewif   | e (3) //Other (specify)      |
| 5.  | Religious affiliation:         |                              |
|     | (1) /Protestant (4             | )                            |
|     | (2) Catholic (5                | ) No present affiliation     |
|     | (3) / Jewish                   |                              |
| 6.  | Ethnic group:                  |                              |
|     | (1) Caucasian (3               | Black                        |
|     | (2) / Mexican-American (4      | Other                        |
| 7.  | Years of formal education co   | ompleted:                    |
|     | (1) / Less than 8 years        |                              |
|     | (2) / 8 years (completed gr    | rammar school)               |
|     | (3) 12 years (completed)       | high school)                 |
|     | (4) / 14 years                 |                              |
|     | (5) / 16 years (completed      | college)                     |
|     | (6) / Greater than 16 year     | s                            |
|     |                                |                              |

|     |          |      |                                | , |                    |                   | 13            |               |         |
|-----|----------|------|--------------------------------|---|--------------------|-------------------|---------------|---------------|---------|
| 8.  | Total    | l fa | mily inco                      | me (if st                               | udent,             | parent'           | s income      | •)            |         |
|     | (1)      |      | Less than                      | \$3,000                                 | (4)                | ∠ \$1             | 2,000 to      | \$19,99       | 9       |
|     | (2)      | 口    | \$3,000 to                     | \$6,999                                 | (5)                | ∠ \$2             | 0,000 to      | \$29,99       | 9       |
| 4   | (3)      | 口    | \$7,000 to                     | \$11,999                                | (6)                | ∠ Gr              | eater th      | nan \$30,     | 000     |
| 9.  | Are      | you  | presently                      | using a                                 | birth c            | ontrol            | method?_      | ***           | -       |
|     | If y     | es,  | which one                      | ? /Pil                                  | ls 🗾               | IUD Z             | _<br>/Diaphra | agm           |         |
|     | F        | oam  | Condo                          | om <u>/</u> /Rhy                        | thm _              | /Combin           | ation A       | Other         | •       |
| 10. | What     | rea  | sons do y                      | you have f                              | or choo            | sing th           | nis metho     | od?           |         |
| 11. | Whic     |      | the fol                        | lowing des                              | scribes            | your or           | al cont       | racepti       | -<br>ve |
|     | (1)      | 口    | continuo                       | rth contrously since                    | they v             |                   |               |               | em      |
|     | (2)      | IJ   | used the                       | rth contro<br>m continue<br>ed. (PLE    | ously s            | ince the          | ey were       | first         |         |
|     | (3)      |      | I have u<br>take the           | sed birth m now. (                      | contro             | l pills<br>ANSWER | , but do      | not<br>AND B. | )       |
|     | (4)      | _7   | I have n<br>(PLEASE            | ever used<br>ANSWER GR                  | birth<br>OUP C.)   | control           | pills.        |               |         |
| ,.  | GROU     | JP A |                                |   |                    |                   |               |               |         |
|     | a)<br>b) | How  | many yea<br>many dif<br>taken? | rs have y<br>ferent br                  | ou take<br>ands ha | n them?<br>ve you |               |               |         |
|     | c)       | Do   | you remem                      | nber (with                              | out che<br>e most  | cking)            |               |               |         |
|     | d)       | Is   | recently                       | been usi<br>informati<br>insert)        | ng? (Sp<br>onal fo | lder              |               |               | Not     |
|     | e)       | Ιf   | brand pa                       |   |                    |                   | Yes _         | _No           | Sure    |
|     | f)       |      | read it?                       |   |                    |                   | Yes<br>Yes    |               |         |
|     |          |      |                                |   | 21                 |                   |               |               |         |

|       | GROU     | РВ                |                    |                                 |               |                  |   |             |                |
|-------|----------|-------------------|--------------------|---------------------------------|---------------|------------------|---|-------------|----------------|
|       | a)<br>b) | How man           | y times            | have yo                         | u sto         | pped u           | sing t                                  | he pil      | l?             |
|       |          | tions.)           |                    |                                 |               |                  | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |             | 1405           |
|       |          | i.<br>ii.<br>iii. | No lone            | to have<br>ger desi             | ced c         | dren<br>ontrace  | eption.                                 | Y <u>es</u> | No<br>//<br>// |
|       |          | iv.               | I had              | 's advice<br>undesiral<br>pill. | ole e         | ffects           | from                                    |             |                |
| ٠     |          | <b>v.</b>         | I was              | afraid of                       | the p         | ill.             | .e                                      |             |                |
| *     |          | vi.               | Other              | (specify                        | )             | ·                |   |             |                |
|       | GROU     | IP C              |                    |                                 | *             |                  |   |             |                |
|       | a)       | Why hav           | ve you             | never us                        | ed th         | e pill           | ?                                       |             |                |
|       |          | i.<br>ii.         | I use              | r desire<br>another<br>tion.    |               |                  |   |             | 7              |
|       |          | iii.<br>iv.       | Doctor             | 's advic<br>t religi            |               | oliefe           |   | 4           |                |
|       |          | v.                | The pi             | lls are<br>my healt             | too d         | angero           | us                                      |             |                |
|       |          | vi.               |                    | (specify                        |               |                  | · · · · · ·                             |             |                |
|       | Go       | on, plesently     | ase ans<br>or neve | wer <u>all</u><br>r have t      | quest<br>aken | ions,<br>birth   | even in                                 | you a pills | re not         |
| 12.   |          |                   |                    | about th                        |               |                  |   |             | eceive         |
|       | ls       | it adeq           | uate?              | (1) //Y                         | es            | (2) _            | /No                                     |             | *              |
| 13.   |          |                   |                    | pills e                         |               |                  |   | the fol     | lowing         |
|       |          |                   |                    |                                 | 7             | es               | No                                      | Don't       | know           |
| *     | (1)      | Weigh<br>Diarr    | t gain             |                                 | 4             | 7                | 4                                       | 4           | ,              |
|       | (3)      |                   | of visi            | .on                             |               | 1                |   |             | 7              |
| * * * | (4)      |                   | reath              |                                 | - 2           | 1                | 11                                      |             | _              |
|       | (5)      |                   | ssion              |                                 |               | <del>, _</del> , | 44                                      | 4           | 7              |
|       | (6)      |                   | a in br            | nonat                           | 4             | <del>//</del>    | 4                                       |             | 7              |
|       | (8)      |                   | mal vag            |                                 |               |                  |   | رے ۔        |                |
|       | , -,     |                   | leeding            |                                 | 4             | /                | 4                                       | Ļ           | <u>/</u>       |
|       | (9)      | Tende             | r or so            | re breas                        | sts Z         |                  | L                                       |             | /              |

|     | Can                                    | birth  |   |   | or cause.         |        | 2.5     |      |
|-----|--|--|---|---|-------------------|--------|---------|------|
|     |  |  |   | × .   | Yes               | No     | Don't K | now  |
|     | (1)<br>(2)<br>(3)<br>(4)<br>(5)<br>(6) | Ulcer<br>Pneur<br>Cance<br>Clots   | monia<br>er   | essure  |                   |        |         |      |
| 15. | Can                                    | birth  | control   | pills ca  | use:              |        |         |      |
|     | (1)<br>(2)<br>(3)<br>(4)               | Diff   | aches<br>throat<br>iculty ge  |   |                   |        |         |      |
| *   |  |  | gnant aft<br>t taking   |   |                   | 口      | 口       |      |
| 16. | vid:                                   | ing in   | tant are<br>formation<br>11 questi  | to you  |                   |        |         |      |
|     |  |  | ar quest.   |   | Very              | Fairly |         | -ant |
|     |  |  | ar quest.   |   | Very<br>Important |        |         | tant |
|     | (1)<br>(2)<br>(3)                      | Maga<br>pap<br>Your<br>Book  | zine and<br>er articl<br>doctor<br>let about                                      | news-<br>les<br>t the                                   |                   |        |         | tant |
|     | (2)                                    | Maga<br>pap<br>Your<br>Book<br>pil<br>rec<br>doo   | zine and<br>er articl<br>doctor<br>let about                                      | news-<br>les<br>t the<br>y have<br>om your              |                   |        |         | tant |
|     | (2)<br>(3)<br>(3)<br>(4)<br>(5)<br>(6) | Maga<br>pap<br>Your<br>Book<br>pil<br>rec<br>doo<br>cli<br>Frie<br>Fami<br>Nurs<br>Phar                                    | zine and er articl doctor let about l you may eived fro etor, nurs nic ends ly ee | news-<br>les<br>t the<br>y have<br>om your<br>se, or    |                   |        |         | tant |
|     | (2)<br>(3)<br>(3)<br>(4)<br>(5)        | Maga<br>pap<br>Your<br>Book<br>pil<br>rec<br>doc<br>cli<br>Frie<br>Fami<br>Nurs<br>Phar<br>Pack<br>may<br>ins<br>of<br>pil | zine and er articl doctor let about l you may eived fro tor, nurs nic ends        | news- les the y have on your se, or  rt you und package | Important         |        |         | tant |

| 17. | What do you do when you remember Thursday morning that you have forgotten to take Wednesday's pill?   |
|-----|---|
|     | (1) Take both Wednesday's and Thursday's pill on Thursday and continue taking one pill daily.   |
|     | (2)  Skip Wednesday's pill and continue with Thursday's pill.   |
|     | (3) Take Wednesday's pill on Thursday, Thursday's pill on Friday and continue taking one pill daily.  |
|     | (4)   |
| 18. | If you were taking your pills correctly, how many men-<br>strual periods can you miss before you should stop<br>taking the pill and call your doctor? |
|     |   |
| 19. | State some advantages of using the pill.  |
|     |   |
| 20. | Which of the following statements most closely reflects your feelings about birth control pills and your health?                                      |
|     | (1) They are completely safe.   |
|     | (2) They are fairly safe.   |
|     | (3) / They are fairly dangerous.  |
|     | (4) // They are very dangerous.   |
| 21. | . How effective do you think birth control pills are at preventing unwanted pregnancy?  |
|     | (1)  Very effective   |
|     | (2) // Moderately effective   |
|     | (3) Slightly effective  |
|     |   |
|     | (4) / Not effective at all  |

| 22. | Do you agree or disagree with the following statement?  |
|-----|---|
|     | I believe the benefits of preventing pregnancy by taking the pill outweigh the risk the pill might be to my health. |
|     | Agree Disagree  |
| 23. | What other comments would you like to make about the pill?  |
|     |   |

Adapted from: Fleckenstein, L. et al. 1976. Oral contraceptive patient information. Journal of the American Medical Association. 235: 1331-1336.

Questionnaire designed to obtain information on the use of, knowledge about, and attitudes toward oral contraceptives.

# APPENDIX C

TEACHING METHODOLOGY

#### ORAL CONTRACEPTIVES

#### Class Outline for Patient Education

Rationale: The patient will have enough information available to her to make an informed decision about
whether or not she should use oral contraceptives.

# Principles of family planning:

- 1. An informed client is a more receptive client who responds better to the treatment program outlined with her.
- Voluntary family planning is an important health measure.
- Optimal contraceptive effectiveness is promoted by thoroughly informing patients.
- 4. Information should be available to individuals through mass media and through printed materials.
- Family planning services should be available to every individual.

# Class Outline for Patient Education (continued)

#### Client Objectives:

At the completion of this lesson, the client will:

- State two medical problems which contraindicate oral contraceptive use.
- State the five warning signals of serious trouble.
- 3. List four noncontraceptive benefits that are expected in most women using oral contraceptives.

# Resources for the Teacher

- Hatcher, R.A.; Stewart, G.K.; Guest, F.; Finkelstein, R.; and Godwin, C. 1976. Contraceptive Technology 1976-1977. Irvington Publishers, Inc. New York. \$2.95.
- Mills, Stephanie. 1975. The Joy of Birth Control.

  Emory University Family Planning Program. Box
  26069, 80 Butler St., S.E., Atlanta, Ga. 30303.
  \$1.00.
- The Inside Story. Birth control information written for teenagers. Planned Parenthood Association. Chicago Area. 185 N. Wabash Ave., Chicago, Ill.

### Class Outline

- Clients for class: Those using oral contraceptives or those interested in beginning a contraceptive methodology.
- Class should be limited to ten clients. Five would be preferable.
- Time: This lesson is expected to take twenty minutes.

  Topics could be expanded if more time is available.

The first five minutes will be spent on introduction. The nurse leader will introduce herself and explain her interest in family planning. Each client will introduce herself and explain her interest in or questions about the birth control pill.

The leader will then answer questions in a discussion format eliciting information and ideas from clients.

The following content will be covered in language appropriate to the clients' levels of understanding:

# Class Outline (continued)

- 1. Conditions in which women should not use pills
- 2. Conditions in which women probably should not use pills

(See: Hatcher, p. 41; Mills, p. 18)

- Common side effects of pill use
   (Hatcher, p. 47; Mills, pp. 27-28)
- Serious side effects of pill use
   (Hatcher, pp. 47-48; Mills, p. 28)
- 5. Five symptoms of serious problems (Hatcher, p. 49; Mills, p. 28)
- 6. Good news: Non-contraceptive side benefits (Hatcher, p. 54; Mills, p. 29)
- 7. Use effectiveness rates for oral contraceptives and other methods (Hatcher, included in each chapter on various methods)

Distribute instruction sheets to clients included in this packet.

#### Taking Your Pills

Start your first pack on the first Sunday after your period begins. If you've just had a baby, start your first Pill the Sunday after your baby is one month old. If you've just had an abortion, start your first Pill the first Sunday after the abortion. Swallow one Pill a day until you finish the pack. If you're using a 21-day pack, stop for one week, then start your new pack on Sunday. If you're using a 28-pill pack, begin a new pack immediately.

Use a second method of birth control (such as foam and condoms) during your first month on the Pill. You may not be fully protected by the Pill alone during that time. Keep a second method handy all the time.

Try to associate taking your Pill with some regularly scheduled activity, like going to bed or eating a meal. This may make it easier to remember. Pills work best if you take one about the same time every day in order to keep a constant level of the drug in your system. This is especially important if you have bleeding between periods.

Check the pack each morning to make sure that you took your Pill the day before.

If you miss <u>one</u> Pill, take the forgotten one (yesterday's Pill) as soon as you remember it and today's Pill at the regular time. You probably won't get pregnant.

If you miss two Pills, take two Pills as soon as you remember and two the next day. Here's an example: You forget your Pills on Saturday and Sunday evenings but remember on Monday morning. What to do? Take two Pills on Monday and two on Tuesday. You may have some spotting. Use another means of contraception until you finish that package of Pills.

If you miss three or more Pills, the chances are great that your ovaries will produce an egg (you will ovulate) and that you may get pregnant. So start using a second method of birth control immediately. Throw away your old pack of Pills. Start a new pack of Pills the Sunday after you realize you have missed 3 or more Pills, even if you're bleeding. Use your second method of birth control while you are off Pills AND for the first 2 weeks that you are on your new package of Pills.

If you miss one or more Pills and skip a period, call your doctor or clinic to ask about a pregnancy test.

If you miss no Pills and skip a period, don't worry too much. You may be pregnant, but it is very unlikely. It is common for women taking birth control Pills to miss periods occasionally. If you are worried, call the clinic. Otherwise, you are on fairly safe ground and you can start a new package of pills at the regularly scheduled time.

If you miss two periods, come to the clinic for a pregnancy test right away, even if you have taken your Pills every day right on schedule.

If you have spotting for 2 or more cycles, call the clinic. You may need an appointment.

Get a complete examination once a year, including blood pressure, Pap smear, test for V.D., a breast examination, and an abdominal exam. Call the clinic for an appointment about one month in advance.

WHEN YOU ARE SEEN BY A DOCTOR FOR OTHER PROBLEMS, BE SURE TO MENTION THAT YOU ARE USING BIRTH CONTROL PILLS.