

Appendix 3

APPENDIX 3.

FIELD TESTING OF A SIMPLIFIED PATIENT PACKAGE INSERT FOR COMBINED ORAL CONTRACEPTIVES

1. BACKGROUND

Fifteen million U.S. women are using combined oral contraceptives (OCs or “the Pill”) pills. Each year, 300,000 of those women become pregnant during a month in which they have been taking the Pill. Such high failure rates do not reflect on the quality of the method itself, as the Pill is over 99% effective if taken consistently. The factors determining how safely and effectively women take the pill are complex but knowledge is the essential first step. Too many women do not have enough information or they have the wrong information or they cannot understand what information they do have.

Approximately 20-25% of American women currently using the pill have literacy skills too poor to be able to understand and apply, or even read all of the information in the current PPI. The average American reads below the 8th grade level. The information in the current PPIs are written at a 10th to 12th grade reading level and contain more than 2000 words. The visual presentation makes it difficult to find the information needed and the text dense and wordy.

This project field tested ways to shorten and simplify the patient insert. The field testing was to help insure that any point of information in the patient insert can be found, read and understood by the majority of pill users. In addition, the revised PPI can serve as a model for clinicians to use to help them use clear and simple wording when counseling patients and or developing education materials. The project should result in the PPI being standardized across different brands of pills as well, so women who change brands will find the same information in the same order in their new pill packs.

2. PURPOSE

The Patient Package Insert (PPI) for oral contraceptives is included in all packs of oral contraceptives. The purpose of this project was to field test iterative versions of a revised PPI in order to make the insert easier to read and understand than the current version.

3. DATA COLLECTION

A. Data Collection Methods and Materials

Focus group guidelines were developed to ensure consistency of topics discussed in the two group discussions convened at the beginning of the study. Six interviewers were trained to conduct the one-on-one interviews about specific items of information from the revised PPIs. Interviewers explored each participant's ability to read the information, her opinions about its clarity, and how she would describe the information on each card to a friend. The information from these interviews was combined to create each revision of the PPI.

B. Participant Recruitment

Women who attended the participating study clinics were eligible to be in the study if they met the following criteria: not sterilized or known to be infertile, and not using an IUD. Flyers describing the project were posted at the three participating clinics to encourage patient participation. At each family planning clinic visit, trained project and/or clinic staff introduced the project and screened the women for study enrollment. Informed consent was obtained from each participant.

Minimal personal data were collected from the participants. These data included age, highest grade level completed, current contraceptive method and history of use with oral contraceptives. No name or other identifying information was collected.

C. Location of Study

Three clinics affiliated with the Family Planning Council served as sites for the study: Lankenau Hospital, Wynnewood, PA; Planned Parenthood of Chester County, West Chester, PA; and Temple University School of Medicine, Philadelphia, PA.

4. REVISION PROCESS

A. Conformance to FDA Guidance

The PPI tested was based on the FDA's (draft) Labeling for Healthcare Professionals, published in the July 8, 2000 *Federal Register*. The ultimate version of the PPI, based on the field testing and expert review, is contained in *Appendix I*, with a discussion of differences between the FDA professional labeling and the PPI contained in *Appendix 2* of this submission to the FDA.

B. Field Testing and Expert Review

The process we used to ensure that the information in the PPI is as readable and understandable as possible for *all* oral contraceptive users involved several steps. We conducted two preliminary focus groups, one with adults and one with teens from two family planning clinics. We incorporated their suggestions for content and wording, then sent the resulting draft to medical experts to insure accuracy and to readability experts for their suggestions for simplification. The trained interviewers then conducted the first round of one-on-one interviews with participants. Further revisions were made and again the document was sent to medical and readability experts. This was followed by a second round of one-on-one interviews and then a final round of expert review. Ultimately we tested iterations of the PPI with 97 family planning clients at the three family planning clinics and obtained reviews from a total of 35 expert reviewers (*see Appendix 4*). The resulting document is written at below a 6th grade reading level, has less than 3000 words and is presented in a format that makes the information easier to find, easier to use and easier to follow.

3. HUMAN SUBJECTS

A. Subject Population

The population involved in this study included any client who attended one of the three participating clinics. A total of 97 sexually active women who were not sterilized or using IUDs participated in the project. The population at the three participating family planning clinics in the Philadelphia region is predominantly African American and at or below 125% of the poverty level. One clinic also draws clients from a nearby college population. About one in three clients are under 20 years of age. All clinics receive Title X funding and represent a diversity of agency organizations (e.g. a Planned Parenthood affiliate, and two hospital based clinics, urban, and suburban).

Only women attending family planning clinics were selected for this project because they are representative of reproductive age women with a range of backgrounds and experiences.

B. Potential Risks

No medical risks were involved as a direct result of this project. There were no known psychosocial risks to human subjects except for the remote possibility of evoking sensitive issues related to oral contraceptives or reading ability.

C. Informed Consent Procedures

Designated project recruiters read the informed consent and gave it to each subject to review. The informed consent was written at a 6th-7th grade reading level.

The statement was to ensure:

1. That the information given by the participants was confidential and that no names would be collected or ever be used in any written or verbal communications; and
2. That their participation would be voluntary and, if they chose not to participate, not to continue at any given time or refuse to answer any question, it will not affect any service they may want at any time. Their risks and benefits involved in participating were described in the consent form as was the incentives.

D. Protection of Subjects

No identifying information (name, address, telephone number, patient number, social security number) was collected from any participant. No information on any individual in the project was shared by project staff with any agency.

E. Potential Benefits to Participants

The potential benefits for participants were that by enrolling in the project they would have an opportunity to learn more about oral contraceptives. They were encouraged to contact clinic staff should they have any questions or concerns about their individual needs that might be raised during any interview. They also had the satisfaction of knowing that their participation in this project could help in providing materials that would be easier to read and understand by all women using or thinking about using oral contraceptives.

F. Evaluation of Risks and Benefits

Whereas the risks to the study participants were minimal, the potential benefits of this project were greater. This project should result in the standardization of PPIs across brands of oral contraceptives. The project provided a draft text for the U.S. Food & Drug Administration in their decision to simplify the current version of the oral contraceptive package insert that is difficult to understand.

G. Material Inducements

Each participant received \$20.

4. DURATION OF PROJECT

The project began in May 2000 and ended in December 2000.

5. SPONSORING AGENCY

A. Family Planning Council

The Family Planning Council is a private, non-profit organization. The mission is to ensure access to high-quality, comprehensive reproductive and related health and prevention services to primarily low-income individuals and families. The Council develops, manages, and promotes programs that are innovative, research-based and responsive to women, men and adolescents. The Council is the coordinating Title X agency for 24 agencies that provided services to over 109,000 women in 2000 in Philadelphia and the four adjacent counties.

B. Qualification of Principal Investigators

Linda Potter, Dr.P.H. and Kay Armstrong, MS, were Co-Investigators for this project.

Dr. Potter has extensive experience in the fields of contraceptive use behaviors, literacy and adherence to contraceptive regimens. She previously developed and tested instructions for use of combined OCs, professional and patient labeling for progestin-only Pills; and, most recently, the professional labeling for combined oral contraceptives package inserts, all of which served as the initial draft for the FDA's guidance to the industry.

Ms. Armstrong has been the Director of Research in the Research Department at the Family Planning Council since 1985. She has conducted and supervised research on improving contraceptive services, and clinic and contraceptive compliance and continuation, as well as numerous longitudinal reproductive and sexual health projects.

5. FUNDING

Unrestricted grants were obtained from Wyeth-Ayerst Laboratories, Ortho-McNeil Pharmaceuticals, Inc., and DHHS, OPHS, Region III.