

EXPERT MEETING ON  
ORAL CONTRACEPTIVE NEEDS  
OF DEVELOPING COUNTRIES

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## SUMMARY OF EXPERT MEETING

On March 8, 1984, a group of experts was assembled by The American Public Health Association (APHA) on March 8, 1984 to discuss oral contraceptive (OC) needs of developing countries. The group reviewed current information on OC clinical trial performance, lipid effects, potency/dosage issues, relationship to female reproductive cancers, specific developing country concerns and various programmatic issues.

Particular concern was voiced about the need to try to avoid OC formulation switching in developing country programs since this can have significant adverse effects. Because of logistical difficulties, many developing country programs have difficulty supplying more than one OC. Recommendations for minimizing this continuity problem included the following: 1) providing a single predominant OC for most developing country programs; 2) engaging in multiple-year procurements; and 3) attempting to continue to provide a particular formulation in special circumstances where it has a high proprietary and/or continuity value, (e.g., social marketing programs).

Some 30-35 ug estrogen OCs currently available in the U.S. appear to perform in clinical trials at roughly the same general acceptable level as the 50 ug estrogen OCs. Accordingly, there was a general consensus among the group that a single predominant pill should be selected from among these particular 30-35 ug estrogen OCs. At the same time, it was clearly not the group's intent to recommend limiting OCs provided to developing countries to this particular set. Based on concerns about human variability, contraceptive efficacy, program continuity, and the desires of developing countries themselves, another list of formulations was also considered suitable.

### Comparative Clinical Trials

Dr. Mark Belsey of the World Health Organization (WHO) reported on the results of WHO multi-center, randomized, double-blind clinical trials involving six different oral contraceptive formulations. These included Ovral, Nordette, Noriday 1+50, Norlestrin, Loestrin, and Ovcon-35-like formulations. In general, his data showed no large differences among these pills. There was a higher rate of menstrual problems in the groups using pills with the lowest ethinyl estradiol (EE) content (20 µg) and pills containing the lowest progestin content (400 µg). When different progestins were compared, levonorgestrel (LNG)-containing OCs tended to be

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associated with slightly higher rates of discontinuation because of nausea and vomiting, while norethindrone (NET)-containing OCs tended to be associated with higher rates of discontinuation because of bleeding problems.

Dr. Belsey emphasized that differences among centers in terms of both quality of care and cultural or regional differences in patient characteristics can affect the acceptance of side effects, as well as compliance and discontinuation rates. Therefore, such center variations must be considered in attempting to provide an accurate comparison of several OCs.

Dr. Belsey also suggested that there are differences among individuals in the rate at which contraceptives are metabolized. Furthermore, interactions with other drugs may cause either more rapid or slower hormone metabolism. For some women, a low rate of metabolism of OCs steroids can provide a residual hormone effect that gives more leeway if pills are missed.

Regarding the progestin-only or mini pill, Dr. Belsey voiced the opinion that there is no place for such a pill in programs for nonlactating women unless there is exceedingly close supervision. He cited high rates of ectopic pregnancy associated with the use of mini pills in the WHO study (1.15 per 100 woman years of use). It was recommended that mini pills be used for lactating women only and that this be clearly indicated on the package.

Dr. Pouru Bhiwandiwala of Family Health International (FHI) reported on the results of a series of randomized, comparative clinical trials being carried out by FHI. These studies are currently ongoing, and only four-month data were available. Some of these clinical trials compare standard with low-estrogen pills, whereas others compare several different low-dose pills. The primary data presented related to short-term acceptability as assessed by continuation rates and reason for discontinuation. It was emphasized that center variations make it difficult to draw totally definitive conclusions; however, there were some general findings. Discontinuation rates due to side effects such as headache, nausea, and vomiting were higher in women using standard-dose pills; discontinuation due to menstrual irregularities was more commonly associated with the low-dose pills. In the trials comparing several OCs, at six months there was no significant difference among the pills, with one exception: in a number of studies, the Brevicon-type formulation (30 µg ethinyl estradiol + 0.5 mg norethindrone) had significantly lower continuation rates. Irregular bleeding was the most common reason for discontinuation of this formulation.

Dr. Bhiwandiwalla also reported on a pooled-center study comparing a Norinyl 1+35-type formulation (35 µg ethinyl estradiol 1+ 1 mg norethindrone), a Norinyl 1+50-type formulation (50 µg mestranol + 1 mg norethindrone), and a Lo-Ovral-type formulation (30 µg ethinyl estradiol + 0.3 mg norgestrel). Although somewhat preliminary, these findings indicate no statistically significant differences in discontinuation patterns among the three formulations at four months.

### Lipid Changes

As background, Dr. Daniel Mishel of the University of Southern California noted that elevated cholesterol is associated with increased risk of coronary disease, as are lowered levels of high-density lipoprotein cholesterol (HDL-C) and increased levels of low-density lipoprotein cholesterol (LDL-C). When the cholesterol/HDL-C ratio increases, rates of coronary disease also increase. In the past, various studies have shown that LNG tends to lower HDL-C, while NET has a lesser effect on HDL-C. Currently, a number of small, well-controlled studies are being done to address the issue of the relationship between lipid changes and OC formulations.

The data currently available have not as yet demonstrated any link between induced changes in lipid patterns and increased risk of coronary disease among normal lipidemic individuals. In Dr. Mishel's opinion, any small changes in lipoproteins observed with OC use should not be considered disturbing. Rather, the primary concern with regard to OC use is a thrombotic effect, predominantly caused by the estrogen component. This is of greatest concern among older women who smoke.

Dr. Bruce Stadel of the National Institutes of Health presented an overview of the significance of various lipid fractions in heart disease. He suggested that there are two main issues to be addressed:

- o Effects among current OC users -- These effects are thought to be mainly related to estrogens and primarily mediated by a thrombotic mechanism regulating the growth of clots and the capacity of vessels to respond to clots. There is little or no association of such effects with duration of use. There has been a trend toward using OCs with lower estrogen levels to minimize these cardiovascular effects in current users.

- o Effects of past use and relationship to duration of use -- Some acceleration of atherosclerosis or some other vascular effect may occur with long-term use of OCs. These effects are thought to be associated with progestins.

Studies cited by Dr. Stadel have indicated some detrimental effect of certain OC formulations on lipids, and perhaps ultimately on cardiovascular disease. The Ovral-type formulation (50 µg ethinyl estradiol + 0.5 mg norgestrel) and Norlestrin 2.5/50-type formulation (50 µg ethinyl estradiol + 2.5 mg norethindrone acetate) were identified as having the greatest effect. Dr. Stadel suggested that it should be possible to avoid large effects on lipids by avoiding such formulations.

### Potency/Dose Effects

Drs. Daniel Mishel and Laneta Dorflinger presented data comparing the potencies of the four common progestins found in OCs marketed in the U.S. These are norethindrone (NET), norethindrone acetate (Net-A), ethinyldiol diacetate (EDD), and norgestrel levonorgestrel (NG/LNG). Norgestrel is a 50/50 mixture of levonorgestrel and dextronorgestrel, the inactive isomer.

Progestin potency was summarized from the Greenblatt delay of menses test; the Sawyer-Greenblatt delay of menses test in the presence of two different concentrations of ethinyl estradiol; effects on HDL-cholesterol; effects on LDL-cholesterol; and two studies on glycogen deposition. The Greenblatt test was the potency ranking quoted by Pike et al. (Lancet 1983; ii: 926-929)

It is important to recognize that relative progestin potency is affected by the concentration of estrogen present. Furthermore, there is a variation in individual, species, and end-organ response such that no single testing procedure gives a series of progestin potencies that is necessarily consistent with other rankings. Nevertheless, some rough "rules of thumb" are possible. NET, Net-A, and EDD have relatively similar "potencies." This is to be expected since Net-A, and EDD are metabolized to NET. NG and LNG are generally more potent, with perhaps 5 to 10 times the potency of NET.

Concerns about potency center around factors that predispose women to the risk of potential serious side effects, such as HDL-cholesterol changes and changes in coagulation parameters. In addition, however, it is important to have

sufficient potency for good bleeding patterns. With regard to HDL-cholesterol changes, a progestin content that essentially leaves the HDL/LDL ratio near control values would probably be optimal. Since estrogens have opposing effects to progestins, an appropriate balance of the two should be sought.

### Cancer--Breast, Cervix, Ovary, Endometrium

Dr. George Rubin of the Centers for Disease Control (CDC) summarized the findings of a large National Institutes of Health (NIH)/CDC Cancer and Steroid Hormone Study. The results confirmed those previously reported and were as follows: 1) there was no demonstrable overall relationship between OC use and breast cancer; 2) there is a protective effect of combined OCs on endometrial cancer (after 12 months of use); and 3) there is a protective effect of OC use on ovarian cancer (after 3 months of use).

Following the publication of the study by Dr. Malcolm Pike, et al. in Lancet which suggested a link between the long-term use of "high-progestin" OCs before age 25 and increased risk of breast cancer, the NIH/CDC data were reanalyzed. This re-analysis, together with data from several other studies, was presented to an advisory committee of the Food and Drug Administration in February, 1984. The committee report stated that "after careful review of the paper of Pike et al., plus a number of other studies relevant to oral contraceptive use and breast cancer, the committee concludes that a significant increase in the risk of development of breast cancer has not been demonstrated for any subgroup of oral contraceptive users."

In conclusion, Dr. Rubin noted that neither the CDC nor another study from Boston is consistent with Pike's findings. Moreover, a number of methodological biases, including detection and recall biases, could help explain the Pike data.

### Folate and Cervical Dysplasia

Dr. Stadel discussed the fact that some evidence suggests a possible adverse effect of OC use on the progression of cervical dysplasia. However, conclusions about OC use and cervical cancer are complicated by a number of major methodological problems. These include the fact that pill users have more frequent Pap smears, and that many studies have not controlled for such confounding variables as sexual behavior and smoking. Nevertheless, there is a growing concern

that the evidence may suggest some adverse effect of OCs on the progression of cervical neoplasia. Various studies may be cited, and while each has limitations, taken together they help support this concern. Currently, the WHO is addressing this issue in a large-scale collaborative study involving 37 institutions in 11 countries. Although these data are not yet available, there are some preliminary indications that also may support a raised level of concern.

Dr. Stadel discussed the question of whether OCs affect cervical dysplasia by decreasing the body's levels of folic acid. If so, the dysplastic process could possibly be reversed by oral folic acid supplementation. A small, well designed clinical trial done by Butterworth et al. (Am. J. Clin. Nutrition 35: 73-82, 1982), provides support for this hypothesis. However, results of further studies are needed to provide more definitive conclusions. One such study is currently being conducted by the National Cancer Institute. It is generally agreed that the data presently available indicate some promise for the folic acid approach.

#### Specific Concerns for Developing Countries

Dr. Mark Belsey addressed three particular concerns related to the use of OCs in developing countries: (1) endemic diseases, particularly schistosomiasis and malaria; (2) nutrition; and (3) lactation.

Studies related to schistosomiasis indicated that no significant complications were traceable to OC use. Similarly, OC use appears to be of minimal concern for malaria. There may, however, be some small interactive effect between OC and chloroquin use.

In the area of nutritional effects, Dr. Belsey focused on two items -- glucose tolerance and vitamin deficiency. Again, in both instances the evidence does not indicate any significant concern for OC use.

Finally, in addressing lactation, Dr. Belsey noted the possibility that combined OCs could be counterproductive to the natural contraceptive effect of lactation, since milk supply is reduced and women using OCs might thereby wean their infants earlier. In those cases, discontinuation of OC use could lead to a greater risk of pregnancy. The progestin-only mini pill is preferred for lactating women since it does not interfere with milk production and does not appear to have any adverse effects on infant growth and early development.

Dr. Michael Rosenberg discussed the results of studies conducted by FHI on the Causes of Death to Women of Reproductive Age (RAMOS Studies) in Egypt. These studies to date have gathered data on causes of death for 1,371 women of reproductive age (15 to 50). A preliminary analysis suggests that the use of OCs in a developing country such as Egypt is safer than the alternative, a possible pregnancy.

The leading causes of death of women of reproductive age were circulatory disorders (mostly rheumatic), accounting for 31% of all deaths; complications of pregnancy, childbirth, and the puerperium, accounting for 20% of all deaths; and trauma, accounting for 14% of deaths.

In comparing causes of death for OC users and nonusers, there were no pregnancy-related deaths among users. In fact, contraceptors in general were shown to have significantly lower overall mortality rates. This is probably related to the fact that pregnancy risk in this group is low. In addition, a self-selection bias may contribute to the lower rate since pill users tend to represent a healthier population on the whole. Mortality rates for nonrheumatic circulatory disease were slightly higher among OC users than nonusers; this is consistent with research findings from developed countries.

Dr. Rosenberg also presented an innovative way of quantifying the effects of OC use in terms of life expectancy, calculated according to age at use. These data indicate that differences in life expectancy for known effects are rather small (i.e., a few weeks); the largest difference is among women over age 35.

#### Special Programmatic Considerations--Formulation Switching, Consistency of Supply, Distinctive Packaging

Dr. Alan Rosenfield of Columbia University raised two issues that he believes to be of particular concern. First was the issue of formulation switching and consistency of supply. He was concerned that AID has been switching pills in recent years because of the competitive bidding process. Competitive bidding, however, has also resulted in important cost savings. Nevertheless, Dr. Rosenfield suggested that the programmatic costs of this switching are high. This issue may be partially obviated by the longer-term OC procurements.

The second issue raised by Dr. Rosenfield is the need for some type of distinctive packaging for OCs. While the traditional "Blue Lady" outer packaging is no longer

being used, different formulations are often difficult to distinguish -- for both family planning professionals and their patients. There was a consensus among the participants that different formulations should be distinctly different in appearance (e.g., in color or shape/size).

### AID Procurement Experience

Donald Newman and Anthony Boni of the U.S. Agency for International Development (AID) addressed some issues related to AID's procurement procedures and experience.

AID's purchasing policy has been to procure a standard and a low-dose pill, based primarily on estrogen content. For many years, one-year contracts were awarded, with Syntex receiving the primary contract for about ten years in a row. Recently, the General Services Administration (GSA) has granted preliminary approval for multi-year contracts.

Several procurement issues have arisen in AID's experience. First, there are some problems associated with the distribution of particular pills in certain countries; for example, Lo-Ovral is not registered in many countries. A second point made was that most developing countries cannot handle multiple pill formulations in the system. Finally, it was noted that for competitive bidding, some packaging uniformity is needed, and that this should be considered in addressing the issue of distinctive packaging raised by Dr. Rosenfield.

QUESTIONS ADDRESSED BY THE ATTENDEES OF THE  
EXPERT MEETING ON OC NEEDS OF DEVELOPING COUNTRIES

1. Considering clinical performance and potency/safety concerns, is there a group of combined OC formulations which would be optimal for predominant use in developing country programs? What is the scientific basis for this determination?
2. Are there OCs which are not generally optimal, but would be acceptable? What is the scientific basis for this determination?

With respect to clinical aspects, a number of formulations available in the United States appear to give results that are in the same general range of performance. These include both some 50 microgram estrogen OCs (Norinyl/Ortho-Novum 1+50, Ovral) and some 30-35 microgram estrogen OCs (LoOvral, Nordette, and Norinyl/Ortho-Novum 1+35). There are very limited data available on another set of OCs (Cvcon 50, Demulen, Demulen 1+35, Norlestrin 1/50, and Loestrin 1.5/30); however, on the basis of those data, as well as similarities in formulation to the OCs listed above, this set would also be expected to be in the same general range of acceptable clinical performance.

In contrast, there is reasonably conclusive evidence that the Brevicon/Modicon Formulation (35 ug EF and 0.5 mg NET) does not perform nearly as well clinically. This is particularly true with respect to breakthrough bleeding and resulting discontinuation. The Ovcon-35 formulation is very similar to Brevicon/Modicon and therefore is expected to have similar performance; this is corroborated by side effect data from the WHO six-pill comparative study. The single OC with 20 micrograms of estrogen (Loestrin 1/20) was not believed to be potent enough to give suitable efficacy.

Regarding potency, it was agreed that, all things being equal, it is appropriate to provide the OC with both the lowest estrogen and the lowest progestin potency. Since some 30-35 ug estrogen OCs appear to perform in clinical trials at roughly the same general acceptable level as the 50 ug estrogen OCs, this group can be considered optimal if a single pill is desired for predominant use in developing countries. Although there is no simple viable concept of "progestin potency," these particular OCs (with the possible exception of LoEstrin 1.5/30) also tend to minimize progestin dose.

There is substantial evidence that switching from any formulation to another can cause markedly increased side effects and OC discontinuation. Therefore, continuity on both an individual and program basis is highly important. Because of logistical problems, many programs in developing countries have difficulty supplying more than one OC. Providing a single predominant pill over a long period of time is one way of helping to minimize formulation switching (see below).

There was general support for a single predominant pill. Minimal effective estrogen and progestin dosages were preferred for this purpose. Nevertheless, there were a number of significant reservations about this position, particularly with respect to developing countries:

- o Human variability dictates that there will be no single formulation that is optimum for every woman.
- o In developing countries, particularly because of the serious health risks of pregnancy, perhaps the single most important health consideration is contraceptive efficacy. There is evidence that some women take OCs irregularly. Therefore, a more potent pill, by providing potentially better efficacy if pills are missed, may actually be safer in some instances. Most clinical trials are conducted under better conditions than typically exist in the field and may not adequately reflect this phenomenon.
- o Continuity with existing formulations already in use and found acceptable is extremely important.
- o In providing OCs, one needs to consider the desires of particular developing countries and their programs; specific situations, including drug registration and proprietary concerns, may be of overriding importance.

Based on the discussion summarized above, the following list of formulations was considered optimal as the basis for future selection of a single predominant OC:

<u>Estrogen</u>	<u>Progestin</u>	<u>U.S. Brand Names</u>
35 µg Ethinyl Estradiol	1 mg Norethindrone	Norinyl 1+35, Ortho Novum 1/35
35 µg Ethinyl Estradiol	1 mg Ethynodiol diacetate	Demulen 1/35
30 µg Ethinyl Estradiol	300 µg Norgestrel	LoOvral
30 µg Ethinyl Estradiol	150 µg Levonorgestrel	Nordette
30 µg Ethinyl Estradiol	1.5 mg Norethindrone Acetate*	Loestrin 1.5/30*

\*The inclusion of Loestrin 1.5/30 was conditional upon some positive assessment of its progestin potency in the human as reflected by potential effects on plasma lipids; otherwise to be included in the list below. Such information was not available at the time of the expert meeting.

The following list of formulations was considered suitable:

<u>Estrogen</u>	<u>Progestin</u>	<u>U.S. Brand Names</u>
50 µg Mestranol	1 mg Norethindrone	Norinyl 1+50, Ortho Novum 1/50
50 µg Ethinyl Estradiol	1 mg Norethindrone	Ovcon-50
50 µg Ethinyl Estradiol	500 µg Norgestrel	Ovral
50 µg Ethinyl Estradiol	1 mg Ethynodiol diacetate	Demulen
50 µg Ethinyl Estradiol	1 mg Norethindrone Acetate	Norlestrin 1/50
35 µg Ethinyl Estradiol	0.5 mg Norethindrone	Brevicon, Modicon
35 µg Ethinyl Estradiol	0.4 mg Norethindrone	Ovcon-35

3. Would it be useful to pursue the addition of folate and perhaps other vitamins to the placebo portion of OC cycles? Are there any disadvantages?

While the group believed the information on the potential effect of folate in ameliorating precursor forms of cervical cancer is noteworthy, they felt that an active effort to include folate in the placebo pills would be premature. However, they did endorse pursuing the matter further with experts specifically knowledgeable in this field; they also endorsed continued research in this area.

4. How should concerns about formulation switching best be addressed?

Concerns about formulation switching can be addressed in the following ways:

- o Providing a single predominant OC for most developing country programs.
  - o Engaging in multiple-year procurement agreements so as to provide a consistent formulation for several years.
  - o Alleviating difficulties in the changeover from one OC to another by using existing stocks to phase in the transition in an orderly manner.
  - o Supplying more than one formulation for those programs capable of handling multiple formulations, and where otherwise feasible.
  - o Making every attempt to continue to provide a particular formulation in special circumstances where it has a high proprietary and/or continuity value (e.g., social marketing programs).
5. Is it necessary to have clearly distinctive packaging for different formulations of OCs?

Different formulations should have clearly distinguishable differences in appearance and packaging. However, it was considered acceptable for various formulations to be packaged with the same overall character. Since the mini pill is aimed for use by lactating women in developing countries, it was also recommended that its packaging contain some clear-cut symbol, such as a woman breastfeeding an infant, to indicate this use.

6. Should OC contracts contain explicit provisions for cancellation and/or mutually agreed-upon product adjustments, including formulation changes or addition of vitamins, based on health or programmatic grounds?

The group agreed that significant new medical evidence could indeed arise which would justify such product adjustments. This would be particularly true if multi-year procurements are anticipated. Whether future contracts can or should actually contain such provisions was outside the scope of the expert meeting.

APPENDIX A

Program For  
"Expert Meeting on Oral Contraceptive  
Needs of Developing Countries"

Date: March 8, 1984

Place: American Public Health Association Headquarters  
1501 Fifteenth Street, N.W.  
3rd Floor Conference Room  
Washington, D.C. 20005

9:00	Welcome	Sinding, Shelton
9:20	Comparative Clinical Trials	Belsey, Bhiwandiwala
10:15	Lipid Changes	Mishel, Stadel
11:15	Potency/Dose Effects	Mishel, Dorflinger
12:00	Lunch	
1:00	Cancer - Breast, Cervix, Ovary, Endometrium Folate and Cervical Dysplasia	Rubin, Stadel
2:00	Specific Concerns for Developing Countries	Belsey, Rosenberg
2:45	Special Programmatic Considerations: Formulation Switching, Consistency of Supply, Distinctive Packaging	Rosenfield
3:30	AID Procurement Experience	Newman, Boni
3:45	Discussion  Optimal and acceptable available alternative formulations Specific formulations for special situations Vitamins in placebo pills Multi-year contract Distinctive packaging	
5:00	Formulation of Recommendations	
5:30	Adjournment	

APPENDIX B

ATTENDEES OF THE OC EXPERT MEETING

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Dr. Louise Tyrer  
Vice President for Medical Affairs  
Medical Director/FPIA  
Planned Parenthood Federation  
of America, Inc.  
810 Seventh Avenue  
New York, NY 10019

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Other Attendees

Office of Population  
U.S. Agency for International Development

Steven Sinding, Director  
Duff Gillespie, Deputy Director  
James Shelton, Chief, Research Division  
Jeffrey Spieler, Research Division  
Laneta Dorflinger, Research Division  
Russel Thomsen, Research Division  
Andrew Wiley, Information and Training Division  
Donald Newman, Chief, Commodities and Program Support  
Division  
Anthony Boni, Commodities and Program Support Division  
Karen Peake, Commodities and Program Support Division

Asia Bureau  
U.S. Agency for International Development

David Oot, Technical Resources Division  
Edward Muniak, Technical Resources Division

U.S. A.I.D./Mexico

Sam Taylor, Population Officer

Government Services Administration

Janet Cyphers

F.P.I.A.

McKinley Coffman

A.P.H.A.

~~Myrna Seidman  
Dwyn Dithmer  
Susi Kessler, M.D.  
Rona Briere, Rapporteur~~