

PN -ACA-627

Family Health International

**Technical Advisory Committee
for
Contraceptive Technology
and Family Planning Research**

June 19-20, 1996

**Radisson Governors Inn
Research Triangle Park, North Carolina**

Summary Agenda

Wednesday, June 19, 1996

Time	Topic	Speaker
8:30 - 9:00	1. Welcome a. Introduction of New Committee Members b. Strategic Planning Groups Review	King
9:00 - 10:00	2. Minutes and Reports: a. TAC Meeting, June 28-29, 1995 b. Summary of TAC Recommendations, 1993-1995 c. Update on Hormonal Contraceptives and STDs d. Expert Meeting on Latex Condom Human Use Studies	Grimes Lewis Cates Joanis
10:15 - 11:45	3. Technical Discussion: IUDs	Shain <i>(Moderator)</i>
1:00 - 2:30	4. Technical Discussion: Barrier Methods	Harper <i>(Moderator)</i>
2:45 - 4:15	5. Technical Discussion: Strategies to Improve Contraceptive Continuation	Rooks <i>(Moderator)</i>
4:15 - 5:00	6. Review of Other FHI Programs a. Mellon Projects b. AIDSCAP c. International Master Contract for HIV Network for Efficacy Trials d. Women's Studies Project	McKay Schellstede Cates Williamson
5:30 - 8:00	7. Reception and Dinner	Bowden <i>(Coordinator)</i>

Thursday, June 20, 1996

Time	Topic	Speaker
8:30 - 10:30	8. Technical Discussion: New Directions in Contraceptive Technology—Implications for FHI's Future	Grimes <i>(Moderator)</i>
10:45 - 11:30	9. Other Business	King/Bowden
11:30	10. Adjournment	Grimes

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Agenda Item 1 – Welcome

Wednesday, 8:30-9:00	Background Materials	Action from TAC	Speaker
a. Introduction of New Committee Members	1996 Advisory Committee Membership List	None	King
b. Strategic Planning Groups Review	Summary and Membership List	None	King

Family Health International
Technical Advisory Committee
for
Contraceptive Technology and Family Planning Research
1995 - 1996 Roster

- | | | | |
|------|---|------|--|
| 1996 | <p>Obstetrics-Gynecology/Reproductive Biology
 Deborah J. Anderson, PhD
 Associate Professor
 Obstetrics, Gynecology & Reproductive Biology
 Harvard Medical School
 Director, Fearing Research Laboratory
 250 Longwood Avenue-SGMB 204
 Boston, Massachusetts 02115
 617/432-0841; 617/432-2190
 FAX: 617/432-0359</p> | 1997 | <p>Social Science
 Amy O. Tsui, PhD
 Project Director, The Evaluation Project
 Carolina Population Center
 University of North Carolina
 CB #8120, University Square
 Chapel Hill, North Carolina 27516
 919/966-1737; FAX 919/966-2361</p> |
| 1996 | <p>Endocrinology/Reproductive Biology
 Gregorio Pérez-Palacios, MD
 Director General de Salud Reproductiva
 Secretaría de Salud
 Insurgentes Sur 1397, 6to Piso
 Insurgentes Mixcoac
 03920 México, DF, México
 52-5-598-5816; FAX: 598-6528</p> | 1998 | <p>Obstetrics-Gynecology
 Soledad Díaz, MD
 Consultorio de Planificación Familiar
 Instituto Chileno de Medicina Reproductiva
 José Ramón Guitierrez 295
 Depto. 3, Correo 22, Casilla 96
 Santiago, Chile
 56-2-632-1988; 56-2-222-5887; FAX: 56-2-633-6204</p> |
| 1997 | <p>Obstetrics-Gynecology/Preventive Medicine
 David A. Grimes, MD (Chair)
 Professor and Vice Chair
 Department of Obstetrics, Gynecology
 & Reproductive Sciences
 University of California, San Francisco
 1001 Potrero Avenue
 San Francisco, California 94110
 415/206-8358; FAX: 415/206-3112</p> | 1998 | <p>Obstetrics-Gynecology
 Mahmoud F. Fathalla, MD
 Senior Advisor
 Biomedical & Reproductive Health
 Research & Training
 The Rockefeller Foundation
 Post Office Box 30
 Assiut, Egypt
 20-88-334820; FAX: 20-88-337333</p> |
| 1997 | <p>Reproductive Biology
 Michael J. K. Harper, PhD, ScD
 Senior Scientist
 CONRAD Program
 1611 North Kent Street, Suite 806
 Arlington, Virginia 22209
 703/276-4022; FAX: 703/524-4770</p> | | <p>New York City Address:
 Senior Advisor
 The Rockefeller Foundation
 420 Fifth Avenue
 New York, New York 10018-2702
 212-869-8500; FAX: 212/764-3468; 398-1858</p> |
| 1997 | <p>Consumer Advocate
 Judy Norsigian
 Co-director
 The Boston Women's Health Book Collective
 240A Elm Street
 Somerville, Massachusetts 02144
 617/625-0271; FAX: 617/625-0294</p> | 1998 | <p>Medical Anthropology
 Cynthia Myntti, PhD, MPH
 Hubert Humphrey Institute
 130 Humphrey Center
 301 19th Avenue South
 Minneapolis, Minnesota 55455
 612/625-0576; FAX: 612/625-6351</p> |
| 1997 | <p>Epidemiology
 Judith P. Rooks, CNM, MS, MPH
 Associate, Pacific Institute for Women's Health
 2706 SW English Court
 Portland, Oregon 97201
 503/243-2253; FAX: 503/248-4671</p> | 1998 | <p>Economics
 James Trussell, PhD
 Office of Population Research
 The Woodrow Wilson School
 of Public & International Affairs
 Department of Economics
 Princeton University
 21 Prospect Avenue
 Princeton, New Jersey 08544
 609/258-4946; FAX: 609/258-1418</p> |
| 1997 | <p>Social Science
 Rochelle N. Shain, PhD
 Professor, Department of Obstetrics/Gynecology
 The University of Texas
 Health Science Center
 7703 Floyd Curl Drive
 San Antonio, Texas 78284
 210/567-5051; FAX: 210/567-4963</p> | | |

FHI STRATEGIC PLANNING GROUPS IN REPRODUCTIVE HEALTH RESEARCH AND EVALUATION

Purposes/Objectives:

- **Information Gathering.** Each group will be responsible for seeking current information on planned and ongoing work of relevance to the group, both within FHI and by other organizations, and assessing whether there is an appropriate role for FHI in this work.
- **Priority Setting.** Each group will be responsible for the development and review of major program strategies, and will set priorities for the implementation of those strategies by FHI divisions.
- **Resource Identification.** Each group will have leadership responsibility for assuring that funding is available to carry out the program strategies identified as priority. Individuals in the group will be expected to play significant roles in fundraising for specific program activities, where needed, and to coordinate with FHI's corporate fundraising efforts.
- **Implementation Team Identification.** As program strategy priorities are set, and resources secured for their implementation, the group will work with division directors to appoint program or project implementation teams to assure that priority activities are carried out. Implementation teams may be interdivisional, depending on the nature of the work. The teams will report back to the group on a regular basis on progress, accomplishments, and problems encountered in implementation.
- **Information Sharing.** Individual members of the group will have a dual responsibility for sharing information from their divisions on activities and programs, as well as conveying information from the groups back to their divisions.
- **Peer Review.** The groups will serve as an internal peer review mechanism not only for strategies proposed for new initiatives, but also as a forum for presentation and peer review of research reports and papers from completed studies.

Logistics:

Each Strategic Planning Group will meet monthly, beginning in February, at a regularly scheduled time for not more than two hours. Once a month, all the Chairs will meet to share information and coordinate on key strategic issues. Once established and functioning, consideration will be given to holding the meetings every two months, rather than monthly.

Membership on the groups will be assigned, will be interdepartmental, and will not exceed 10 people, including the Chair and Group Manager.

An agenda for each meeting will be shared with all Division Directors at least one week prior to the meeting. Suggestions for the agenda are welcome from all FHI staff, but must be received at least two days prior to circulation of the agenda. Individuals who are not assigned to the group may attend the meeting at the invitation or with the permission of the Chair/Co-Chair. Minutes will be prepared with action items and due dates, and will be shared with all Division Directors within two days after the meetings. Group Managers will be responsible for producing and distributing the agendas and minutes (with input of Chair), and for monitoring implementation of action items. (An agenda item for each group for the first meeting will be to organize a topic for the June Contraceptive Technology TAC meeting.)

Strategic Planning Groups for calendar year 1996 will be as follows, with a division of labor defined by the conceptual framework for FHI Reproductive Health Research and Evaluation:

New Leads in Reproductive Health Technologies (Contraceptives, STD drugs and diagnostics, HIV vaccines and therapies, etc. This group will focus on technology development, evaluation and approval, including early identification of potential consumer concerns, public education issues, etc.)

Alan Corbin, Chair
Diane Campen, Co-Chair
Gina Dallabetta
Randy Dunson
Paul Feldblum
Beth Robinson
David Sokal
Nancy Williamson
Julia Welch, Group Manager

Existing Technologies in Reproductive Health (This group will focus on technology introduction and evaluation, including pre-introductory/introductory trials, other research on existing technologies to answer key programmatic questions, including acceptability, use dynamics, and compliance with a broad range of reproductive health technologies, as well as research utilization and dissemination of information to optimize appropriate use of existing technologies)

JoAnn Lewis, Chair
Laneta Dorflinger, Co-Chair
Lynda Cole
Rosalie Dominik
Carol Joanis
Sheila Mitchell
Susan Palmore
Roberto Rivera
Susan McIntyre, Group Manager

Reproductive Health Programs (Costs, quality of care, benefits and risks of technologies, health interventions, training, etc., in a broad range of reproductive health programs)

Peter Lamptey, Chair
Ward Cates, Co-Chair
Judith Fortney
Barbara Janowitz
Anne Phillips
Beth Preble
Cindy Waszak
Nancy Lamson, Group Manager

Agenda Item 2 -- Minutes and Reports			
Wednesday, 9:00-10:00	Background Materials	Action from TAC	Speaker
a. TAC Meeting, June 28-29, 1995	Minutes	Approval	Grimes
b. Summary of TAC Recommendations, 1993-1995	Summary Report	None	Lewis
c. Update on Hormonal Contraceptives and STDs	1. Dear Colleague letter, 5/7/96 2. NIH Agenda for Meeting on Steroid Contraceptives and HIV Transmission Agenda, 6/6/96	None	Cates
c. Expert Meeting on Latex Condom Human Use Studies	None	None	Joanis

TAC topics in the previous 3 years will be reviewed and FHI's subsequent actions will be summarized. Two topics--IUDs and Barrier Methods--will be agenda items for the 1996 TAC. The issues highlighted between 1993 and 1995 were:

- 1993
 - Barriers and Spermicides
 - Methodologies for Contraceptive Introduction
- 1994
 - Barriers and Spermicides
 - Nonsurgical Sterilization
 - Improving Provider Practices
- 1995
 - IUD Research
 - Contraception for Young Adults
 - Contraceptive Issues in Integration of Family Planning/Reproductive Health

FAMILY HEALTH INTERNATIONAL

**Technical Advisory Committee
for Contraceptive Technology
and Family Planning Research**

**Minutes
Annual Meeting
June 28-29, 1995**

**Radisson Governors Inn
Research Triangle Park, North Carolina**

PARTICIPANTS

TAC Representatives

Dr. Deborah J. Anderson
Dr. Vicente Diaz-Sanchez (for Dr. Gregoria Pérez-Palacios)
Dr. William Droegemueller
Dr. David A. Grimes
Dr. Michael J.K. Harper
Ms. Judith P. Rooks
Dr. Rochelle N. Shain (Chair Pro Tem)
Dr. Amy O. Tsui

USAID/W Representatives

Ms. Sarah Davis
Dr. Marjorie Horn
Dr. Erin T. McNeill
Dr. James D. Shelton

Cooperating Agency Representatives

Dr. Pamela Stratton, NIH (NICHD)
Dr. Rosemarie Thau, Population Council
Dr. Francis T.G. Webb, WHO/HRP

FDA Representative

Dr. Ridgely Bennett

FHI Board of Directors Representative

Dr. Ursula Lachnit-Fixson

Mellon Fellow

Dr. Jin-xun Xu

FHI Staff

Barbara Barnett
 Sandra Bowden
 Diane Campen
 Eli Carter
 Willard Cates, Jr.
 Lynda Cole
 Alan Corbin
 Joseph De-Graft-Johnson
 Rosalie Dominik
 Laneta Dorflinger
 Randy Dunson
 Gaston Farr
 Paul Feldblum
 Judith Fortney
 Laurie Fox
 Lucinda Glover
 Lucy Harber
 Karen Hardee
 David Hubacher
 Barbara Janowitz
 Theodore King

Nancy Lamson
 JoAnn Lewis
 Tapani Luukkainen
 Charles Morrison
 Liisa Ogburn
 Susan Palmore
 Marie Porter
 Linda Potter
 Howard Price
 Vana Pruett
 Roberto Rivera
 William Schellstede
 David Sokal
 John Stanback
 Evelyn Studer
 Cynthia Waszak
 Michael Welsh
 Nancy Williamson
 Tom Wilson III
 Emelita de Leon Wong

TAC Members Absent

Linda Anderson
 Gregorio Pérez-Palacios
 Judy Norsigian

Ted King opened the meeting by welcoming members, observers, and guests. He introduced Rochelle Shain as Chair Pro Tem, replacing Linda Atkinson, who was unable to attend. Following introductions around the table, Rochelle Shain asked the Committee members to review the June 29-30, 1994, meeting minutes; they were accepted as written.

Reports

Lynda Cole presented highlights from the Experts' Meeting "Understanding STDs and the Public Health Approaches to Their Control: The Appropriate Role of Family Planning Programs." At the request of the U.S. Agency for International Development (USAID), the meeting was convened in Rosslyn, Virginia, by FHI on December 7, 1994. More than 100 participants representing various organizations with an interest in family planning and reproductive health attended the 1-day meeting, which provided a basic understanding of STD prevention, diagnosis, and treatment issues affecting family planning programs. Topics covered included basic principles of STD transmission and control; general issues and constraints regarding the public health approach; behavior change lessons learned from

STD/HIV prevention programs; messages for women at risk because of partner behavior; and the importance of evaluation. More specific information resulting from this meeting is located in agenda (pages 39-71).

Roberto Rivera provided an overview of "New Frontiers in Male Contraception," the theme for the Mellon Reproductive Biology Centers' Meeting, co-sponsored by FHI and The Mellon Foundation and held April 23-26, 1995, in Durham, North Carolina. This meeting focused on selected areas of male reproductive biology and the possibilities each offers for novel contraceptive approaches. Eighty participants attended this meeting representing a diverse group of basic and clinical reproductive scientists from developed and developing countries. Also included in this group were postgraduates and junior faculty from the Reproductive Biology Centers and their international "twinning" centers, as well as contraceptive development researchers, social scientists whose work focuses on contraceptive and family planning issues, and women's reproductive health advocates. A series of plenary presentations on the major aspects of male reproductive biology and contraception included a keynote address by James Trussell entitled "The Cost-effectiveness of Contraception." These initial presentations served as a foundation for discussions on subsequent days when working groups and special interest groups reviewed and assessed several topics. These included 1) control of testicular function, 2) control of post-testicular function, 3) current status of hormonal methods of male contraception, 4) current status of male immunocontraception, 5) prevalence and acceptability of male contraception, and 6) women's views of male contraception. A copy of the published proceedings is filed with agenda.

Progress Reports

The following updates were presented:

- Contraceptive Technology Update modules - Susan Palmore
- The Bellagio meeting on emergency contraception - JoAnn Lewis
- Mellon-sponsored projects - Roberto Rivera
- Research and development initiatives - Alan Corbin

Summaries of these updates are available upon request.

Program Review

Contraceptive Technology, Family Planning Research - Ted King

Ted King directed the group's attention to the materials provided in the agenda (pages 189-208), and briefly reviewed the ongoing activities and the workplan priorities for FY 1995. He also commended the interdivisional working groups for their collaborative work in addressing the complex issues that FHI confronts. He announced that FHI is exploring the possibility of establishing an office in La Paz, Boliva, similar to those in Kenya and Nepal, to provide assistance for FHI's research programs supported by both the contraceptive technology/family planning research and women's studies project cooperative agreements.

AIDSCAP - Bill Schellstede

AIDCAP, now into its fourth year of implementation of a 5-year program funded by the USAID/Office of Health, has developed large-scale HIV-AIDS prevention programs in 30 countries (15 priority/15 associate) across three continents. The Project encompasses three major strategies to reduce the sexual transmission of HIV-AIDS in Africa, Asia, Latin America and the Caribbean through: 1) a communications program designed to promote changes of high-risk behavior; 2) a condom distribution program for the prevention of STD transmission, including HIV; and 3) an STD prevention and control program to promote access to, and improve the quality of, STD diagnosis and treatment services.

The fundamental purpose is to provide expertise and technical assistance to targeted developing countries, based upon field assessments and resource availability, to develop and strengthen the capacity of these countries to manage a national level HIV prevention program. Institutional strengthening to ensure the sustainability of AIDS prevention services is a major commitment of the AIDSCAP Project. More than 225 subprojects have been implemented by governmental and indigenous nongovernmental organizations.

Support and assistance for the AIDSCAP Project requires an extensive, multi-leveled and well-coordinated management system. Since 1993/1994, AIDSCAP has devoted attention on increasing effectiveness of three main strategies: 1) strengthen capacity building, 2) actively seeking feedback from the field, and 3) disseminating lessons learned through the AIDSCAP experience. Three major initiatives were introduced within the past year: 1) the AIDSCAP Women's Initiative, 2) the Refugee/Displaced Persons Program, and 3) AIDS Care and Management.

The AIDSCAP Project is under the direction of Dr. Peter Lampthey. The work program is overseen by an independent Technical Advisory Group.

International Master Contract for HIV Network for Prevention Trials - Ward Cates

In early 1993, NIH (National Institute for Allergy and Infectious Disease) announced a competition to develop a research infrastructure to implement large-scale HIV vaccine efficacy trials. With both domestic and international components, the infrastructure would allow the clinical trials to begin as soon as candidate vaccines were approved. NIH has labeled this infrastructure the HIV Network for Prevention Trials (HIVNET). FHI submitted a proposal to be the International Master Contractor (IMC) and was awarded the contract in September 1993.

Between October 1993 and December 1994, FHI organized its internal staff, developed background materials, and solicited proposals from international HIV research centers. Subcontracts were awarded to cover two main research objectives: 1) Preparatory AIDS Vaccine Evaluation Studies (Part A) to document HIV seroincidence in a high-risk cohort appropriate for enrollment in future HIV vaccine trials. The Part A cohort studies also will help elucidate biologic and behavioral cofactors of HIV transmission under conditions which would occur during a prototype vaccine efficacy trial. These conditions

include counseling in safer behaviors, promotion of condom use, exchange of clean needles, and treatment of STDs. In addition, serum samples acquired and stored during Part A studies will be evaluated to determine antigenic variability of HIV and early markers of HIV infection; and 2) Non-Vaccine Preventive Intervention Trials (Part B) to evaluate HIV prevention approaches other than vaccines. The Part B intervention trials also will help delineate educational needs associated with obtaining fully informed, consensual participation in a placebo-controlled, HIV vaccine efficacy trial. Both of these research designs will provide valuable information for future HIV prevention efforts, which can be used both internationally by FHI's AIDSCAP and domestically by FHI's U.S. AIDS Initiative.

Participation through the IMC in the HIVNET team allows FHI to play a central role in HIV prevention research. Results from ongoing USAID-funded FHI research in HIV prevention can be directly communicated to HIVNET for consideration in the design and implementation of future clinical trials. FHI's global leadership in such areas as condom and spermicide research, barrier method acceptability, evaluation of the integration of STD/family planning services, and analysis of policy effects of HIV interventions will help the HIVNET stay abreast of the latest-breaking prevention science. Likewise, information gained by FHI through its collaboration within the international HIVNET team will help us to stay at the cutting edge of HIV prevention knowledge. Thus, the key FHI HIV preventive organizations, AIDSCAP and the U.S. AIDS Initiative, can be in a position to apply the most current and effective methods of HIV prevention, internationally and domestically.

Women's Studies Project - Nancy Williamson

The Women's Studies Project, under a 5-year cooperative agreement from the Office of Population of the U.S. Agency for International Development, is exploring the impact of family planning on women's lives. The purposes are to 1) support social and behavioral science research on immediate/long-term consequences for women of family planning programs and methods; 2) help improve family planning and related reproductive health policies and programs through increased knowledge of needs and perspectives of women; and 3) foster inclusion of women's perspectives in all of FHI's research.

Research program development is underway in the emphasis countries: Philippines, Brazil, Indonesia, Egypt, Bolivia, and Zimbabwe, with Jamaica and Mali as associate countries. Secondary analyses have been supported on data from Nigeria, the Philippines, Bangladesh, and Malaysia. In each of the emphasis countries, there are many research-related activities including In-Country Advisory Committees. Among the in-house activities are the development of a core questionnaire and preparation of working papers and resource materials. There are also many information dissemination efforts, including electronic distribution of findings.

Technical Discussion: IUDs

Tapani Luukkainen and Laneta Dorflinger presented background information on IUD and levonorgestrel IUD research, respectively. While IUD contraception remains one of the most efficacious and cost-effective contraceptive methods, IUD use has experienced a marked

decline in recent years for various reasons. Recently, however, family planning policymakers have shown a renewed interest and emphasis in the use of IUD contraception.

In consideration of an approach to demonstrate the advantage and correct use of IUD contraception and in reply to FHI's three technical questions, the TAC offered the following guidance:

- FHI should carry out research to evaluate **immediate post-abortion IUD insertion** (for example, a randomized comparison with NORPLANT®) and research on **postpartum IUD insertion** (i.e., 4-6 weeks non-lactating women and 6-10 weeks during lactation) and the integration with maternal/child health services (i.e., immunizations of newborns).

Jim Shelton commented that the TAC recommendations would parallel USAID/W priorities: 1) postabortal contraception, 2) integrating family planning counseling at 6- to 10-week postpartum visit when newborns receive immunizations, and 3) promoting breastfeeding.

The TAC discussion proceeded to the advantages of the levonorgestrel (LNg) IUD (LevoNova, Leiras Pharmaceuticals), marketed in Europe but not approved in the United States. A progestin-only device, the LNg IUD has demonstrated excellent efficacy, long duration of action (5+ years), minimal bleeding and pain, reduced pelvic inflammatory disease (PID) and endometritis, minimal failures, and contraceptive reversibility. An important non-contraceptive health benefit is reduced menstrual bleeding (i.e., potential alternative to hysterectomies in pre- and perimenopausal women).

During discussions on the issue, David Grimes recommended that FHI aggressively pursue the levonorgestrel IUD. He stated that the current copper and LNg IUD are so good that they should be considered reversible forms of sterilization rather than reversible forms of contraception; their efficacy rivals that of tubal sterilization. The Centers for Disease Control and Prevention will release the CREST data in September 1995, which will show higher than expected failure rates for sterilization methods. This will add more support for use of a device such as the LNg IUD. He also mentioned that the issue of acceptance is a thorny one. The Ortho annual surveys revealed that IUDs have a poor image among U.S. women, except among those who use them. IUD users have higher satisfaction with their contraceptive method than do users of all other methods. We should think of the levonorgestrel IUD as an intrauterine hormone delivery system. The issues that stand in our way are sociological and legal, and less biomedical. Women (and clinicians) hold obsolete and incorrect views about IUD safety and efficacy. In a study in San Diego County, the threat of litigation was shown to be the single largest deterrent to physicians using IUDs in their practices. This is a non-issue, since neither physicians nor manufacturers are being sued at present. However, the perception still prevails. The levonorgestrel IUD looks superb, and women need another IUD option (i.e., vis-à-vis TCu 380A).

Extensive discussion ensued on our knowledge of the potential effect of the LNg IUD on HIV transmission. Deborah Anderson concurred with the group that the LNg IUD data demonstrated superb efficacy; however, she stated that more basic scientific research on the three conventional IUDs (medicated, non-medicated, and progestin-containing) should be conducted to validate or refute: 1) viral shedding in the endometrium, 2) the antimicrobial properties of copper IUDs, 3) the enhanced immunological effects of progestin-only IUDs on the genital tract, and 4) the health effect on the epithelium. In addition, two essential LNg IUD research issues that should be investigated are: 1) cervical mucus as a hostile host to sperm to determine the mechanism of action, and 2) PID.

According to Jim Shelton, the LNg IUD has two limiting factors--product cost and insufficient validation of the PID question. It was noted that USAID/W is considering support of the Contraceptive Research and Development Program (CONRAD) for a generic model of the LNg IUD; however, this should not impede FHI's IUD research on the LevoNova. Obtaining FDA approval for a generic model of the LNg IUD would be an arduous undertaking and product development would be expensive. Frank Webb commented that WHO has a large IUD study underway that includes the LevoNova; whether PID was addressed in this study is unknown.

The Committee offered the following guidance:

- Thoroughly review studies of LNg IUD research and possible effect on PID.
- Design an LNg IUD study for a population at moderate risk of PID.
- Design a small study to evaluate viral shedding in HIV-positive women.

Nancy Williamson recommended studying the LNg IUD in Third World women who would be highly motivated candidates for female sterilization, but in settings where the skills and resources are in short supply. David Grimes recommended conducting the needed IUD research in highly motivated IUD-use populations, such as Hispanics. To address the various issues discussed and to design an IUD program strategy, Laneta Dorflinger recommended that an FHI working group be formed. Jim Shelton mentioned that an LNg IUD experts meeting would convene within 3 months.

Contraception for Young Adults

With half of the world's population under the age of 25 years, and with the continuing drop in age at first sexual intercourse, a compelling challenge exists to address contraception for young adults (10-25 years of age). From the reproductive health perspective, sex education, family planning choices, and counseling should be available for youth. While barriers to conducting research in a young population (particularly below age 18) appear formidable ethically, legally, socially, and culturally, they are not insurmountable.

Discussions following presentations by Cynthia Waszak (general background) and Roberto Rivera (factors related to use of specific methods), as well as Vicente Diaz-Sanchez (meeting the special needs of youth), provided several ideas as FHI sets research priorities for the next 5 years:

- Fundamental reproductive education, fertility awareness, and counseling are critical interventions which could be improved through biomedical and acceptability research. For example, expectations and the tolerance level of side effects are important factors.
- Factors such as educational status, sexual behavior, characteristics or bleeding patterns, maternal and infant mortality and morbidity, knowledge of reproductive health, and decision-making/problem-solving skills need to be assessed.
- Contraceptive methods, such as Depo-Provera, NORPLANT, and IUDs, have shown acceptance among young consumers. However, safety issues and long-term effects in youth (particularly those below age 18) have not been validated.
- The combined monthly injectable would likely be a minimal risk contraceptive for youth.
- Emergency contraception, postabortion contraception, social marketing, and linkage with family planning services should be investigated (The Netherlands has concrete data on the integration of emergency contraception with contraceptive services).
- Choice-driven contraceptive models rather than method-driven models should be investigated.
- Contraceptive acceptability and use dynamics should be investigated.
- More data are needed on the economic cost/consequences of unwanted pregnancy versus the prevention of pregnancy.
- Research is needed for this age group on cost of service delivery, cultural biases of providers, perceptions of menstrual patterns (particularly amenorrhea) by non-users and users of contraceptives.

It was noted that when designing research studies involving young adults, particular attention must be paid to: 1) differences in biological, socio-demographic and cultural characteristics, each must be addressed individually; 2) physiological differences in growth and development between ages 12 and 19; 3) biomedical (safety/efficacy) and programmatic issues; and 4) barriers, compliance problems, and "power" relations within this age group. Tapani Luukkainen commented that sex education coupled with availability of contraceptives and counseling has resulted in low pregnancy rates among Scandinavian youth.

The Committee recommended the following priorities:

- Biomedical and programmatic (acceptability) contraceptive studies (menstrual pattern perceptions/side effects tolerance level), postabortion contraception, and the availability of emergency contraception (evaluation of provider attitudes).
- Choice-driven study design (use dynamics method to method).
- Safety/efficacy of contraceptive methods for ages 20 to 25 years.
- Outcomes/benefits of two FHI adolescent longitudinal studies.

Materials Laboratory

The group adjourned to the Meridian facility for a tour of the laboratory followed by dinner at the Headquarters facility.

The Committee was re-convened by Rochelle Shain on June 29 at the Governors Inn.

Contraceptive Issues in Integration of Family Planning and Reproductive Health

Karen Hardee discussed the general issues involved in integrating family planning and other reproductive health services. She stressed the implications of the 1994 International Conference on Population Development (Cairo, Egypt), which encouraged the use of the term "reproductive health" beyond contraceptive services. She presented the results of her survey which determined what package of services countries have begun to offer as part of more comprehensive reproductive health packages. Ward Cates then focused on the challenges of integrating a specific service, STD/HIV prevention, into traditional family planning settings. He discussed a variety of FHI research activities, including 1) evaluation of improved methods (slip-on condoms, new delivery systems for spermicide); 2) anatomic impact of particular contraceptives (oral contraceptives and cervical ectopy, spermicides and cervical lesions); 3) etiologic effects of contraceptives on STD/HIV (nonoxynol-9/STD/HIV); 4) circumstances in which to encourage dual methods versus a dual purpose methods (clinical trials of factors affecting consistent condom use); and 5) effects of family planning/STD service integration (impact of counseling for STD prevention on family planning services).

Amy Tsui discussed the emerging consensus definition of reproductive health based on her work with the Institute of Medicine's Panel on Reproductive Health. Core elements of reproductive health include 1) consensual sex free from coercion, 2) avoidance of unplanned pregnancies, and 3) avoidance of reproductive tract infections. She suggested using a term "contrafection" to describe STD/HIV prophylactic methods, providing semantics similar to the term "contraception." She discussed the gender implications of integrating STD services, which would include greater proportions of males in traditional family planning settings. Finally, given resource limitations, she discussed the necessity of choosing the most cost

effective approaches to service integration; this may involve a greater emphasis on contraceptives which serve the dual purpose of protecting against unplanned pregnancy and reproductive tract infections.

A free-wheeling exchange of ideas ensued, exceeding FHI's expectations. While the eventual outcome served to generate useful research concepts, the broad nature of the themes diverted focus from specific research topics and/or answers to the three technical questions posed to the TAC. Nonetheless, several main issues emerged:

1. *What reproductive health services do women most want added to family planning? What services don't they want. Similarly, what services do they need?*

The Committee and observers agreed that each country represented a uniquely different situation. While family planning services would provide the core of reproductive health services, the most crucial additions to this core would be STD/HIV prevention, post-abortion care (including providing contraceptive services), and breastfeeding. Given limited resources, most countries do not need or want services that involve tertiary infertility care, cancer treatment, or extensive counseling for sexual fulfillment. The evolving Mexican health system, which has fused family planning services into other reproductive health activities, presented a potential opportunity to allow an FHI evaluation of this "natural experiment." In addition, the impact of adding contraceptive services to facilities providing primarily STD diagnosis and treatment needs to be evaluated; outcome variables would include the effect on both recurrent STD and unintended pregnancies.

2. *How will adding other reproductive health services affect acceptance and continuation of specific methods among typical family planning populations?*

Discussion on this topic was more limited. Discussants realized that variation occurred among the types of primary contraceptives emphasized, as well as the impact of suggesting additional barrier methods (to prevent STD) to complement a primary contraceptive more effective against unplanned pregnancy. Participants emphasized that the full spectrum of non-contraceptive health benefits (including STD and cancer prevention) should be taken into consideration when recommending specific family planning methods. Policy level implications occur when the prevalence of a particular condition (e.g., HIV) is high enough that the non-contraceptive advantages of a particular method (e.g., condoms) would meet the population's primary health needs. FHI was urged to address research questions involving the effects of new contraceptive methods on a variety of health conditions, not only on pregnancy prevention, but also on STDs, anemia, and cancers as well. Moreover, the need for additional research on factors affecting the acceptability of barrier methods should be undertaken. Creative designs to ferret out the differences between emphasizing dual contraceptive methods or relying on barriers as a dual purpose method are essential to allow comparative research among different international settings.

3. *How will adding other reproductive health services change the nature of populations using family planning services? Will this lead to an emphasis on different contraceptive methods?*

Service expansion has potential for changing the client populations. Participants felt that an evolution of the typical family planning population from a predominance of women to one that was more gender balanced would be favorable. It would allow additional counseling regarding condom use directly to men by family planning providers. In addition, if contraceptive services could be added to existing STD clinics, the nature of the high-risk population attending these clinics would expand contraceptive availability to such hard-to-reach clientele as commercial sex workers. Key research questions involve the impact of a more gender balanced clinic population on clients' acceptance and use of female-oriented contraceptive methods. Another question is what impact this would have on clinic staff behaviors and training needs. Moreover, an "emergency STD prophylactic" (similar to emergency contraception) should be investigated. The less than perfect, albeit moderately protective, methods of post-coital urination and post-coital douching should be evaluated for their impact on both STD and unintended pregnancy. Finally, pilot studies to evaluate the feasibility of these integrated reproductive health programs in developing countries need to be undertaken so that empiric data are available to address the theoretical advantages to the client.

Date and Site of 1996 Meeting

The 1996 annual meeting of the Technical Advisory Committee will be held at the Radisson Governors Inn, Research Triangle Park, North Carolina, on Thursday, June 6, and Friday, June 7.

Adjournment

Prior to adjourning the meeting, Ted King expressed his gratitude to all the participants for their exemplary efforts in helping to define FHI's research priorities for the future.

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**FHI's Response to Recommendations
Made by
Technical Advisory Committee
1993 - 1995**

Introduction

The annual meeting of the Technical Advisory Committee provides a forum for discussion and recommendations of technical issues considered when strategically planning the direction of FHI's contraceptive technology and family planning research program. We have prepared a summary of issues and recommendations addressed during the past three meetings, 1993-1995.

The summary provides a history of issues considered and an update of the action that subsequently impacted on the recommendations. Issues are organized by topic, beginning with those first addressed in 1993 and ending with those discussed at the 1995 meeting. The recommendations, which were extracted from the meeting minutes, have been identified by the year in which they were made and are highlighted as box text. In addition, following each recommendation is a brief, bullet-form summary of actions taken, including notes on results obtained from research that addressed the issues and recommendations.

This overview is intended both: 1) to illustrate the overall value and importance of the recommendations, and 2) to suggest ideas for how the Committee can best provide technical guidance to FHI's program. Your comments on its usefulness and suggestions for improvement will be appreciated.

Barriers and Spermicides: Contraceptive Safety and Efficacy

'93 Recommendation: A comparative study of the thermoplastic and latex condoms for the prevention of pregnancy should assume a high priority.

- Study protocols for both a comparative breakage and slippage study and a comparative contraceptive efficacy trial have been developed.
- In July 1995, the U.S. Food and Drug Administration released its draft "Testing Guidance for Condoms Made From New Materials" document, requiring specific types of clinical trials in order to support premarketing applications. FHI's draft study protocols closely parallel the requirements set forth in the 1995 FDA guidance.
- Due to iterative design and process development circumstances, FHI's thermoplastic condom will not be ready for human-use clinical investigation until late this year when FHI plans to initiate a comparative efficacy trial of FHI's slip-on condom and latex condom, with a nested breakage and slippage component.

'93 Recommendation: A comparative study of spermicidal film (C-film) versus spermicidal foaming tablets for the prevention of pregnancy should also be pursued. This was given only slightly less priority than the comparative condom study, mentioned above.

- In January 1995, the USFDA issued a draft "Guidance for Development of Vaginal Contraceptive Drugs" which made FHI's spermicidal research even more timely and important. An FHI draft protocol for a

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comparative study of the vaginal contraceptive film (VCF) versus foaming tablets, already drafted, was further amended to take into account the new guidance.

- In September 1995, FHI initiated a comparative clinical trial of contraceptive efficacy VCF and Conceptrol in 8 clinics in Mexico, Guatemala, Ecuador, Ghana, and Tucson, AZ. The plan is to enroll 720 women over the course of one year, with each woman to be followed for 28 weeks. As of April 1996, 354 participants were enrolled.

'93 Recommendation: A study of whether or not plastic condoms produce more or less irritation than do latex condoms should assume a lower priority than the two studies mentioned above.

- A protocol for such a study has not been developed for several reasons, including its lower priority and the difficulty in fielding such a study until the new condom had undergone sufficient testing to assure that the condom could potentially provide protection against STDs and HIV.
- In 1994, however, FHI conducted a Phase I Safety study of the roll-on polyurethane condom prototype. Among 50 low-risk, protected couples who used the new condoms for a total of 517 intercourse acts, only two cases of irritation were observed (one female, one male). These were determined by the investigator to be mild, possibly related, non-serious adverse events.

'93 Recommendation: A study of the Gynaseal diaphragm tampon should assume the lowest priority, when compared to the other barrier/spermicide studies noted above.

- Given the generally negative comments and low priority that was assigned to this device by the TAC, clinical studies have not been pursued to this point in time.

Barriers and Spermicides: STDs and Prophylactic Effectiveness

'93 Recommendation: A clinical study to measure the difference between the efficacy of condoms used alone versus condoms used with a separate spermicidal preparation would require such a large sample that the feasibility of such a study was judged to be poor.

- There was consensus that a study comparing the *contraceptive effectiveness* of plain condoms and spermicidal condoms would be prohibitively large.
- FHI did, however, conduct a study of the prophylactic effectiveness of condoms with spermicides versus those without spermicides. The outcome measures were cervical gonococcal and chlamydial infections. Data collection is complete; analysis will be done in 1996.

'93 Recommendation: The Committee considered FHI's strategy of assessing barrier products for efficacy first against gonorrhea and chlamydia infection and secondarily against HIV as entirely appropriate; though they noted there may be situations when the strategy should be reversed.

- It is now well understood that use of vaginal spermicides reduces the risk of cervical infections, but controversy persists about the effect of spermicide products on HIV risk. FHI is conducting a study of N-9 film use and the incidence of HIV infection. This study is supported by funding from NIH.

'93 Recommendations: In the opinion of the Committee, the barrier methods to receive priority testing for STD protection should be: 1) male latex condoms versus male plastic condoms, and 2) female plastic condoms versus male condoms.

- We have not yet tested the protective effect of plastic condoms against STD. Only recently has a plastic condom become available. We will consider testing that product and other plastic condoms.
- FHI has not yet conducted a female condom prophylaxis study; some work has been done by WHO and NICHD on this topic. FHI has begun to develop a proposal for a female condom prophylaxis study, but it will be costly and other donors must be identified to join USAID, perhaps including the manufacturer in providing full support for this study. A straight comparison of the female condom and the male condom will be technically difficult, however.

'94 Recommendation: Due to chemical compound limitations, the Committee strongly advocated more research on the female condom in the prevention of HIV and other STDs; also re-use of the device should be evaluated.

- As noted directly above, FHI has not conducted a female condom prophylaxis study; some work has been done by WHO and NICHD on this topic. FHI has begun to develop a proposal for a female condom prophylaxis, but the study will be costly.
- FHI is studying the re-use of Reality®. A study involving testing of physical integrity of the device after a single use has been completed. There was no evidence of loss of physical integrity after one use.
- A multiple re-use study is planned to take place following a microbiologic study. The microbiologic study is evaluating the residual bacterial contamination after a single use and after cleaning with water.

'94 Recommendation: Following a presentation describing an *in vitro* approach to measure the dissolution times of spermicides as well as to present FHI's preliminary findings concerning the efficacy of povidone iodine against the papillomavirus, the Committee noted limitations of the *in vitro* method for testing spermicidal dissolution. Research methodology should be designed to move experimental products from *in vitro* testing to *in vivo*.

- Following the TAC meeting, USAID requested that FHI stop work in this area.

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'94 Recommendation: When asked whether FHI should study new products, such as Advantage 24—described as a long-acting vaginal N-9 product—or povidone iodine, despite its problems, as the latter seems to be effective against HPV (human papillomavirus) whereas N-9 is not, the Committee did not advocate clinical research in the prevention of HPV at this time. Note was made of the epidemiologic data that support a certain degree of protection of currently available barrier contraceptives against cervical cancer.

- Despite the TAC's lukewarm advice, USAID expressed interest in this area, and some additional work has been pursued.
- A 1995 FHI article in *Sexually Transmitted Diseases* reports that betadine inhibits HPV *in vivo*; a 1995 letter to the editor of *AJPH* also addressed priorities for vaginal microbicide research. NIAID has agreed to support a pilot study of several potential microbicides/spermicides using an animal model of papillomavirus infection which was developed with NIH funding. FHI is also presently collaborating with NIAID and laboratory researchers to coordinate further development of an animal model that could be used to screen agents for activity against papillomavirus.

'94 Recommendation: Explore gramicidin as a vaginal microbicide for HIV prevention.

- Further information was gathered on gramicidin and discussions were held with CONRAD to arrange for testing in their screening program.
- Based on this testing, gramicidin's efficacy against HIV was considered to be poor. Subsequently, FHI has not pursued additional research on this compound.

'94 Recommendation: The Committee recommended that the research and development of spermicidal and microbicial agents should include clinical evaluations of both efficacy endpoints (contraceptive and STD prevention); reliance upon the monograph regulatory process should be avoided.

- FHI agrees and is currently conducting a clinical trial of VCF and Conceptrol foaming tablets looking at contraceptive efficacy (noted earlier). In addition, we are conducting a study to evaluate the effectiveness of VCF in preventing HIV transmission.

Barriers and Spermicides: Behavioral Research and Program Issues

'93 Recommendation: The Committee suggested that barrier method use among current users of other methods (dual method use) and the impact of partner's contraceptive behavior on the use of barrier methods by men were the most important questions and could be designed as one study. Longitudinal research was suggested as one strategy.

- In 1995, FHI sponsored a six-month dual method longitudinal study in Texas among OC users at increased risk of STDs (N=183). This study found that OC users provided with two barrier methods (male condoms and VCF) used a barrier method more often than those provided with condoms only. Dual-method use increased from 18% to 26% of total acts. Data were collected to help evaluate the impact of barrier use on OC compliance; those results are currently being analyzed.

- In a second dual-method study, female clients at two family planning clinics in Jamaica were interviewed to evaluate prevalence and correlates of dual-methods use; these same clients were interviewed about their assessment of their own risks and tested for STDs to determine methods for identifying family clients at increased risk of STD. Preliminary findings indicate 18% of those interviewed used a condom in addition to their primary contraceptive method at least once in the month prior to the study. Roughly 25% of those interviewed tested positive for at least one STD. Further analysis of this study is ongoing.
- A third dual-method study, similar to the one in Jamaica, has just been initiated in Kenya with the Family Planning Association of Kenya.

'94 Recommendation: Asked to comment on the design of a study intended to assist in latex condom quality assurance decisions, the Committee expressed concern over the complex study design and the measurement of an unusually large number of parameters.

- FHI has decided not to further develop the original protocol to assess latex condom lab parameters and human use performance as discussed.
- Instead, a new concept proposal was drafted and reviewed by FHI staff as well as a panel of outside experts. An Expert Meeting was convened May 3, 1996 at FHI to further advise on protocol issues which will adequately address the objectives of USAID. At that meeting, it was decided smaller studies of latex condoms would yield better results than the previously proposed multi-year study. The suggested studies in order of priority are: 1) a study of lubricants (types, formulation, volume and placement); 2) condom size and shape; 3) condom pre-stress and fatigue; 4) plain vs. reservoir tip; and 5) condom thickness profiles.

'94 Recommendation: The inclusion of more diverse groups in condom breakage studies and the investigation of breakage during anal intercourse was recommended by the Committee.

- Many of FHI's studies have taken into account younger participants as well as more culturally diverse populations.
- A study in Brazil of condom breakage among participants practicing anal intercourse has passed PHSC review and is scheduled to be initiated later this year.

'93 Recommendation: In considering the pros and cons of adding STD services to family planning services, and whether or not FHI should consider an intervention study to assess the impact, the Committee suggested it might be better to start with a naturalistic observation of family planning facilities where STD services had been added rather than an intervention study.

- In 1995, FHI and the Salvadoran Demographic Association (SDA) undertook a retrospective study of STD service integration in its San Salvador clinic. Data sources included service and laboratory statistics, interviews with key clinic and laboratory staff, and a database of 3900 clinic records of clients treated for STDs and family planning during the integration period (1992-1994).

Users of gynecology services increased steadily, while growth in new Maternal and Child Health (MCH) clients and acceptors of female sterilization was flat. Among new users of temporary family planning methods, visits declined every year. Likewise, STD visits, after reaching a peak in 1992, declined sharply in 1993 and again in 1994. In the case of STD visits, apparent declines may be due to changes in how visits were reported.

The study showed that it is feasible to fully integrate services which attract different types of clients. But our approach did not allow us to make solid conclusions about the impact of integration on other program services or on staff productivity. The effects of multiple external factors—including changes in program emphasis, funding, prices, and location—are difficult if not impossible to disentangle.

'93 Recommendation: A relevant question to address is whether the contribution of family planning will be greater if the focus is on educational intervention rather than STD treatment.

- Although FHI has not conducted studies specifically to address this question, the STD Risk and Dual Method Use study conducted in Jamaica in 1995 may provide relevant information. The study was conducted at two clinics, one of which initiated an HIV prevention intervention in 1993. Comparisons of the levels of perceived HIV/STD risk and use of condoms to prevent STD and STD rates at each clinic will give us an idea about the effect of the educational intervention. A report is expected this fiscal year.

'95 Recommendations: Service expansion into other areas of reproductive health such as STD prevention has potential for changing the client populations. In this regard, key research questions involve the impact of a more gender-balanced clinic population on clients' acceptance and use of female-oriented contraceptive methods as well as on clinic staff behaviors and training needs.

- In the FHI study conducted with the Salvadoran Demographic Association, some of these issues were explored. For example, results showed that "high risk" clients, adolescents and men can share the waiting room with traditional family planning clientele.
- Furthermore, providers assumed STD service provision without undo stress. In fact, they enjoy the offering of additional services. However, in that case, just a few clinicians were selected to be trained.

'95 Recommendations: An "emergency STD prophylactic" (similar to emergency contraception) should be investigated.

- FHI has not tested an emergency STD prophylactic.

Methodologies for Contraceptive Introduction

'93 Recommendation: The Rapid Feedback Research approach, as presented to the Committee, should not be applied as a substitute for clinical research of experimental contraceptive methods, according to the Committee. The new methodology would be appropriate, however, in the introduction of USFDA-approved contraceptive methods and in assessing efficacy rates based on programmatic use.

- Since the TAC meeting in 1993, FHI has not used the specific methodology of Rapid Feedback Research although it has conducted programmatic research (rather than controlled clinical trials) to assist in the introduction of Norplant and DMPA into country programs.

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Nonsurgical Sterilization

'94 Recommendation: Design the next animal study for iodine research based on previous studies, but fully define the parameters to eliminate previous design features which led to failure. Specifically: a) conduct preliminary test of the retrograde approach, using dye to visualize the path of the formulation; b) use mature pigs; c) minimize peritoneal spillage by using a media viscosity solution; d) consider developing a solid formulation (eg, pellets) to place directly into the uterus; and e) publish the results of the expanded animal study.

- Because there were stability problems with the iodine formulation, further animal studies were put on hold until a new formulation could be developed.
- The Materials Technology Development Division developed several formulations, with the objective of better stability, which were to be tested in animals.
- A Strategy paper was prepared entitled "Nonsurgical Sterilization: A Review of Recent Research and Identification of New Approaches for Further Consideration." A presentation was made to USAID, CONRAD and several other agencies in early April 1996 in Arlington. Various drug and non-drug approaches in both females and males were discussed but no definitive decision was made. It was agreed that vigilance be maintained in this general area.
- FHI believes that alternatives to an iodine-based formulation should be considered.
- With the closure of FHI's Materials Technology Division, any further formulation work would be done by outside sources.

'94 Recommendation: The committee recommended considering an additional human study to determine feasibility of administering iodine to women using a radiopaque, but inert, solution equiviscous to that of the proposed iodine-containing formulation.

- Because of the issues described above, no clinical testing of an iodine-containing formulation could be implemented.

'94 Recommendations: Given the value of a nonsurgical female sterilization method for developing countries, FHI should move forward with the toxicology and carcinogenicity research on quinacrine. While noting that available data on quinacrine are encouraging, but basic safety and efficacy data are insufficient, it was recommended an animal carcinogenicity study should be conducted as soon as possible.

- FHI had convened a toxicology panel in early 1994 to provide guidance and recommendations.
- FHI subsequently sponsored four initial genetic toxicity studies. The results of three of four studies were positive. The Ames mutagenicity assay, mouse lymphoma mutagenesis assay, and mammalian cytogenetic assay tests were positive. The micronucleus cytogenic assay was negative.
- In addition, we obtained estimates for the cost of a rodent carcinogenicity and have tried unsuccessfully to obtain funding for this study. The estimate that the necessary new animal studies and formulation work could take four years and about \$3.5 million to complete, has prompted the decision that FHI will not proceed.

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'94 Recommendation: The sample size of the planned long-term prospective study of quinacrine in Vietnam should be reviewed and possibly enlarged; results may be eligible to supplement a New Drug Application to the USFDA.

- The sample size of the Vietnam study was reviewed, and subsequently enlarged. It will now be possible to obtain a better estimate of the risk of ectopic pregnancy by comparing rates in three groups: those who had received one insertion of quinacrine, those who had received two insertions of quinacrine, and an IUD control group.
- The first analysis of data from this study is expected by mid-1997.

'94 Recommendation: Other caustic candidates should be screened as potential sclerosing agents; a single application would be ideal. The goal should be for 95+ percent efficacy.

- At USAID's request, FHI has recently completed a review of other possible agents for a nonsurgical method. The results of this review were discussed with USAID, CONRAD and AVSC staff on April 8, 1996.
- FHI will prepare a summary of the discussion in order to define further work in this area.

'94 Recommendations: Regulatory approval should be obtained for any further clinical trials of quinacrine. At the same time, international ethical/medical standards should be respected. When FHI is ready to clinically test its best regimen, the following issues should be addressed: a) dose and number of administrations; and b) delivery system and insertion method. Given lower efficacy compared to surgical sterilization (informed consent issue), consideration should be given to renaming the method inasmuch as "sterilization" implies permanency.

- Given the lack of funding for needed preclinical studies, FHI is not planning to proceed with the further development of this method.

Improving Provider Practices

'94 Recommendation: In responding to what activities FHI could best undertake to improve provider practices and reduce unnecessary obstacles to the provision of contraceptive methods, FHI was encouraged to provide contraceptive-related training and education on quality of care issues to health providers.

- Over the past three years, FHI has designed and implemented numerous educational and training activities in Asia, Africa, the former Soviet Union, the Caribbean and Latin America which promoted and addressed quality of care issues for a variety of public and private sector family planning service providers (nurses, midwives, and physicians).
- These activities include, but are not limited to, FHI's CTU Module Series on specific methods, issue of *Network on Quality of Care*, regional conferences on maximizing access and quality (MAQ), and national-level trainings and continuing education programs for specific service provider groups.

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Risk/Benefits Model

'94 Recommendation: It is important for health providers to receive the recommendations and guidelines which are generated at the policy level. Linked to this recommendation is the importance of understanding how women weigh the benefits or risks of various contraceptives. This is a neglected research area that should be given priority.

- FHI has been engaged in several activities which respond to this recommendation. Instructional modules designed to provide accurate and updated information to health providers on the safety and use of several methods of contraception have been developed and distributed.
- In addition, FHI, as part of the USAID Technical Guidance Working Group (TGWG), has developed oral contraceptive and injectable checklists for use by Community Based Service (CBS) workers based on the WHO Medical Eligibility Criteria for initiating and continuing contraceptive methods.
- FHI has also been a major contributor to the development of Volume II of the Recommendations for Updating Selected Practices in Contraceptive Use.
- The Women's Studies Division has included several questions about women's perceptions of the risks and benefits of contraceptives into their core questionnaire and other instruments. In-depth interviews in the Philippines queried the perceptions of risks associated with family planning methods, as well as the impact of family planning on quality of life.

'94 Recommendation: It was noted women will risk an unsafe abortion. Therefore, it is important to understand the perception of the risks associated with illegal abortion, particularly in view of how women perceive the importance of their future fertility.

- Research on the perception of risk associated with abortion has not been conducted due to competing priorities.

'94 Recommendation: Contraceptive method costs should be incorporated into the risk perception research model.

- FHI has begun to investigate the availability and quality of cost data in developing countries in order to integrate this into risk/benefit models. The data needs are substantial to conduct these analysis, and there is some skepticism as to the availability of appropriate data.

'94 Recommendation: In responding to whether FHI should expand its modeling efforts to enhance or adapt existing decision trees for use in developing countries, the Committee voiced the opinion that a computer algorithm was considered an impractical approach to guide the contraceptive decision process in Third World settings. It was also noted that contraceptive compliance and continuation could be enhanced through improved provider counseling. A study design that would focus on influential factors in women's contraceptive choices should be considered.

- FHI has not pursued work on computer algorithms to guide the contraceptive decision process.
- Research on the impact of provider counseling on compliance and continuation is being considered in a study of oral contraceptive compliance.

IUD Research

'94 Recommendations: The Committee was asked for suggestions to guide data analysis for IUD research where FHI's results from previous studies indicated women with more frequent follow-up visits have more problems diagnosed than women with fewer visits. In an effort to avoid an inherent bias, complicated by a tendency for providers to over-diagnose and prescribe, the following comments were offered: a) create an output variable to describe severity of symptoms; b) check the censoring of data because of loss to analysis (differential loss to follow-up in the experimental groups may affect results); and c) information on a more definitive outcome event, such as hospitalization, would help the analysis.

- In the analysis of the Mexico IUD data, which was the focus of the above discussion, the Committee's three suggestions were incorporated into the analysis.
- An output variable was created to summarize severity of symptoms according to the seriousness of the resulting medical intervention. Palliative treatments (e.g. analgesics) were contrasted with more serious medical interventions (e.g. use of antibiotics) which described more severe health problems.
- A life-table analysis was undertaken to account for censoring of data. The results showed that the rate of serious medical interventions was still higher among women in the 4-visit scheme compared to women in the 2-visit scheme.
- In order to reduce further the possible impact of differential loss to follow-up, the data would need to be analyzed using statistical simulations; this may be pursued at a later date.
- FHI attempted to supplement the study results with additional data from the hospitals' patient records; however, the task proved to be too complicated to recover the needed information.

'95 Recommendation: FHI should carry out research to evaluate immediate postabortal IUD insertion (for example, a randomized comparison with NORPLANT®); postpartum IUD insertion; and the integration of IUD insertion with maternal/child health services (i.e., immunizations of newborns).

- While the recommended areas of research are ones in which FHI has great interest—and in the case of postpartum IUDs, has previously invested considerable resources—competing priorities for time and resources over the last year have been such that studies in these areas have not yet been planned.

'95 Recommendation: It was recommended that FHI aggressively pursue activities on the LNG IUD and that we should think of this IUD as an intrauterine hormone delivery system. The Committee offered the following guidance: a) that FHI thoroughly review studies of LNG IUD research and possible effect on PID; b) design a LNG IUD study for a population at moderate risk of PID; and c) design a small study to evaluate viral shedding in HIV-positive women.

- FHI staff have been working to design a clinical trial to evaluate the possible protective effect of the LNG IUD on PID. The literature has been thoroughly reviewed, and a variety of design issues related to evaluating the LNG IUD in a population at moderate risk of PID have been considered. The required sample size and study duration to ensure sufficient cases of PID to determine a statistical difference, indicates that cost is likely to be a significant issue.
- Of note, Dr. Grimes mentioned that we should think of the LNG IUD as an intrauterine hormonal delivery system, i.e. just another way of delivering hormones. This consideration focused us on the question of whether the proper comparison group in a study of the LNG IUD and PID should be another IUD or another hormonal method like Norplant® contraceptive implants? Particulars of the study design and other relevant issues are discussed in detail in the 1996 background documents provided to the Committee.

- FHI staff have begun drafting a protocol to study PID rates in women using the LNG IUD versus the TCu 380A IUD. Although the size, duration and cost of the study make it a daunting prospect, we will continue to develop this project and will begin contacting donors and the LNG manufacturer for support to implement such a study.

Another essential LNG IUD research issue that should be investigated is "cervical mucus as a hostile host to sperm to determine the mechanism of action."

- We have not specifically designed a study related to the suggestion to evaluate the action of the LNG IUD on cervical mucus. Some data exist from other investigators which suggest that cervical mucus production is reduced by the LNG IUD and that water content of mucus is changed thereby inhibiting sperm passage. One might consider further evaluation of this topic nested within the PID study of this device which is addressed above.

'95 Recommendations: The Committee concurred that the LNG IUD data demonstrated superb efficacy; however, more basic scientific research on the three conventional IUDs should be conducted to validate or refute: a) viral shedding in the endometrium; b) the antimicrobial properties of copper IUDs; c) the enhanced immunological effects of progestin-only IUDs on the genital tract; and d) the health effect on the epithelium.

- A study is being carried out in Kenya to compare short-term complications following insertion of TCu 380A IUDs among HIV-infected and HIV-uninfected women.
- As part of this study, HIV viral shedding at the cervix is being compared at 4 months post-insertion with shedding before insertion among 156 HIV-infected women. The qualitative measure of HIV viral shedding by PCR analysis will provide evidence on whether insertion of a copper IUD among HIV-infected women influences their infectiousness to sexual partners.
- Studies to address suggestions 2, 3 and 4 of Dr. Anderson have not yet been developed.

Contraception for Young Adults

'95 Recommendation: Asked to recommend key research topics relating to contraception for young adults, the Committee included the following: a) biomedical and programmatic (acceptability) contraceptive studies (menstrual pattern perceptions/side effects tolerance level), b) postabortion contraception, and c) the availability of emergency contraception (evaluation of provider attitudes).

- FHI has done several new studies to improve access to contraceptive methods for young adults, including studies to better understand the knowledge and needs of young adults. In addition, FHI has worked with health care providers to find ways to improve their access to services and contraceptive methods.
- In 1996, FHI completed a study in Dakar, Senegal to evaluate access to family planning information and services among young adults. A household survey was conducted and interviews were completed with 1,973 young single and married women and 936 young single men. A mystery client study was also conducted to examine the attitudes of clinic personnel when providing services to young adults. The results indicated gaps in knowledge of family planning methods and reproductive health, as well as numerous service delivery obstacles. As an illustration of the latter, none of the mystery clients who requested a contraceptive method received one.

- With money from USAID and the Rockefeller Foundation, FHI plans to implement a descriptive study to understand the context of illegally induced abortions among young adults in Côte d'Ivoire. The overall goal of the study will be to develop postabortion family planning services for young adults. Data collection should be completed by the end of 1996.

'95 Recommendation: Further evaluate the safety/efficacy of contraceptive methods for women ages 20 to 25 years.

- A research proposal for a three-year, multicenter longitudinal study on the use of Depo-Provera and bone growth in females under age 20 was submitted to NICHD in February, 1995. The proposal was not funded but was revised based on NIH reviewers' comments and resubmitted in November 1995. The resubmitted proposal was again not funded; FHI will not pursue this further.
- FHI has initiated a case-control study in Mexico to determine whether IUD use among women increases their risk of developing tubal infertility. It is expected that a sizable proportion of women in this study will be under 26 years of age.

'95 Recommendation: The outcomes/benefits of two FHI adolescent longitudinal studies also deserve priority.

- Two adolescent longitudinal studies, one in Jamaica and one in Brazil, were implemented through the Women's Studies Division. Both studies are currently ongoing.
- With the Women's Centre in Jamaica, FHI is evaluating a project which aims to delay first pregnancy among high-risk adolescents through improved self-esteem, decision-making skills and knowledge of sexuality issues. Data collection should be completed in June, 1997. Preliminary analysis of data collected in September 1995, found sexual activity among adolescents in the study population (ages 11 to 13) is vastly different for girls and boys. Whereas, only 8% of girls report having had sex, 64% percent of boys report they have. Reported use of contraception at first intercourse, on the other hand, was higher among sexually active girls (49%) than boys (38%).
- A second longitudinal study has been implemented in Fortaleza, Brazil to examine the social and behavioral consequences of pregnancy for two groups of adolescents aged 11-18, who have sought medical attention at a major teaching hospital. The first group is composed of pregnant teens seeking prenatal care and the second groups consists of teens who have undergone incomplete abortion and are seeking treatment. Data collection will be complete in 1998.

Contraceptive Issues in Integration of Family Planning and Reproductive Health

'95 Recommendations: In terms of integration issues, the Committee noted that while family planning services would provide the core of reproductive health services, the most crucial additions to this core would be STD/HIV prevention, post abortion care (including providing contraceptive services), and breastfeeding. The impact of adding contraceptive services to facilities providing primarily STD diagnosis and treatment needs to be evaluated; outcome variables would include the effect on both recurrent STD and unintended pregnancies.

- In 1994, FHI had already begun to implement a Situational Analysis in the Dominican Republic. In addition to family planning, this particular analysis assessed STD and MCH service provision at family planning sites throughout the country. Although clients were not specifically asked about additional services they might prefer, results indicate that family planning clients are generally satisfied with staff and services. Most staff have received some training and have begun to provide some level of STD prevention and treatment services—although quality and supplies are irregular.
- STD prevalence data among family planning populations are lacking in the Dominican Republic. Nevertheless, in the Situational Analysis, more than half of the clinical providers estimate a moderately high combined STD prevalence (between 2% and 25%) among their family planning clients. Their claim is supported by data collected by the HIV Sentinel Surveillance project: among low risk antenatal clients between 1991 and 1993, HIV seroprevalence ranged from 0.3% to 1.2% in three Dominican cities.
- Preliminary results of another, previously mentioned, Jamaican study to assess STD risk and dual method use among 800 family planning clients revealed relatively high STD rates: 11.4% chlamydia, 2.2% gonorrhea, 5.8% syphilis. All clients and staff expressed great satisfaction with the additional clinical benefit provided during the study.

'95 Recommendations: FHI was urged to address research questions involving the effects of new contraceptive methods on a variety of health conditions, not only on pregnancy prevention, but also on STDs, anemia, and cancers as well.

- As noted by the description of FHI's on-going and recently completed barrier and spermicide studies, we have increasingly conducted research which jointly addressed issues of STDs and pregnancy prevention.
- Since 1995, we have not undertaken studies of new contraceptive methods which specifically address anemia. A study to assess the effect of Depo-Provera on bone metabolism was submitted (and rejected) by NIH.
- FHI staff are investigating the association between vasectomy and prostate cancer, including the issue of detection bias in previous studies. The relationship of barrier methods, parity and smoking, and combined OC use to cervical cancer *in situ* is also being investigated.

FAMILY HEALTH INTERNATIONAL

May 7, 1996

Dear Colleagues,

A recent animal study has raised questions about the connection between hormonal contraceptives and the risk of HIV infection, the virus that leads to AIDS. It found that rhesus monkeys given the hormone progesterone are more likely to become infected after vaginal exposure to simian immune deficiency virus (SIV) than monkeys that have not been given the hormone.

The finding raises the possibility that contraceptives containing progestins, which are synthetic versions of the natural hormone progesterone, may increase the risk of acquiring HIV infection among humans.

While Family Health International was not involved in the study, we feel it is important for every woman who uses a hormonal method (oral contraceptives, implants, injectables or the hormonal IUD) to have a clear understanding of how this new information may relate to her decisions about contraceptive use.

First and foremost, all couples at risk of any sexually transmitted disease (STD), including AIDS, should be advised to use latex condoms. This long-accepted recommendation remains unchanged by the new study. While other barrier methods of contraception may provide a degree of protection from bacterial STDs, using latex condoms consistently and correctly during intercourse continues to be the most effective prevention strategy.

Other options to reduce sexual transmission of HIV are possible. Abstinence from sexual activity is the safest one. Also, no sexual transmission is possible within a mutually-faithful relationship where both partners are uninfected.

While hormonal methods do not protect against STDs, they are excellent for preventing unintended pregnancy. They are safe, convenient to use and effective. Women should continue using them, but those women who are uncertain of their partners' HIV infection status should also encourage their partners to use condoms. This "dual use" approach combines excellent contraception with the best practice for STD prevention.

Regarding the new study, findings from animal models do not necessarily translate into evidence of disease transmission in humans. More research is needed to examine any relationship between progestins and HIV transmission. Progesterone occurs naturally in every woman's body, with higher levels during the second half of the menstrual cycle and during pregnancy.



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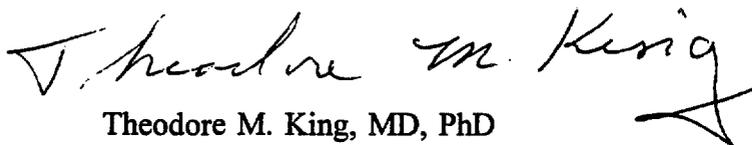
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Women should also consider the health risks they face from not using adequate contraception. Each year, an estimated 500,000 women die worldwide from complications due to pregnancy and child birth, and millions more suffer from significant health problems. These health problems can range from simple discomforts to infertility, and may continue for years.

FHI believes this new study should bolster physicians and other health providers to advise women regarding their risks of STDs, including HIV. Clients at risk should be strongly encouraged to use latex condoms if they choose hormonal contraception or other non-barrier methods to prevent unintended pregnancies.

Included in this packet, please find a "question and answer" text prepared by FHI, which offers scientific information on contraceptive methods as they relate to this study. A concise list of related studies is also included, with a brief description of their key findings. We have also included a one-page "fact sheet" that briefly describes popular hormonal methods, including information about their contraceptive effectiveness and ability to prevent STDs. Please use these materials in any way that will assist women in making their decisions about contraceptive use.

Sincerely,



Theodore M. King, MD, PhD
President



Willard Cates, Jr., MD, MPH
Corporate Director of Medical Affairs

Hormonal Contraceptives and the Risk of Sexually Transmitted Diseases (STDs)

*A Question and Answer Sheet Prepared by
Family Health International
Research Triangle Park, NC, USA*

A recent animal study has found that rhesus monkeys given doses of the hormone progesterone, a hormone produced naturally by the human body, are more likely to become infected after exposure to simian immune deficiency virus (SIV), a virus similar to HIV in humans. More research is needed to assess the implications of this study for humans. Progestins, which are synthetic versions of progesterone, are the active ingredients of modern hormonal contraceptives (oral contraceptives, injectables, implants and the hormonal IUD). FHI believes any person at risk of a sexually transmitted disease should use latex condoms consistently and correctly. Condoms can be used in combination with hormonal methods which provide excellent contraception. The following questions and answers discuss current scientific knowledge about the relationship between hormonal methods and STDs.

Question: **What did the new study find?**

Answer: The study found that rhesus monkeys implanted with long-acting pellets of progesterone are more likely to become infected after vaginal exposure to SIV, compared with monkeys that have not been given the hormone. Of 18 monkeys treated with progesterone for six months, 14 became infected with the virus, compared to only one in 10 monkeys not implanted with progesterone.

Researchers theorize that the reason progesterone-treated animals became infected more easily was that the vaginal epithelium -- the protective lining of the vagina -- was significantly thinner compared with the other monkeys. A thinner lining may provide an easier pathway for the virus.

The National Institutes of Health, which financed the study, has said that the possible increased risk of SIV infection in monkeys does not necessarily have any implications for HIV transmission among humans. Further research is needed to examine any relationship between progestins and HIV transmission. Existing epidemiological studies among humans do not demonstrate consistent findings to support the postulated hormonal-STD risk.

The new study was conducted at the Aaron Diamond AIDS Research Center in New York City, and the AIDS Animal Models Laboratory at the Laboratory for Experimental Medicine and Surgery in Primates in Tuxedo, NY. Study results are preliminary and have not yet been published in a scientific journal.

Question: Are women who use hormonal methods at greater risk of acquiring HIV?

Answer: Hormonal contraceptives provide effective protection against pregnancy, but offer virtually no protection against STDs, including HIV.

Progestins, which are synthetic versions of the natural hormone progesterone, are used in all hormonal methods. While several studies have attempted to explore the relationship between HIV infection and progestin-containing contraceptives, the relationship remains unclear.

Some researchers suggest that certain physiological changes caused by progestin use may increase susceptibility to HIV. These include, for example, the thinning of the vaginal lining.

Question: Should women using hormonal contraceptives continue using them?

Answer: The results of this initial animal study are not expected to change the current consensus among public health and family planning organizations about the recommended uses for hormonal contraceptives. These methods are safe, effective and convenient to use, and many women benefit from using them. FHI joins NIH and the World Health Organization in saying the current data are not sufficient to change current family planning recommendations. However, the findings underscore the importance of barrier method use to prevent STD/HIV.

Each woman should choose the contraceptive option that best suits her needs, in consultation with her physician or family planning provider. A mutually faithful monogamous couple free of HIV infection faces no risk of sexually infecting each other with HIV. Anyone at risk of any sexually transmitted disease should use latex condoms with every act of intercourse. Condoms can be used simultaneously with hormonal methods to provide excellent contraception with the best practice for STD prevention.

Question: Should a woman at risk of STDs consider initiating hormonal method use, if she is not currently using them?

Answer: Anyone engaging in high risk sexual behaviors -- whether using progestin methods or not -- should use latex condoms consistently and correctly. Hormonal methods can provide excellent contraception for couples using latex condoms for STD protection, and should be considered by people who wish to increase their protection against unintended pregnancies.

The health risks from an unintended pregnancy are sizeable. Approximately 500,000 women worldwide die each year due to pregnancy-related complications, and many more suffer major health problems related to unintended pregnancy or childbirth.

Question: Do hormonal methods protect women against STDs?

Answer: Hormonal contraceptives do not protect against STDs of the lower genital tract, the site where HIV is thought to be acquired. Oral contraceptives have been associated with increased detection of cervical STDs, but also are correlated with lower risks of symptomatic pelvic inflammatory disease (PID).

Barrier methods of contraception (such as condoms, diaphragms and spermicides) offer better protection against STDs than other contraceptive methods, but are somewhat less effective at preventing pregnancy.

Question: What should a couple use to protect against both unintended pregnancy and STDs?

Answer: Couples who want effective protection against pregnancy and STDs should consider using two contraceptive methods -- one to prevent pregnancy and latex condoms to prevent STDs. Condoms must be used correctly, and with every act of intercourse, to provide the best protection against STDs, including HIV.

Other barrier methods, such as spermicides and the female condom, offer some protection against STDs, but further study is needed to document the degree of protection. When a woman cannot convince a man to use a condom, these barrier methods may offer a degree of protection.

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Selected Bibliography of Scientific Studies and Reviews on Hormonal Contraceptives and STDs

*Prepared by
Family Health International
Research Triangle Park, NC, USA*

Daly CC, Helling-Giese GE, Mati JK, et al. Contraceptive methods and the transmission of HIV: implications for family planning. *Genitourin Med* 1994; 70(2):110-17.

Choice of contraceptives may influence a woman's risk of contracting HIV, depending on her exposure to HIV. The relationship between oral contraceptives and HIV is unclear, although researchers suggest that some physiological changes caused by OC use may increase susceptibility to HIV. These include ectropion of the cervix; a higher incidence of chlamydia among OC users; irregular menstrual bleeding; and a thinning of the lining of the vagina. Injectable contraceptives containing progestins might also increase susceptibility to HIV by causing irregular menstrual bleeding and thinning of the vaginal lining. The relationship between IUD use and HIV risks also is inconclusive. Spermicides containing nonoxynol-9 inactivate HIV in the laboratory, but studies in humans (Kenya and Zambia) show conflicting results. No studies have been conducted to determine the effectiveness of the female condom in protecting against HIV.

Cates W Jr., Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part I. *Fam Plann Perspect* 1992; 24(2):75-84.

Numerous studies have been conducted on the effects of contraceptive use on STD risks. Condoms alone, spermicides alone, or a combination of physical and chemical barriers appear to offer protection against some STDs. Male latex condoms provide an effective barrier against most bacterial and viral STD organisms, including HIV, the virus that causes AIDS. Vaginal pouches, including the female polyurethane condom, have been shown to be effective in vitro in protecting against HIV. Spermicides can kill or inactivate HIV in vitro, but few studies have been done in vivo. Spermicides also appear to be effective in vitro in protecting against other STDs, including gonorrhea and herpes. Barrier methods, used in combination with spermicides, also protect against infection.

Cates W Jr., Stone KM. Family planning, sexually transmitted diseases and contraceptive choice: a literature update-part II. Fam Plann Perspect 1992; 24(3):122-28.

Oral contraceptives, intrauterine devices (IUDs) and sterilization provide effective protection against pregnancy, but offer no protection against STDs, including AIDS. Oral contraceptives appear to protect against symptomatic pelvic inflammatory disease, yet the effect of OCs on HIV risks is unclear. IUD use may increase the risks of PID, but this risk usually occurs around the time of insertion. Tubal sterilization appears to reduce the risk of PID, but research is not conclusive. Sterilization protects against upper genital tract infections but not lower tract infections. Women who have cervical gonorrhea and chlamydia are at increased risk of endometritis following abortion, even when aseptic practices are followed. Couples who want effective protection against pregnancy and STDs may need to use two contraceptive methods -- one to prevent pregnancy, another to prevent STDs. Couples who want to use only one method are faced with trade-offs; they must either risk increased likelihood of pregnancy or STDs. Also, couples must assess the risks of childbirth. A more effective woman-controlled contraceptive method that also protects against STDs is needed.

Kapagi SH, Shao JF, Lwihula GK, et al. Risk factors for HIV infection among women in Dar-es-Salaam, Tanzania. J Acq Immun Def Syndr 1994; 7(3): 301-09.

A study of 2,285 women at high risk for HIV was conducted at three family planning clinics in Dar-es-Salaam. After controlling for known and potential risk factors, women who had used an IUD had a significantly increased risk for HIV infection. Women who used other contraceptives, including oral contraceptives, did not have an increased HIV risk. Other study findings were that women with two or more partners in the five years prior to the study had twice the HIV risk as women with only one partner. Also, women who experienced abnormal vaginal discharge (often an STD symptom) had an increased risk of HIV, and unmarried women, particularly women in cohabiting relationships, had the highest HIV-positive prevalence. HIV risks increased as women and men's education levels increased.

Mati JKG, Hunter DJ, Maggwa BN, et al. Contraceptive use and the risk of HIV infection in Nairobi, Kenya. Int J Obstetrics and Gynecology 1995; 48: 61-67.

A study of 4,404 women attending family planning clinics in Nairobi, Kenya examined the relationship between contraceptive use and HIV-1 infection. The study examined previous and current use of various methods, including oral contraceptives, injectable contraceptives, IUDs and condoms. There was no significant trend in risk of HIV infection with duration of use of oral contraceptives, injectables or IUDs. Prevalence of HIV was slightly elevated among women who had used OCs more than two years, however researchers did not find this significant.

Saracco A, Musicco M, Nicolosi A et al. Man-to-woman sexual transmission of HIV: longitudinal study of 343 steady partners of infected men. J Acq Immun Def Syndr 1993; 6(5): 497-502.

A study of 343 seronegative women (women who are not infected with HIV) found that condoms do offer protection against contracting HIV. The women were in stable monogamous heterosexual relationships. Their only risk for acquiring HIV was having sex with their HIV-infected partner. The annual seroconversion rate (the rate of women who became infected with HIV) was 5.7 percent to 9.7 percent among couples never or not always using condoms. The seroconversion rate fell to 1.1 percent among couples who always used condoms. Among the 22 women who used oral contraceptives, none became HIV-positive. One of two women using an IUD became HIV-positive.

Rehle T, Brinkmann, Siraprapasiri T, et al. Risk factors of HIV-1 infection among female prostitutes in Khon Kaen, Northeast Thailand. Infection 1992; 20(6); 328-31.

A study of sex workers in Khon Kaen in northeast Thailand was conducted to determine what factors increase HIV risks. More than 350 prostitutes were interviewed about sexual practices, including women who worked in brothels ("direct prostitutes") and women who worked in massage parlors ("indirect prostitutes"). Researchers found that direct prostitutes were 7.4 times more likely to be HIV-positive than indirect prostitutes. Users of injectable contraceptives had a 2.4 times higher risk of becoming HIV-infected than did users of other contraceptives, including pills, condoms or IUDs. Researchers did not determine whether HIV-contaminated needles were the reason for higher HIV infection risks. Higher risks may have been associated with atrophy or weakening of the vaginal lining, making it more susceptible to tears during intercourse and creating a route for HIV infection. Other risk factors for HIV were duration of work in Khon Kaen (women who had worked in the town less than a month were 5.5 times more likely than those who had been there more than two years) and work in provinces with greater than 40 percent HIV prevalence.

Allen S, Lindan C, Serufulira A, et al. Human immunodeficiency virus infection in urban Rwanda. JAMA 1991; 266(12): 1657-63.

A study of 1,458 women in Rwanda examined risk factors for HIV infection. Thirty-two percent of the women were HIV-positive. Twenty-two percent of women had used oral contraceptives, and 20 percent had used injectables in the five years prior to the study. Both groups had a significantly higher prevalence of HIV-infection than nonusers. However, higher-risk women -- those living alone or in non-monogamous unions -- were more likely to have used oral or injectable contraceptives. When type of sexual relationship was taken into account, hormonal contraceptive use was not associated with increased prevalence of HIV infection. Factors increasing women's risk of HIV infection included being unmarried and having more than one lifetime sexual partner.

Fact Sheet on Hormonal Contraceptives

*Prepared by Family Health International
Research Triangle Park, NC, USA*

Method	Contraceptive Effectiveness <small>(Typical use, one-year)</small>	Effect on STD Transmission	Women Using Worldwide
Oral contraceptives	97 percent	No protection except against some forms of pelvic inflammatory disease (PID); may increase risk of cervical chlamydia; effect on HIV under study	70 million
Injectables DMPA, NET-EN	>99 percent	No STD protection; added risk unknown	12 million
Norplant subdermal implant	>99 percent	No STD protection; added risk unknown	3 million
LNg IUD	>99 percent	No STD protection; added risk unknown	500,000

What are progestins?

The term "progestin" refers to both natural and synthetic hormones. Progesterone, the natural progestin, is produced primarily in a woman's ovaries, and is associated with menstruation, the monthly shedding of the uterine wall (endometrial lining). Progesterone is also essential to support a pregnancy. A number of different synthetic progestins, which are chemically and molecularly very similar to progesterone, are used in hormonal contraceptives.

How do hormonal contraceptives work?

Used with synthetic estrogen or alone, progestins block hormonal signals that trigger ovulation. Progestins also thicken a woman's cervical mucus, making it difficult for sperm to get through. (Cervical mucus normally fluctuates in thickness throughout a woman's cycle, becoming thin and watery at the peak of fertility.)

of

PRELIMINARY AGENDA

**STEROID CONTRACEPTIVES AND HIV TRANSMISSION:
PLANNING FOR RESEARCH**

National Institute of Child Health and Human Development
Office of AIDS Research
National Institute of Allergy and Infectious Diseases

DATE: June 6, 1996

PLACE: Natcher Building, Conference Room E/F (NIH Campus)

CHAIR: Ward Cates, MD, MPH; Family Health International

8:00 Registration

8:30 Welcome

Robert Spirtas, DrPH (Contraceptive and Reproductive
Evaluation Branch, NICHD)

Felicia Stewart, MD (Department of Health and Human Services)

8:45 Biomedical Research

Sharilyn Stanley (National Institute of Allergy and
Infectious Diseases): Vaginal Transmission of HIV

David Eschenbach, MD (University of Washington): Normal
Vaginal/Cervical Physiology and Effects of Sex Steroids

Deborah Anderson, PhD (Harvard): Changes in Vaginal,
Cervical and Systemic Immunology Associated with Sex Steroids

Preston Marx,, PhD (Aaron Diamond AIDS Research Center):
Vaginal Transmission of SIV in Macques

10:15 Panel Discussion

10:45 Break

11:10 Characteristics of Users of Injectable Contraceptives

James Shelton, MD (U.S. Steroid Contraceptives International
Development): International Experience with Progestin-containing
Contraception

Jacqueline Darroch Forrest, PhD. (Alan Guttmacher Institute):
U.S. Experience with Long-Acting Hormonal Contraceptives

11:30 Panel Discussion

12:00 Lunch

- 1:00 Population-based Research
- Pierre Plourde, MD (University of Manitoba): HIV Infection
 in Women Attending STD Clinic in Kenya
- Susan Allen, MD (University of Alabama): Human
 Immunodeficiency Virus Infection in Urban Rwanda
- David Hunter, MD (Harvard School of Public Health): Cohorts
 of Women Attending Family Planning Clinics in Kenya and Tanzania
- Bea Vuylsteke, MD, MPH (Institute of Tropical Medicine):
 Results from Studies among Sex Workers in Zaire and Cote d'Ivoire
- 2:20 Break
- 2:50 Session Continues
- Joan Kreiss, PhD (University of Washington): Effect of
 Hormonal Contraception on HIV Susceptibility and Infectivity
 among Women in Kenya
- Ann Duerr, MD (Centers for Disease Control and Prevention):
 Cohort of Discordant Couples in Thailand
- 3:30 Panel Discussion
- 4:00 Judith Wasserheit, MD (Centers for Disease Control and Prevention):
 Gaps in our Knowledge - Directions for Research
- 4:15 Recommendations for Future Research - Open Discussion
- Possible areas needing research:
 -relationship between animal model and human disease
 -mechanisms by which steroid contraceptives can affect HIV transmission
 -epidemiology
 -other
- 6:00 Adjourn

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Agenda Item 3 – Technical Discussion: IUDs			
Wednesday, 10:15-11:45	Background Materials	Action from TAC	Moderator
FHI Presenters: Rivera Raymond	1. Ongoing FHI IUD Research and Programs	Identify key methodologic and public health issues	Shain
TAC Discussants: Trussell Pérez-Palacios	2. Summary of Design Issues on LNg IUD Protocol		

FHI has been involved in research on IUDs since its inception. After discussions at the 1995 TAC meeting, FHI has carried out a variety of initiatives to "rehabilitate" the image of the IUD as a form of "reversible sterilization." For example, FHI has published the Winter 1996 *Network* devoted to Intrauterine Devices, and produced and distributed a new Contraceptive Technology Update Module on IUDs. In addition, a study in Kenya is addressing the appropriateness of IUDs for women who become HIV infected, and a planned investigation in Mexico evaluates the risk of tubal infertility when the TCu 380 devices are used in nulliparous women.

CDC's CREST data indicate that female sterilization is less effective over the long term than has been widely believed. These findings, when considered with the cost of female sterilization and the risks associated with a surgical method, lend additional weight to emphasizing the IUD as a long-term reversible alternative to sterilization.

FHI staff have also been working on a study protocol to confirm earlier findings from Europe that the levonorgestrel IUD (LNg IUD) reduced the risk of pelvic inflammatory disease (PID) when compared with copper-bearing devices. A number of questions have arisen related to the study design, feasibility, and policy implications summarized in the attached document. A major issue is that the proposed study to answer the specific question of PID, because of its necessary size and duration, is both expensive and lengthy. USAID has indicated that their support for the study would be partial; other donors will need to be identified to fund the major share of the costs. A related issue is whether the anticipated programmatic payoff of the proposed study is worth the investment, especially if the LNg IUD will have limited availability in developing country programs.

We would like the TAC to discuss both scientific and policy issues regarding FHI's future research on IUDs.

1. What additional research or research utilization activities should FHI undertake to improve attitudes of both providers and clients toward the IUD, and to increase the use of long-term devices such as the TCu 380A in family planning programs?
2. Given the methodologic and program issues discussed, what research or research utilization role should FHI play regarding the LNg IUD? If the TAC advises that FHI continue to develop the LNg-IUD/PID protocol, what are the recommendations regarding the appropriate comparison method and study population? *funding?*
3. In which additional specific populations (young, nulliparous women in monogamous relationships; women interested in long-term fertility limiting methods; women with chronic medical conditions such as diabetes; etc.) should FHI carry out research to extend those eligible for IUD consideration?

HIGHLIGHTS OF FHI'S ONGOING IUD RESEARCH & PROGRAMS

Safety and Efficacy Studies/Activities

- ▶ Twenty-three papers have been published using FHI's TCU 380A IUD database. Two more are in preparation.
- ▶ *A Copper IUD and Tubal Infertility:* A case-control study to investigate TCU 380A use and tubal infertility has been designed. A site in Mexico has been identified and the protocol approved, but additional funding is needed before the study can be initiated.
- ▶ *Complications of IUD Use Among HIV-infected Women:* An on-going study in Kenya is being conducted to determine whether HIV+ women are at greater risk of short-term complications related to IUD use than HIV- women; and to determine whether HIV+ women are more infectious after, as compared to before, IUD insertion.
- ▶ *LNg in Breastfeeding Women:* FHI's Fellowship in Contraceptive Technology provides limited funding for a re-entry grant for each Fellow. The 1995-96 Fellow, Dr. Gamel Sayed of Assuit, Egypt, has proposed a study of the LNg IUD and the CuT 380 IUD to assess whether there are any differences in the rate of breastfeeding and infant's growth between the two groups of users. The protocol will be further developed over the next few months and supplemental funding sought for this study.

Information, Education and Training Activities

- ▶ *Contraceptive Technology Updates:* FHI continues to present the latest IUD research results and address unnecessary obstacles to IUD provision in numerous contraceptive training seminars and workshops. During 1995-96, contraceptive technology trainings were held in Jamaica, Indonesia (for the Asia region), and Niger. In August, another will be held in Jordan.
- ▶ *IUD Module:* As part of a series of slide presentations entitled Contraceptive Technology Updates, a Module on IUDs was prepared. Over 370 copies of the Module have been distributed. (The introduction is attached, providing further details).
- ▶ *Expert Slides:* A set of 35mm color slides were prepared for clinical presentations on family planning. In addition to slides on combined oral contraceptives and DMPA, slides were produced on the topic of IUDs. To date, more than 120 sets of these slides have been distributed to a select group of experts.
- ▶ *Network:* FHI's quarterly scientific bulletin, *Network*, regularly mentions IUD research. A copy of the Winter 1996 issue on Intrauterine Devices (distributed in January 1996) is included in the Committee's background materials. To date, 61,793 English copies and 11,404 French copies of the issue have been distributed.

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Programmatic IUD Research

- ▶ *Study of Follow-Up Schedules:* A prospective study was recently completed which examined the costs and benefits of frequent follow-up schedules. It compared the incidence of medical problems among a study population of 1,713 new IUD users, half of whom were told to return for check-ups four times in the first year while the other half were told to return only twice. The results showed that a higher proportion of visits among women in the two-visit scheme was made by women with symptoms or side effects, compared with women in the four-visit scheme. Ultimately, the percentage of visits resulting in a medical intervention was equivalent in the two schemes. Women with symptoms or side effects were twice as likely to receive a medical intervention compared to women without symptoms.

- ▶ *Method Specific Costs Study:* A study was begun in late 1995 to determine the method-specific cost per couple-year-of-protection of family planning services within the Mexican Ministry of Health programs. The study will include an examination of different service delivery models and place particular emphasis on the IUD, since this is the most common form of reversible contraception in Mexico. The study will include clinic-based and rural outreach services.

- ▶ *IUD Provision by Nurse Midwives:* An evaluation of a pilot project which trained rural midwives in IUD insertion and follow-up care is being undertaken in Mexico. Data collection is scheduled to begin in mid 1996.

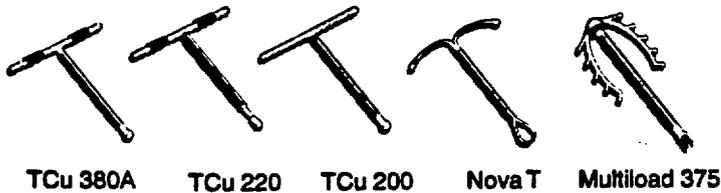
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Intrauterine Devices (IUDs)

Introduction

IUDs are safe and very effective for many years. They provide reversible contraception that requires little action on the part of the user. IUDs do not have any systemic effects, interfere with intercourse or require the active participation of a partner. IUDs have a low annual cost and, after the first follow-up visit, require only routine yearly examinations.

Currently Available Copper IUDs



Mechanisms of Action of Copper IUDs

Although the mechanisms which prevent fertilization are not precisely known, studies suggest that the copper released into the uterine cavity acts to impair the viability of the sperm or interfere with their movement. Research has proven that the IUD is not an abortifacient — its primary mechanism of action is to prevent fertilization rather than implantation.

IUD Safety

Reducing Risks

The risk of perforation, expulsion, and pelvic inflammatory disease can be decreased when providers:

- Carefully screen clients
- Use sterile IUDs and equipment
- Follow aseptic insertion procedures
- Correctly insert and place the IUD
- Counsel clients about when to return to the clinic
- Provide proper follow-up care



Screening

Who Can Use Copper IUDs

Any woman who wants long-term, effective, reversible contraception can use IUDs.

IUDs are especially suited for women who are:

- at low risk for STDs
- postpartum, postabortion, or breastfeeding

IUDs may be used by women who are:

- young
- nulliparous

Copper IUDs not recommended for women with:

- known or suspected pregnancy
- current or recent STDs, PID or purulent cervicitis
- cervical, endometrial, ovarian cancer, or unexplained vaginal bleeding
- malignant trophoblastic disease or known pelvic tuberculosis
- uterine distortion that impedes correct IUD placement
- infection following childbirth or following incomplete abortion

Copper IUDs usually not recommended for women with:

- increased risk for STDs, HIV infection or AIDS. (If no other method is available or acceptable and the client chooses an IUD, counsel her to also use another method to prevent the transmission of disease)
- benign trophoblastic disease

Counseling

If a woman wishes to use the IUD, be sure to discuss the following issues with her:

- Characteristics of IUDs
- Client's current and future risk for STDs
- Effectiveness and how the IUD works
- Insertion and removal procedures
- Instructions for use and follow-up visits
- Possible side effects and complications
- Signs of possible complications

Common side effects

- During insertion: some pain and cramping
First few days: mild cramping and bleeding
First few months: heavier menstrual bleeding
 mild intermenstrual cramping
 intermenstrual bleeding

Instructions for Use and Follow-up Visits

Teach the woman to feel for the IUD strings:

- with clean fingers
- after each menses (expulsion most likely in the first six months.)

Schedule follow-up visits at:

- 3-6 weeks after insertion
- 1 year, if no problems; yearly thereafter.

Encourage her to return to the clinic if she has any questions, problems, or signs of complications.



Artwork adapted from PATH and The Population Council.

Management of Complications

If a client returns to the clinic with:	Check for:
Severe bleeding or abdominal cramping in the first 3-5 days →	Perforation or infection
Irregular bleeding and /or pain every cycle →	Dislocation or perforation
Fever, chills, or unusual vaginal discharge →	Infection
Pain during intercourse →	Partial expulsion, perforation or infection
Missed period, expelled IUD →	Pregnancy; if pregnant, check for ectopic
Shorter, longer, or missing string →	Expulsion or perforation
A request that the IUD be removed →	Remove it promptly

Insertion Issues

Timing of Insertion

- Interval:** anytime other than the 6 weeks following delivery
- Postpartum:** preferred within 10 minutes post placental expulsion; acceptable up to 48 hours, or wait until 6 weeks postpartum
- Postcesarean:** directly following delivery
- Postabortion:** anytime, if during first trimester
if second trimester, insertion must be performed by a specially trained provider, or delayed for six weeks

Infection Prevention

- Wash hands
- Wear sterile gloves
- Carefully disinfect the vagina and cervix
- Use sterile IUDs and sterile or high-level disinfected equipment
- Properly decontaminate instruments after use
- Safely dispose of contaminated waste materials

Reducing Risks During Insertion

- Maintain aseptic conditions
- Follow manufacturer's instructions for insertion technique
- Use IUD only if sterile package is not damaged or opened and has not expired

Tarnished or discolored IUDs are still effective.

Programmatic Issues

Provider Training

Practice:

- interval and postpartum insertions, and removals
- with different types of IUDs
- with plastic pelvic models
- in supervised clinical setting

Level of Health Care Provider

IUDs can be inserted and removed by any trained provider, including nurses and midwives.

**Levonorgestrel Intrauterine Device Study:
Issues Related to Study Design**

Laneta Dorflinger, Paul Feldblum, Beth Raymond

Prepared for Annual Meeting of FHI's Technical Advisory Committee
Contraceptive Technology and Family Planning Research
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Except in China, intrauterine devices (IUDs) are not widely utilized primarily because of the widespread perception that IUDs increase the risk of pelvic inflammatory disease (PID). There is some evidence that the levonorgestrel (LNg) IUD is associated with a low risk of PID. Therefore, FHI began designing a study of the relation between the LNg IUD and PID. The study will be a randomized clinical trial comparing the incidence of PID in a group of women using the LNg IUD to the incidence in a comparison group using another contraceptive method. In designing this study several issues arose.

Choice of a Control Method

The LNG IUD can be considered either as a traditional IUD that also delivers hormone, or as a hormonal method that is mounted onto an intrauterine delivery device. Therefore, options for the control method in our study might include either a copper IUD or a hormonal method such as Norplant®, Norplant-II®, DepoProvera®, and oral contraceptives (OCs). Important concerns in choosing a control method:

1. **Policy implications.** How would positive or negative results of the study using each of the different choices affect the reputation of the IUD and potential IUD use?
 - a. LNg IUD associated with lower PID risk than Cu IUD. People might argue that the LNG IUD is nevertheless an IUD, and that like all IUDs, it will increase PID risk. Alternatively, they might conclude that since the increase in risk with the Cu IUD is low, then the LNg IUD with an even lower risk is acceptable.
 - b. LNg IUD associated with same or lower PID risk than a hormonal method. Undoubtedly would enhance the use of the LNG IUD; might change perceptions of the IUD; might allow consideration of use of the LNG IUD in women at moderate-high risk for PID.
 - c. LNG IUD associated with higher PID risk than a hormonal method. Might seriously damage the reputation of the LNG IUD.

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2. **Availability of Norplant and Norplant-II.** The acceptability of Norplant seems to be declining worldwide. Could we recruit and retain enough women over the course of the study if Norplant were the control method? If we showed that the LNG IUD is equivalent to a method that is no longer acceptable or available, would our study have been wasted? How likely is it that political pressures could actually prevent us from completing the study if Norplant were the control? Alternatively, will Norplant-II be available for use in the study by the time the study is fielded?

3. **Bias due to differential follow-up frequency.** The frequency of scheduled follow-up visits with DepoProvera would be greater than that with the LNG IUD. This difference might result in surveillance bias.

4. **Compliance and continuation rates.** Unlike the LNG IUD, OCs and DepoProvera might be used inconsistently by study participants, or could be discontinued without a clinic visit. How would these factors affect the study size calculations and the results?

5. **Recruitment issues.** Could we find women willing to be randomly assigned to either the LNG IUD or to a hormonal method?

Study Population

Many practitioners and experts believe that the Cu IUD should be restricted to women at very low risk of sexually transmitted diseases or PID. How restricted should the study population be for this study? Does the answer depend on the choice of control methods? Would the admission criteria be more restrictive if the control method were a Cu IUD than if it were a hormonal method? Certainly the more restricted the admission criteria, the larger the study size would have to be.

Feasibility

The incidence of PID reported in previous studies varies widely because of differences in populations and methods of case ascertainment. Preliminary calculations suggest that depending on the anticipated PID rate and the specific difference we want to detect between groups, between 3,000 and 5,000 women would be needed to provide sufficient power for the study. Is a study of this size feasible?

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Agenda Item 4 – Technical Discussion: Barrier Methods				
Wednesday, 1:00-2:30		Background Materials	Action from TAC	Moderator
FHI Presenters:	Joanis Feldblum	1. Ongoing FHI Barrier Research Program	Identify key research questions and priorities	Harper
TAC Discussants:	Anderson Shain	2. Barriers. <i>Network</i> , Spring 1996.		

FHI has been involved in research on barrier methods of contraception for more than two decades. Key scientific findings have led to FDA approval of the sponge and the female condom; demonstrated that the use of nonoxynol-9 increased the contraceptive effectiveness of diaphragms; found that more than once-daily insertion of N-9 increased vaginal irritation; showed that use of N-9 in various forms (sponge, suppository, film) can reduce genital bacterial infections; found that non-latex male condoms are acceptable; and demonstrated that male condom breakage/slippage rates differ across populations and among individuals.

FHI's current research activities on barrier methods fall into four main areas:

- 1) evaluation of improved barrier methods to prevent pregnancy and STD/HIV, e.g., slip-on plastic condoms;
- 2) anatomic impact of particular barriers on genital epithelia, e.g., the effect of physical and chemical barriers on vaginal irritation and cervical lesions;
- 3) circumstances in which to encourage dual methods vs. a dual purpose method, e.g., evaluating factors affecting consistent condom use, whether backed up by another method or not; and
- 4) study designs to better quantify effectiveness and efficacy of barrier methods.

In light of the above research heritage and the current program activities, FHI would like the TAC to address the following two questions involving barrier use:

1. FHI proposes studying different approaches to using dual methods, i.e., barrier methods used with more effective contraceptives such as hormonal methods or emergency contraception with the regular use of barrier methods. In comparing these alternative strategies, what are the most important research issues: effectiveness, acceptability, or compliance?
2. Given the possible outcomes for the Cameroon N-9/HIV study, what research directions should be taken?
 - a. N-9 group has higher HIV incidence (harmful effect).
 - b. N-9 and placebo rates equivalent (no effect)
 - c. N-9 reduces HIV rate 20% (low level protective effect)
 - d. N-9 reduces HIV rate 70% (high level protective effect)

FHI BARRIER CONTRACEPTIVE STUDIES

Type and Name of Study	Country*	Year Began	Notes
<i>Safety</i>			
Irritation following frequent insertion of N-9 (phase I)	Thailand	1990	First study designed to measure spermicide irritation
Irritation following frequent insertion of N-9 (phase II)	Dominican Republic	1992	More than once-daily insertion increased irritation
Irritation after insertion of low-dose N-9 gel (phase I-II, HIVNET)	Kenya	1995	No difference in irritation between N-9 and placebo
Irritation after insertion of acid-buffer gel (phase I, HIVNET)	U.S./Thailand/ India/Malawi/ Zimbabwe	1996	Will assess safety, toxicity and acceptability of new type of microbicide
<i>Contraceptive Effectiveness</i>			
Collatex sponge	U.K./ Bangladesh/ Yugoslavia	1978	First studies of polyurethane vaginal sponges
Diaphragm with N-9 spermicides	Yugoslavia	1978	
NeoSampoon	Egypt/ Bangladesh	1978	
Collatex sponge vs NeoSampoon	Taiwan/ Bangladesh/ Yugoslavia	1979	
Collatex sponge vs diaphragm	U.K.	1980	
NeoSampoon vs Emko® foam	Yugoslavia/ Egypt	1981	
NeoSampoon vs EVT foaming tablets	Ghana/Egypt	1981	
Today® sponge vs diaphragm	U.S. (13)	1981	Led to U.S. Food and Drug Administration approval
Non-spermicidal fit-free diaphragm	U.K.	1981	Pregnancy rate at high end of diaphragm range
EVT vs OVT foaming tablets	U.S./Egypt	1982	EVT caused more discomfort
Propranolol tablets	Chile	1983	Found to be ineffective

OVT 60mg menfegol vs OVT 100mg N-9 foaming tablets	Ghana/U.S./ Thailand (6)	1984	
Diaphragm with vs without N-9 spermicide	England	1985	N-9 increased effectiveness
Lea's Kap® (phase I)	U.S.	1988	
Delfen™ foam vs N-9 gel caps	Colombia (2)	1988	
NeoSampoon vs Conceptrol foaming tablets	Pakistan (12)	1989	
Reality® female condom	Mexico/USA/ Dom. Rep. (8)	1990	Led to U.S. Food and Drug Administration approval
Lea's Shield® (phase II)	U.S. (6)	1992	Will soon enter phase III testing
VCF® vs Conceptrol foaming tablets	U.S./Ghana/ Mexico/Ecuador/ Guatemala (7)	1995	Most accurate data on VCF, complies with FDA guidance on spermicide testing
Femcap vs diaphragm	U.S. (10)	1995	CONRAD/FHI study
True contraceptive efficacy of condoms and VCF®	U.S.	1996	New methodology to measure efficacy

Prophylactic Effectiveness

Barrier methods and STDs in a family planning population	U.S.	1984	
Contraceptive N-9 sponge and STDs (pilot study)	Thailand	1985	
Contraceptive N-9 sponge and STDs	Thailand	1986	Randomized controlled trial showed that the sponge can prevent cervical infections
Barrier method use by HIV-discordant couples	Zambia	1988	Condoms protected well; N-9 protected seronegative women
Condom and spermicide use and HIV infection among women	Cameroon	1989	First evidence that N-9 can prevent HIV infection
Condoms and spermicides among women at high risk of STDs	Colombia/ Dom. Rep.	1991	Randomized study of different STD prevention messages
Vaginal N-9 film vs placebo and risk of cervicitis	Thailand	1991	Prophylactic effect of condoms and N-9 film similar
Plain vs N-9 condoms and risk of cervicitis	Dominican Republic	1994	Currently under way

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N-9 film plus condoms vs placebo plus condoms and HIV incidence among women	Cameroon	1994	Randomized study will be best measure of N-9 use and HIV
In vitro effect of betadine on BPV	U.S.	1995	Demonstrated potential feasibility of microbicide use to prevent papilloma infection
N-9 gel plus condoms vs placebo plus condoms and HIV incidence among high-risk women (phase III, HIVNET)	Kenya	1996	Randomized study to assess low-dose N-9 product in long-acting gel formulation

Acceptability and Use

Acceptability of two N-9 lubricated latex condoms	Ghana/Egypt Bangladesh/ Honduras	1987	
Barrier acceptability among couples at risk of HIV	Rwanda	1987	Determined products included in heterosexual transmission study
Acceptability of a female condom	U.S. (2)	1988	
Acceptability of latex condoms among U.S. military men	U.S.	1988	
Acceptability of condoms among male prostitutes	Thailand	1988	
Acceptability of N-9 products among female prostitutes	Colombia/ Dom. Rep. (3)	1988	
Preliminary function tests of prototype condoms: first to seventh iterations	U.S.	1988 1989	Evaluation of FHI's first plastic condom prototypes
Modified female condom use among women risk of STDs	Thailand	1989	Evaluation of a smaller female condom
Acceptability and breakage of stronger vs standard latex condoms	Dom.Rep./Mali/ Sri Lanka/Kenya/ Jamaica/Mexico	1989	Minor differences in breakage rates
Acceptability and breakage of larger vs standard latex condoms	Ghana/Kenya/ Mali	1989	Minor differences in breakage rates
Spermicide acceptability among STD clinic attenders	Zambia	1990	First study to distribute N-9 female products to men at high risk of STDs
Evaluation of prototype condoms: Leffler 1-5	U.S.	1990	Evaluation of sizes and thickness of plastic condoms
Function test of prototype condoms: round vs square flange	U.S.	1990	Evaluation of two styles of retention mechanisms



Function test of prototype condoms: Astroglide and Silicone lubricants	U.S.	1990	Evaluation of two types of lubricants on Prototype 9
Function tests of prototype condoms: film thickness comparison	U.S.	1990	
Latex condom breakage: Barbados and St. Lucia	U.S.	1990	Evaluation of quality of two 2-year old condom lots
Correlation between latex condom breakage in human use and laboratory tests	U.S.	1990 1991	
Female condom acceptability	Cameroon/ Kenya	1990	Studies among CSWs and health care workers
Acceptability and breakage of smaller vs standard latex condoms	Nepal/ Philippines	1991 1992	Minor differences in breakage and slippage rates
Impact of lubricants on latex condoms during human use	U.S.	1991	Effects of oil-based and aqueous products on breakage
Plastic condom prototype: twin aperture design	U.S.	1991	Product refinement
Comparison of breakage and consumer preference: Ring prototypes 6-8 vs latex	U.S.	1991	
Evaluation of three different prototype condoms (#1)	U.S.	1992	Three different sizes of retention mechanisms
Acceptability of vaginal film vs vaginal foaming tablets	Dom.Rep./ Mexico/Kenya	1992	Women in Kenya and Mexico strongly preferred film
Prospective aging of latex condoms	U.S.	1992	4-year study of human use
Behaviors associated with latex condom breakage	Dom.Rep/ Philippines/ Mexico	1992	Identify users at risk of breakage and reasons for it
Male attitudes towards female condom	Mexico/ Malawi	1992	
Evaluation of three different prototype condoms (#2)	U.S.	1993	Three different sizes of retention mechanisms
Investigation of plastic condom donning	U.S.	1993	
Acceptability of plastic condom during intercourse	U.S.	1993	
Long-term barrier use by HIV-discordant couples	Zambia	1993	Data on female condom use by married couples

Functionality and acceptability of 3 Tactylon™ and standard latex condoms	U.S.	1993	Comparative study
Dual method acceptability	U.S.	1993	Acceptability of barrier use with the Pill
Latex condom breakage with use of 4 lots of differing quality	U.S.	1994	Quality measured by the Condom Quality Index (CQI)
Effect of single use of female condom on structure and microbial retention	U.S.	1994	Initial assessment of safety of female condom re-use
Diaphragm acceptability	Philippines	1994	Collaboration with WHO and Population Council
Female condom acceptability among female sex workers	Costa Rica	1995	Preferred female condoms to male condoms
Acceptability of male contraceptive modalities	USA	1995	
Female condom distribution and survey	22 nations	1995	Study of initial USAID distribution
Comparison of condom breakage during vaginal versus anal intercourse	Brazil	1996	
Relationship between manufacturing, lab test results and human breakage rates	USA	1996	
Acceptability of reversible methods	Bolivia	1996	

*Numbers in parentheses indicate the number of study sites.

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Barrier Methods

How Barrier Methods Work

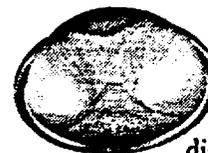
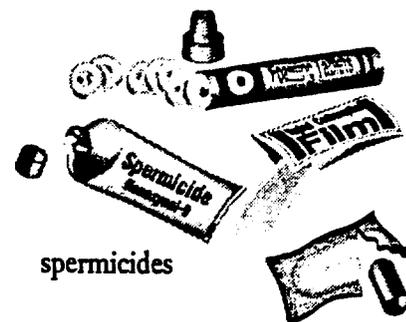
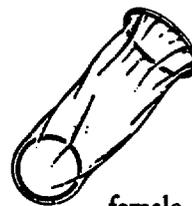
Barrier methods create a barrier, either physical or chemical, that prevents sperm from reaching the egg. Condoms, diaphragms and cervical caps are physical barriers. Spermicides are chemical barriers and are delivered using foam, cream, jelly, film, suppositories or tablets.

Barrier methods are the only contraceptives recommended for STD prevention.

Prevention of Sexually Transmitted Disease

Method	Bacterial STDs	HIV
Male condom	yes	yes
Female condom*		
Spermicides (N-9)		
Diaphragm with spermicides	yes	under study
Cervical cap*		

* theoretical



General Characteristics of Barrier Methods

- effective at preventing pregnancy and STDs when used consistently and correctly
- safe
- no systemic effects
- easy to initiate or discontinue
- immediate return to fertility
- most do not require a clinic visit
- not as effective as other methods in typical use
- can be difficult to use consistently and correctly
- may require partner participation
- may interrupt sexual activity
- may have cultural barriers to use
- need for proper storage and resupply
- expensive in some settings

Considerations for Potential Users

Good Candidates for Barrier Method Use

Women or men who:

- are at increased STD risk, to protect fertility
- are any age
- cannot or do not want to use hormonal methods
- need a back-up method
- have sex infrequently
- want a method that is user-controlled and private

Who Should Not Use Barrier Methods

General:

- usually not recommended in cases of allergy to latex or spermicides

Diaphragm and Cervical Cap:

- not recommended in women
 - with cervical or vaginal anatomical abnormalities
 - during first six weeks after childbirth
- usually not recommended
 - with history of toxic shock syndrome

Effective Counseling for Barrier Methods

It is important to help clients to prioritize between pregnancy prevention and disease prevention. Some clients may choose dual method use. Counseling elements include:

- characteristics/side effects
- how to use the method correctly
- importance of consistent use
- partner communication and participation required
- how to make it a part of sexual activities (where appropriate)
- common problems in use (and solutions)
- where to get resupply
- use of emergency contraception, where available



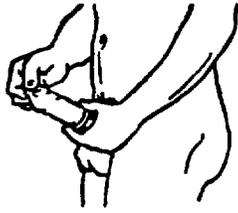
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Male Condom

The male condom is the only method recommended for prevention of all STDs, including HIV. It is male-controlled and safe for almost everyone. However, condom use may interrupt sexual activity and may reduce sensation.

Correct use:

- unroll onto erect penis before genital contact
- unroll condom all the way to the base of the penis
- hold onto condom and remove penis from vagina while still erect



Behaviors likely to cause breakage and slippage:

- opening package with teeth or sharp objects
- putting on condom incorrectly
- using oil-based lubricants
- reusing condoms
- prolonged or vigorous intercourse

Most condom breakage is due to human error/incorrect use, not manufacturing defects.

Spermicides

Spermicides prevent transmission of gonorrhea and chlamydia. They can be stored for long periods of time. They may be messy, cause mild discomfort or minor allergic reaction and can lead to yeast infections. They also may cause vaginal irritation with frequent use.

Correct use:

- place high in the vagina against cervix
- use clean hands and clean applicator for insertion
- follow package directions carefully
- for maximum effectiveness, use with another barrier method; use for each act of intercourse
- no douching for six hours after last act of intercourse

Vaginal Sponge

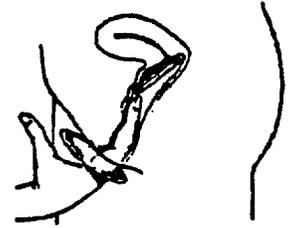
The vaginal sponge needs no fitting and is available over-the-counter. It is effective for 24 hours, for multiple acts of intercourse. It may be less effective in parous women; it is not widely available.

Female condom

The female condom is female-controlled, made of plastic and loose-fitting. It can be inserted prior to initiation of sexual activity and is likely to prevent transmission of STDs. However, it may be difficult to learn to insert and may be expensive to obtain.

Correct use:

- avoid genital contact before it is in place or after removed
- inner ring is inserted high in the vagina
- outer ring placed outside of the vagina

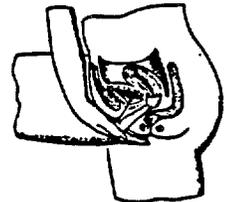
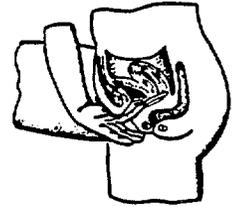


Diaphragm and Cervical Cap

The diaphragm and cervical cap must be fitted by a trained health-care provider. They can be inserted up to 6 hours prior to intercourse. They must be properly cleaned and stored for reuse. They provide some protection against cervical infections, but may cause increased urinary tract infections. The cervical cap may be less effective in parous women.

Correct use:

- must be left in place 6 hours after intercourse; can be left up to 24 hours (diaphragm), up to 48 hours (cap)
- additional spermicide needed for diaphragm for each act of intercourse; no additional spermicide needed for cap



Follow-up Issues:

- return for periodic checkups
- may need refitting if a woman has weight change, full-term pregnancy or 2nd or 3rd term abortion
- should be refitted if a woman complains of discomfort
- if necessary, give instructions on management of urinary tract infections

Barrier Methods -- Essential for Reproductive Health

Barrier Methods are available through:

- family planning clinics
- community-based distribution programs
- AIDS prevention community projects
- STD clinics
- youth programs
- private/commercial sector

Barrier methods can be used as part of "dual-method" approach: use of one highly effective method for pregnancy prevention, and barrier methods for disease prevention.

The following actions are important to help protect reproductive health:

- screen for STD risk and provide information on preventing STDs
- provide counseling for changing high-risk sexual behavior
- promote and distribute condoms through:
 - social marketing programs using advertising, promotion and other commercial marketing techniques, and
 - community-based distribution
- through direct services or referral, provide STD management services: diagnosis, treatment and partner notification and treatment
- ensure proper storage and well-managed supply distribution system

Agenda Item 5 – Technical Discussion: Strategies to Improve Contraceptive Continuation			
Wednesday, 2:45-4:15	Background Materials	Action from TAC	Moderator
FHI Presenter: Dorflinger TAC Discussants: Tsui Myntti	1. "Contraceptive Discontinuation: The Potential for Improvement" (L. Cole and L. Lackey)	Recommend FHI Program Priorities	Rooks

FHI research has demonstrated that many unintended pregnancies worldwide result after contraceptive discontinuation. Key reasons for discontinuation include dissatisfaction either with the particular contraceptive methods clients obtain or with the quality of services they are provided. While efforts continue to develop new contraceptives with broader appeal and easier compliance, we must simultaneously strive to address the reasons why many couples discontinue their existing methods.

We identified four major approaches to improve contraception continuation:

1. **Improving method choice.** There is some evidence that users who can make voluntary, informed choices are more likely to continue their methods than those who do not get what they want.
2. **Better contraceptive counseling.** Several studies have shown that if clients are adequately counseled about what side effects to expect, they have lower discontinuation rates.
3. **Improved medical management.** Standardized approaches have been used to manage side effects, but little research has been done to document the effects on discontinuation. *controlled studies of impact of bldg. including a "highway road" on*
4. **Switching to another method.** In some programs, less than half of the women discontinuing one method because of health concerns and/or side effects, switch to another method to prevent unintended pregnancies.

We would like the TAC to discuss potential areas of research within these categories:

1. On which category or categories should FHI focus its efforts? Can TAC reach a consensus on the rank order of the four categories?
2. Within each selected category, which research areas are most important (do not necessarily limit this to areas suggested in the background paper).

Contraceptive Discontinuation: The Potential for Improvement

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May 1996



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Contraceptive Discontinuation: The Potential for Improvement

Introduction

A key concern for family planning programs is the rate at which users discontinue use of contraception and the reasons for such discontinuation, particularly if due to dissatisfaction with either the contraceptive methods being used or the quality of services provided. Efforts to attract and recruit new clients contribute to program success, but failure to keep clients can negate that success. Clients have many reasons to discontinue using contraception: some, programs may be able to influence (e.g., concern over side-effects) and some, they will not (e.g., planning a pregnancy). This paper discusses the magnitude of the problem, reasons for discontinuation and the consequences for women, focusing on discontinuation for side-effects and possible solutions for reducing such problems. It concludes with identification of knowledge gaps and suggestions for future research.

Magnitude of the Problem

Amount of Discontinuation

The impact of contraceptive discontinuation is profound. DHS data show that in many countries between one-third and one-half of pill acceptors discontinue within the first year (8, 17, 18, 19, 20, 21, 22, 23). At least one-third of the women report actual side-effects or health concerns as reasons for discontinuation (Table 1). Injectable users have similar rates of discontinuation, and higher percentages discontinue for side-effects / health reasons. Although discontinuations for IUD users are lower (probably because medical intervention to remove the IUD is needed), the percentage of discontinuations related to side-effects / health is similar.

Most of the DHS reports show side-effects and concern about health combined. In the Mexico study, discontinuation for side-effects was shown separately from discontinuation for health concerns. About twice as many women using the pill or the IUD discontinued for side-effects as did for health-related concerns. For Indonesia, the discontinuations were equally split between side-effects and health concerns.

Zimbabwe had lower than average discontinuation for the pill and IUD. Side-effects and health concerns were responsible for one-third of the discontinuations, however; this is consistent with rates for other countries.

Vaginal methods and Norplant have consistently low prevalence rates in most countries, with two exceptions. In Bangladesh, 3.0% of the women reported condom use with a one-year discontinuation rate of 72 per 100 women. In Indonesia, the Norplant prevalence was 4.9%. One-year discontinuation rates for Norplant were not given. Information on reasons for discontinuation, however, indicated that 25% of those discontinuing did so because of side-effects and an additional 20% for health concerns.

The DHS data are supported by other research:

- FHI asked women in Niger and the Gambia who discontinued their original contraceptive method why they had done so. The only reason spontaneously mentioned by women in both countries was side-effects, such as excessive bleeding, abdominal pain, nausea and headaches (5).
- Usually 25-50% of women who start pills are not using them after one year (13).
- In a multicenter WHO trial of DMPA, 50% of users discontinued after one year, 33% for side-effects and the rest for personal reasons (37). In the largest US study of DMPA, discontinuation was 40% at one year (13).
- In five international studies, 10-24% of Norplant users had discontinued after one year (33).

It has been suggested that the reasons women give for stopping a method may not always be the real reasons. Some may want to stop for personal reasons but think that providers will accept medical reasons more readily (27). The data world-wide are remarkably similar, however, suggesting that side-effects are a problem and do lead to discontinuations among a significant number of users.

The Importance of Menstrual Pattern Changes and Other Side-effects

For the pill, injectables, Norplant and the IUD, the most important side-effects leading to discontinuation are changes in menstrual patterns (Table 2). The changes that women experience vary greatly. They include bleeding on more days per cycle, heavier bleeding, spotting between periods, infrequent or scanty bleeding and amenorrhea. Unanticipated bleeding can be disruptive, frightening and inconvenient for users.

In a study in Sri Lanka, headaches, nausea, vomiting and dizziness were closely associated with each other and strongly predictive of pill discontinuation (2). In a WHO trial, after one year 15% of DMPA users had discontinued use because of bleeding problems and about another 12% because of amenorrhea (36).

For IUDs, bleeding disturbances account for 40-50% of all IUD discontinuation, which is about 10-15% of users. Prolongation of menses rarely contributes to discontinuation; heavy bleeding often results in discontinuation (31). About 7-15% of IUD users stopped using the method because of side-effects such as irregular menstrual bleeding, spotting and cramps. Women may have a dislocated IUD or an IUD incompatible with the uterine cavity (16).

In 1993, FHI hosted an interagency meeting on Long-acting Progestins: Management of Bleeding Disturbances. The issues covered included current medical treatment and counseling for irregular bleeding caused by long-acting progestins. Participants agreed that, although bleeding disturbances do not typically pose immediate life-threatening changes in hematocrit or hemoglobin, they do affect their quality of life (14).

Consequences of Discontinuation

What users do after discontinuation of a method is as important as the reasons for discontinuation. In Egypt, the DHS data showed what happened to those who stopped using a method because of side-effects and health-related reasons (8). In the first month after discontinuation, 6% reported pregnancy, 38% switched to another method and 56% did not use anything at all. Of the 56% who did not use anything, in the second month 23% became pregnant, 10% started using another method and 67% were still not using a method. Other studies confirm these findings:

- A Thai contraceptive prevalence study of 1,268 women showed that 69% of women who discontinue a method because of side-effects switch to another method, but 31% drop contraceptive practices altogether (34).
- In a US study of 550 women aged 15-24, 6% quit using pills because of poor menstrual cycle control; 23% experienced unplanned pregnancies after discontinuation (3).
- A study of 26,000 former pill users in the US using data from the 1982 National Survey of Family Growth showed that 19% did not switch to another method. One-fourth of these women were at risk of unplanned pregnancy (28); the rest were pregnant or seeking to be pregnant, were not in a sexual relationship or were sterile.
- In the US, one million unintended pregnancies have been attributed to OC misuse or discontinuation each year. The greatest proportion, 61%, occur in women who discontinue OCs and fail to substitute other contraceptives or adopt less reliable methods (30).

Possible Solutions

Recommendations for improving continuation can be grouped into four major categories:

- improving method choice
- better counseling
- medical management
- switching to another method

Improving Method Choice

Based on a study in Indonesia by Pariani and associates, Population Reports suggests that users who can make a free and informed choice are more likely to continue using their methods than those who do not get what they want (26). Some 506 Indonesian women who received oral contraceptives, IUDs, or condoms at any of five family planning clinics were asked 18 months later whether they had received the method they had requested, whether they were still using contraception, and, if not, when they had stopped. Among those who said that they had not received the method they wanted, 85 percent had discontinued use within a year, compared with only 25 percent of those who had received the method they wanted. Whatever the method provided, women who were denied their original requests had lower continuation rates. The

retrospective study relied on women's recalling whether they had received the method of their choice. The large difference between the two groups suggests that it is important to listen to what clients say and to give them the methods they want if possible.

A second study in Indonesia by Pariani confirmed the crucial importance of giving women what they ask for (25). In a prospective study, 1,945 women initiating contraceptive use were asked about their choice of method before entering the clinic and what method they received, then followed 12 months later to determine method continuation. In this study, 86% of users were given their methods of choice. Nearly three-fourths of those whose choice was denied discontinued in the first year, compared with only 9% of those whose choice was granted. The interaction between whether choice was granted and whether the husband and wife concurred on the method choice was also important in determining continuation.

If the magnitude of this difference can be substantiated in other countries, this method choice intervention alone would reduce discontinuation rates significantly. It would also be relatively easy to implement in programs worldwide.

Better Counseling

Studies have shown that users are likely to have lower discontinuation rates if they are adequately counseled, particularly about what side-effects can be expected. The following results are illustrative:

- Affandi and associates reported that IUD users in Indonesia who routinely received counseling before and after insertion had a discontinuation of 10% after one year; those who were counseled only if they had complaints had a discontinuation rate of 48% (26).
- Counseled adolescents in the US had a one-year discontinuation rate of 22% and a failure rate of 5% for all methods; adolescents who were not counseled had a discontinuation rate of 70% and a failure rate of 30% (24).
- In Sri Lanka, IUD users who were not counseled had a discontinuation rate of 25% at 18 months, compared with 18% for those who received counseling (26).
- In Niger and the Gambia, FHI found insufficient counseling about potential side-effects to be a principal service delivery reason that women stop using contraception. In Niger, users who felt that they were not well counseled were nearly twice as likely to abandon contraception as were users who considered themselves to have been adequately warned of potential side-effects (37 percent versus 19 percent). In the Gambia, women who perceived they were not adequately counseled were three times as likely to stop contracepting as those who felt they received sufficient information about side-effects (46 percent versus 14 percent) (5).

Although no research has directly addressed the issue, counseling may be one of the best means to combat rumors and misinformation about contraceptive methods. Rumors and misinformation are widespread in many countries, and they seem to be major barriers to contraceptive use. In a survey among women age 18 to 45 in eight developing countries, the women worried that oral contraceptives caused cancer, sterility and birth defects (12). Almost

none were aware of their beneficial effect in reducing the risk of anemia. Women's perceptions of the risks of oral contraceptives affect continuation. Between 6 and 60 percent of ever-users had stopped taking oral contraceptives because of safety worries.

The benefits of counseling and their effect on discontinuation rates have been known for at least ten years, yet discontinuation remains high in most countries, especially discontinuation related to side-effects and health-related concerns. What changes must occur at the program level to make an impact on discontinuation rates?

The Interagency Meeting on Long-acting Progestins: Management of Bleeding Disturbances recommended that a counseling protocol be developed addressing health and safety issues, impact of bleeding on daily life and the effect it might have on sexual relations (14).

Medical Management

Table 3 shows some commonly used ways of medically managing side-effects associated with pills, injectables, Norplant and IUDs recommended by the Program for International Training in Health. Practitioners believe that these treatments work, although few randomized trials have been conducted and the effect on continuation has not been documented fully.

Bleeding Complaints

Some women cannot accept frequent or heavy bleeding despite counseling. Medical treatment for hormone-related bleeding disturbances has included:

- one to three weeks of combined oral contraceptive or of estrogen
- non-steroidal anti-inflammatory drugs, such as ibuprofen, which block the synthesis of prostaglandins.

In a study in Chile, women who were just beginning Norplant were randomly given any of four oral medications: levonorgestrel, 0.030 mg twice daily; ethinyl estradiol, 0.050 mg daily for 20 days; ibuprofen, 800 mg three times daily for five days; or placebo, once daily for 20 days. When the women experienced bleeding episodes longer than eight consecutive days, they were instructed to take their prescribed regimen. The three active agents produced fewer bleeding days and fewer episodes of treatment than did the placebo (6). Dorflinger reanalyzed the Diaz data, showing that ibuprofen markedly reduced the total days of bleeding with an average of only 14 treatment days during the year, compared with 44 for ethinyl estradiol (7).

The Interagency Meeting on Long-acting Progestins: Management of Bleeding Disturbances identified the following studies to evaluate possible treatment modalities (14):

Hormonal

- Oral contraceptives—over different dosings and time frames, possible treatment schedules might include 150 mg progestin / 30 µg EE for 21 or 28 days; versus 150 mg progestin / 30 µg EE for seven days.
- Estrogen—50 µg versus 20 µg for 21 days. Studies have indicated this treatment is effective but often has limited availability, is costly, and possibly influences contraceptive efficacy.
- Progestins—Levonorgestrel (L-Ng) 0.03 mg TID for 20 days.
- Combination: OCs and ibuprofen.

Nonhormonal

- Ibuprofen—800 mg TID for five days. Possible reduction of dose; use of and comparison with the cheapest NSAID available in-country.
- Aspirin—No prior research is available. Possibility of follow-up study with comparison with ibuprofen if NSAIDs are shown to be effective.

One WHO multicenter, international study shows that medical therapy for hormone-related bleeding may be no more helpful than counseling for improving method continuation. Women with bleeding lasting seven days or more during the first six months of DMPA use were given ethinyl estradiol, estrone sulfate, or a placebo; 93% of the estrogen group stopped bleeding, compared with 76% of the estrone sulfate group and 74% of the placebo group—a significant difference. However, the ethinyl estradiol advantage was marginal with an average reduction of one bleeding day and three spotting days compared with the other two groups. After one year, discontinuation for bleeding was similar for all three groups: 25, 17 and 17; overall discontinuation rates at one year were 44, 41 and 41 (38).

A suggested method of reducing bleeding during early months with DMPA is to give the next injection sooner than three months. This appears to result in the patient entering the amenorrhea phase sooner, although again there appear to have been no randomized trials (35).

For IUDs, medical management for heavy blood loss includes:

- antifibrinolytic agents
- nonsteroidal anti-inflammatory drugs
- iron supplementation
- changing either the IUD or its location (31)

The Interagency Meeting recognized that there is a vast amount of anecdotal experience with various treatments but limited published data and studies. Goals for treatment need clarification. Is the goal complete cessation of bleeding problems, a reduction in problems or temporary

improvements to get users "over the hump" in method use. The participants called for a protocol for medical management of bleeding (14).

Other Complaints

Other side-effects, such as headaches, nausea, weight gain and mood swings are often treated by switching pill formulations either to a lower-dose estrogen pill or to a progestin-only pill (4). But some practitioners are concerned that formulation change may increase noncompliance or pill discontinuation because switching may cause confusion about how to take the pill.

FHI carried out a study in Sri Lanka to evaluate whether a daily supplement of vitamins taken in conjunction with the pill might lead to reduced levels of side-effects and to higher continuation rates. Results indicated that vitamin supplementation was not a significant factor in reducing side-effects or improving continuation rates (1).

A second FHI study measured the effect of vitamin B6 on early side-effects and discontinuation associated with a low-dose pill in Mexico. There was no effect of the vitamins on common pill-related side-effects. In fact, the vitamin B6 group had a higher percentage of women who discontinued pills or were lost to follow-up (11).

Switching to Another Method

After discontinuing one method, the rates of choosing another vary widely. Only 38% of Egyptian women discontinuing because of health concerns and side-effects switched to another method. In the US, 80% of women stopping the pill chose another method. Sometimes the switch is to an equally or more effective method, but sometimes it is not:

- In Egypt, 31% switched to another modern method (from the pill to the IUD or from the IUD to the pill) and 1% were sterilized; six percent switched to less-effective methods (8).
- In the US, 13% of pill users switched to the IUD, 21% were sterilized and 47% switched to less effective methods (28). Data on how long the next method was used were not reported, but only 10% had no break in use at the time of the survey, and 12% reported an unintended pregnancy after switching methods.

Any time the cessation of contraception relies on contact with professional medical personnel (IUD, Norplant), advice on switching to another method should be given whenever the reason for stopping is not a desire to become pregnant.

Potential Areas of Research

Method Choice

- Document the magnitude of the effect of method choice on continuation in countries other than Indonesia; study both high and low prevalence countries in all regions of the world.

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- Determine why women are not given their initial method choices and what reasons for discontinuation are given by those who receive their choice and those who do not.
- Determine whether women are better able to tolerate side-effects if they received the method that they wanted.
- Determine the characteristics of a “discontinuer” for each contraceptive method and evaluate whether or not “risk screening” before method selection can improve continuation.

Counseling

- Determine what components of a counseling program affect the acceptance of side-effects (and continuation) the most (discussion of side-effects, options for other methods, etc.).
- Develop a methodology that identifies women at high-risk for side-effects, thus allowing programs to focus on counseling efforts.
- Determine the impact of counseling on discontinuation for health concerns.

Medical Management

- Determine the optimal point in the counseling process at which medical management of side-effects, especially bleeding, should be offered.
- Evaluate simple treatment regimens for bleeding problems where counseling alone does not work.
- Evaluate the consequences of pill-switching for women with side-effects on the persistence of these side-effects and continuation rates.

Method Switching

- Document the success of switching from one contraceptive to another with relation to total length of contraceptive use and the frequency of unintended pregnancy.
- Evaluate methods of counseling women to continue contraception when the cessation of contraceptive use does not rely on contact with medical personnel (pills, injectables).

In conclusion, family planning programs need guidelines to help improve contraceptive continuation rates for those women who do not want to become pregnant. Those guidelines should be based on the results of research and should address the areas of method choice, counseling, medical management of side-effects and method switching.

Table 1
Prevalence and One-Year Life Table Discontinuation Rates
by Selected Contraceptive Methods for Selected Countries

<u>Country/Method</u>	<u>Prevalence</u>	<u>Total Discontinuation</u>	<u>Discontinuation for Side-effects / Health</u>
Bangladesh			
Pill	17.4	45.0	25.6
Injectables	4.5	57.6	40.0
IUD	2.2	37.1	29.9
Philippines			
Pill	8.5	40.1	13.9
Injectables	0.1	--	--
IUD	3.0	22.4	7.6
Indonesia			
Pill	17.1	33.8	10.9
Injectables	15.2	29.1	15.0
IUD	10.3	15.2	8.4
Egypt			
Pill	12.9	42.4	18.1
Injectables	--	--	--
IUD	27.9	12.6	6.1
Zimbabwe			
Pill	33.1	15.5	4.7
Injectables	3.2	15.9	5.4
IUD	1.0	--	--
Dominican Republic			
Pill	9.8	63.2	23.8
Injectables	--	--	--
IUD	1.8	39.9	19.2
Peru			
Pill	5.7	56.7	28.6
Injectables	1.9	62.6	34.3
IUD	13.3	10.3	7.0

DHS Reports, Bangladesh, 1993-94; Philippines, 1993; Indonesia, 1994; Egypt, 1992; Zimbabwe, 1994; Dominican Republic, 1991; Peru, 1991-92

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Table 2
Typical Percentage of Users Discontinuing for Selected Side-effects
by Contraceptive Method

Side Effect	Pills ¹	Injectables ²	Norplant ³	IUD ⁴
Menstrual Problems	6%	9-24%	15-18%	10-15%
Headaches	6%	1-2%	1-2%	
Weight Change	2%	1-2%	1-2%	
Dizziness		1%		
Nausea	4%			

¹ Pratt, W.F. and Bachrach, C.A. What do women use when they stop using the pill? *Family Planning Perspectives*. Vol 19, No 6, Nov/Dec 1987. pp. 257-266.

² New Era for Injectables. *Population Reports*. August 1995. and Fraser, I.S. and Weisberg, E. A comprehensive review of injectable contraception with special emphasis on depot medroxyprogesterone acetate. *The Medical Journal of Australia*. 1981, 1, Spec. Suppl. 1: 1-20.

³ Sivin, I. International experience with Norplant and Norplant-2 contraceptives. *Studies in Family Planning*. Vol 19, No 2, Mar/Apr 1988. pp. 81-94.

⁴ Contraceptive Technology p. 352.

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Table 3
Medical Management of Side-effects by Contraceptive Method

1. Combined Oral Contraceptives

Side-effects	Management
Amenorrhea	Switch client to a pill with more estrogen for three cycles. If available, a 50mcg estrogen pill may be used. If client has already been on 50mcg estrogen for at least three months, switch to a pill with a progestin, which gives more endometrial support.
Spotting or Bleeding Between Periods	Switch client to a more potent progestin. If she is already using one of these, switch to a higher estrogen pill (50mcg if available, but not above 50mcg) for several cycles until spotting resolves.
Nausea	Switch client to a lower estrogen pill or a progestin-only method.
Headaches	Switch to a progestin-only or non-hormonal contraceptive method as appropriate.
Breast Tenderness	Decrease estrogen in pill, or if already on lowest estrogen, try a different progestin.
Loss of Libido	Ask if the client sees this as a serious problem. If "yes," switch to a pill with a more androgenic progestin or switch to a pill with 50mcg of estrogen.
Acne	Provide a low-androgen pill. If low-androgen COCs are not available, try an increase in estrogen dose (to a maximum of 50mcg) or try progestin-only pills.

2. Progestin-only Pills (POPs)

Side-effects	Management
Heavy Bleeding	Double up on POPs for two weeks to stop bleeding, then resume one daily.

3. Injectables

Side-effects	Management
Heavy Bleeding	If client is between eight and 12 weeks of the first or second injection, give another injection of DMPA or NET-EN. If client is on her third or later injection, then give one tablet daily of low dose COCs for 21 days. Give supplemental iron tablets.
Spotting or Bleeding Between Periods	Give COCs, one tablet daily for seven days if there are no estrogen-related precautions.

4. Norplant

Side-effects	Management
Heavy Bleeding	Provide one tablet daily of low-dose COCs for 21 days if there are no estrogen-related precautions. Give iron supplement.
Spotting or Bleeding Between Periods	Give COCs, one tablet daily for seven days if there are no estrogen-related precautions.

5. Intrauterine Devices

Side-effects	Management
Cramping	Provide an analgesic for mild cramping. For severe cramping, not due to menses, remove IUD. If distortion of the removed IUD or difficulties in removal, suggest that it was or had become improperly placed; replace with a new IUD immediately.
Irregular or Heavy Bleeding	Remove current IUD and insert a new (copper containing) IUD; give three months of iron tablets and reexamine in three months. (If progesting-containing IUDs are available, they should be used for women with severe amenia, to decrease blood loss.)

¹ Program for International Training in Health. *Guidelines for Clinical Procedures in Family Planning: A Reference for Trainers*. Second Edition, Revised 1993.

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Agenda Item 6 -- Review of Other FHI Programs

Wednesday, 4:15-5:00	Background Materials	Action from TAC	Speaker
a. Mellon Projects	Executive Summary	None	McKay
a. AIDSCAP	Executive Summary	None	Schellstede
b. International Master Contract for HIV Network for Efficacy Trials	Executive Summary	None	Cates
c. Women's Studies Project	Executive Summary	None	Williamson

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Andrew W. Mellon Foundation Sponsored Projects

Presented by Arlene McKay
to the Technical Advisory Committee
for Contraceptive Technology and Family Planning Research
June 19, 1996

Since 1983, The Mellon Foundation has provided support to Family Health International for contraceptive development and related activities. Primary activities supported by The Mellon Foundation include the Postdoctoral Fellowship Program in Contraceptive Technology, research on nonsurgical female sterilization, and collaboration among scientists and the public and private sectors involved in reproductive biology research and contraceptive development.

Postdoctoral Fellowship in Contraceptive Technology Research

The goal of the fellowship program is to increase the number of scientifically capable researchers in third world countries who will be able to conduct contraceptive development and evaluation research in their respective countries. Through the program, we seek to provide practical and comprehensive training in modern contraceptive research including:

- Protocol, information consent, and data forms design
- Study implementation and monitoring
- Data management and analysis
- Grant proposal development
- Scientific report and paper publishing

The fellowship program consists of a 12-month training program at FHI followed by a research project conducted at the Fellow's institution. A list of current and previous fellows is provided in Table 1.

Nonsurgical Female Sterilization

Mellon support has permitted FHI to conduct the retrospective study on the safety and efficacy of quinacrine hydrochloride pellets as a transcervical method of nonsurgical female sterilization in Chile. It has enabled us to analyze and prepare reports and articles for publication. In the Summer of 1995, one article was published in *Fertility and Sterility*. With Mellon funding, we were able to develop and initiate a follow-up to the original retrospective study that will allow us to examine the health experiences of the participants in the original retrospective study during the 4-year period, 1991-1995. In 1995, USAID provided funding for data collection, and in 1996, The Mellon Foundation is providing funding to complete data collection and cleaning, to analyze the results and to prepare a report for publication.

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In the last year, a number of organizations, including FHI, have attempted to assess the costs and benefits of continuing to develop quinacrine hydrochloride as an NSFS method and take it through all the steps to obtain regulatory approval from a national or international regulatory agency. In addition to the high cost and uncertainty of bringing the product to a stage where it could be considered for regulatory approval, there were a number of other concerns that have made it doubtful that quinacrine hydrochloride would ever receive regulatory approval. In December 1995, the Wellcome Trust held a consultative meeting on quinacrine to review the clinical and epidemiological perspectives on the potential benefits and risks of the use of quinacrine pellets for voluntary female sterilization. Dr. David Sokal of FHI was invited to present the clinical aspects of quinacrine as an NSFS method. Two toxicologists, both from the United Kingdom, were also present as were representatives of U.S. and U.K. agencies. There was agreement that it would be very difficult to obtain regulatory approval either in the U.S. or the U.K.

Subsequently, the Wellcome Trust appears to have decided that it would not fund any research related to quinacrine as an NSFS method. Therefore, there seem to be no funding sources for the basic toxicological research which is essential to any further development of quinacrine NSFS. FHI will maintain its stated policy of completing the Chile follow-up study and a similar study in Vietnam to assess the long-term safety issues. FHI has no plans to conduct any pre-clinical or clinical trials with quinacrine. We do believe that the research from Chile and Vietnam are important studies for the women and their service providers who need to know about the long-term effects of quinacrine NSFS.

Coordination of Mellon-funded Reproductive Biology Research Centers and Contraceptive Development Programs

This program reflects the need to bridge the fields of reproductive biology and contraceptive development. Other goals are to ensure communication between reproductive biologists and contraceptive development researchers, acquaint basic scientists with the contraceptive development process and the steps necessary to get a product to market and to identify possible new leads.

FHI is responsible for coordinating periodic meetings that bring together researchers from the Mellon Reproductive Biology Centers and contraceptive development programs, agencies supporting contraceptive development research, the pharmaceutical industry, and the U.S. Food and Drug Administration. The first meeting was held in November 1993, followed by a second meeting in April 1995.

The success of this initiative can be seen in the responses to the second Reproductive Biology Centers meeting in April 1995. Participants confirmed that the original concept of improving communication between basic reproductive scientists and those working in contraceptive development research is feasible. The second meeting took the initiative to a new level of involvement reflecting the diversity of interests that must be addressed in the contraceptive development process. In planning for the third meeting, the level of involvement from the different sectors indicates a growing commitment to improving communication and interaction among the major actors in the contraceptive development process.

The focus on the next meeting will be on building partnerships among the pharmaceutical industry, basic reproductive biology centers, and the contraceptive development agencies. This theme follows on the 1994 Institute of Medicine Workshop on Contraceptive Research and Development and the 1995 Bellagio Conference on Public/Private Sector Collaboration in Contraceptive Research and Development and the strategies being developed to involve industry in new contraceptive development. It is scheduled for November 1996. Planning began soon after the April 1995 meeting. A scientific steering committee comprised of Drs. Alan Corbin, Henry Gabelnick, Michael Harper, Mahmoud Fathalla, Carolyn Makinson, Roberto Rivera and Mr. Randy Dunson, is working to structure a meeting that will enhance the possibility of effective partnerships between the for-profit and non-profit sectors.

Each of the Reproductive Biology Centers will continue to sponsor its members. Other participants will be senior industry officials involved in contraceptive development, representatives of Mellon-funded reproductive biology centers, representatives of the Rockefeller-funded Contraception-21 research centers, as well as donor and regulatory agencies involved in contraceptive development, such as USAID, NICHD, WHO, and FDA. There is considerable interest in the meeting as indicated by the number of people who have already accepted an invitation to attend.

The importance of building bridges among the different sectors involved in contraceptive development is reflected in the decision of The Rockefeller Foundation to co-sponsor the third meeting. FHI is pleased that The Mellon Foundation and The Rockefeller Foundation, two foundations that are strongly committed to ensuring that there are more effective, efficient, safe, and economical contraceptive options, are now co-sponsoring both the Contraceptive Technology Research Fellowship and the Coordination of Reproductive Biology Centers and Contraceptive Development Program.

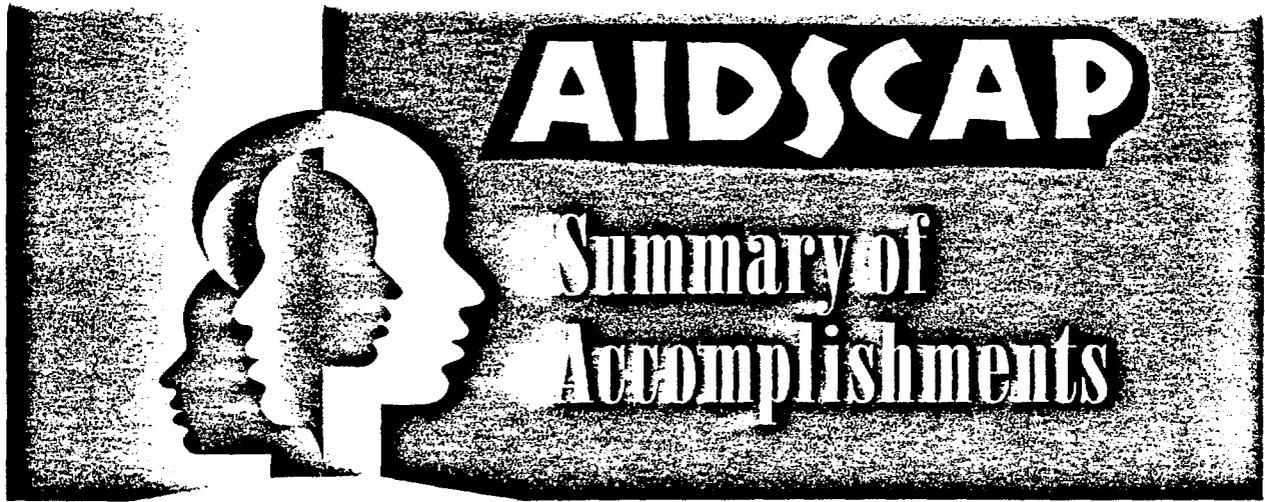
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Table 1. Postdoctoral Fellowship in Contraceptive Technology Research

<u>Year</u>	<u>Fellow/Affiliation</u>	<u>Re-entry Research Project</u>
1992-1993	Dr. Xu Jin-Sun People's Republic of China	"Comparative Study of Two Immediate Postplacental Vaginal Insertion Techniques Used to Apply the TCU 380A IUD"
1993-1994	Dr. Carlos Petta CEMICAMP, University of Campinas, Brazil	"Timing of Onset of Contraceptive Effectiveness in Depo-Provera Users as Determined by Changes in Cervical Mucus"
1994-1995	Dr. Joseph Ruminjo Department of Ob/Gyn University of Nairobi, Kenya	"Comparison of Acceptability of Depo-Provera and Cyclofem"
1995-1996	Dr. Gamal Sayed Department of Ob/Gyn University of Assiut, Egypt	"Effects of the LNG IUD on Breastfeeding"
1996-1997*	1. Dr. Marta Durand-Carbajal Department of Reproductive Biology, Instituto Nacional de la Nutrición, Mexico 2. Dr. Kamal Hazari Institute for Research in Reproduction, Mumbai, India	

*Beginning in 1996-1997, an additional fellow will be funded by The Rockefeller Foundation.

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Funded by the United States Agency for International Development (USAID) and implemented by Family Health International, the AIDS Control and Prevention (AIDSCAP) Project has:

- Reached more than 3.2 million people with HIV/AIDS prevention education.
- Trained almost 59,000 people to support HIV/AIDS programs in their countries.
- Distributed or sold over 118 million condoms (90 percent sold through social marketing projects).
- Directed HIV/AIDS prevention programs in over 40 countries.
- Provided capacity building to more than 210 governmental and nongovernmental organizations (NGOs) to design, manage and evaluate HIV/AIDS prevention programs. AIDSCAP capacity building assistance includes technical, organizational and management skill building, and network and organizational system strengthening.
- Built consensus among government ministries, the USAID Mission, NGOs and other donors in each of 20 countries on a multiyear HIV prevention strategy and a detailed plan for translating that strategy into action.

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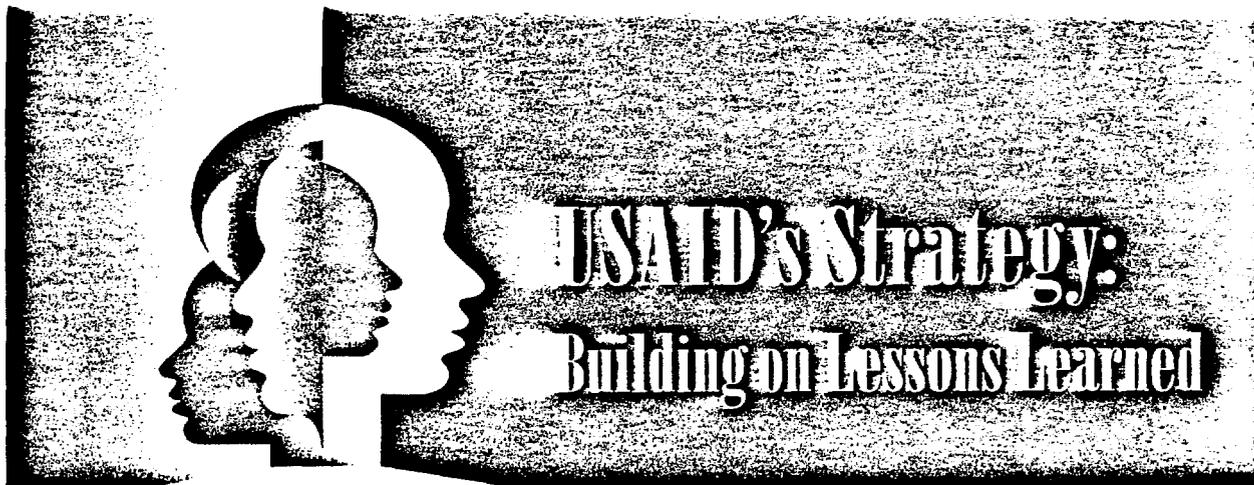


AIDSCAP builds local capacity to prevent HIV/AIDS by working with government ministries and nongovernmental organizations to design, implement and evaluate prevention programs. Almost 80 percent of AIDSCAP activities in developing countries are carried out by NGOs and U.S.-based PVOs.

Family Health International spearheads the project in collaboration with its nine subcontractors:

- The Program for Appropriate Technology in Health, Prospect Associates, and Ogilvy Adams & Rinehart for behavior change communication;
- Population Services International (PSI) and John Snow, Incorporated (JSI), for condom supply and distribution;
- The University of Washington at Seattle, the University of North Carolina at Chapel Hill, and the Institute for Tropical Medicine in Antwerp for STD prevention and control; and
- The Center for AIDS Prevention Studies, University of California, San Francisco, for behavioral research.

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AIDSCAP was designed to capitalize on USAID's previous experience in HIV prevention through the AIDSTECH and AIDSCOM projects.

The project focuses on preventing sexual transmission of HIV, which accounts for three-fourths of all HIV transmission worldwide. Its approach incorporates the three strategies that have proved most effective in preventing HIV: (1) encouraging people to change their behavior to avoid HIV infection or transmission; (2) improving treatment and prevention of other sexually transmitted diseases (STDs) that enhance the spread of HIV; and (3) making affordable, acceptable and high-quality condoms readily available.

AIDSCAP relies on the proven ability of PVOs and NGOs to reach communities with AIDS prevention messages and condoms.

In order to have a measurable impact on the epidemic, AIDSCAP concentrates most of its resources in a select number of "priority" countries. These countries include Cameroon, Ethiopia, Kenya, Nigeria, Rwanda, Senegal and Tanzania in Africa; India, Indonesia and Thailand in Asia; and Brazil, the Dominican Republic, Haiti, Honduras and Jamaica in Latin America and the Caribbean. AIDSCAP also has major programs in South Africa, Zimbabwe and Nepal. The project provides technical assistance to other USAID-supported countries upon request.

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Demand for the project's services has far exceeded expectations. AIDSCAP was originally expected to design and support comprehensive prevention programs in 12 to 15 countries and to provide limited technical assistance in a small number of additional countries. Since fiscal year (FY) 1992, AIDSCAP has designed large-scale programs in 22 countries, implemented projects in another 22 countries, and provided technical assistance in another 5.

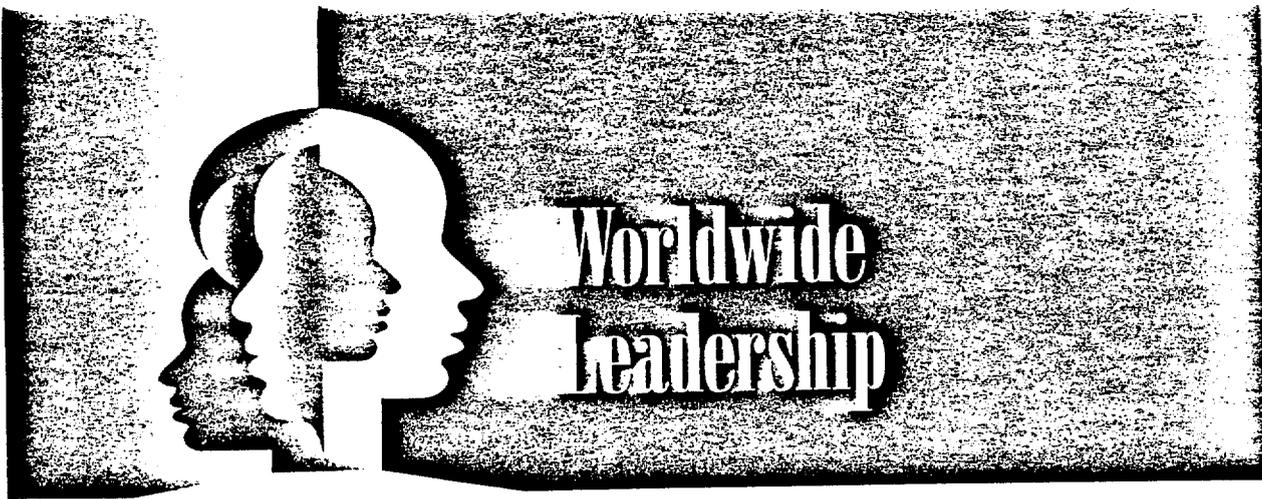
AIDSCAP was expected to work in four countries during its first year. But by the end of FY 1992, the project had responded to Mission requests for assistance in 15 countries.

As of June 1995, USAID Missions and Bureaus had committed a total of \$94.2 million to the AIDSCAP Project, of which \$77.7 million has already been received (against a life-of-project target of \$100 million).

Host-country governments also look to AIDSCAP for technical advice and strategic guidance. In Brazil, for example, AIDSCAP has helped the government to establish a national condom logistics system, design a strategy to include AIDS education in the school curriculum, and provided technical assistance to the National HIV/AIDS/STD Prevention and Control Program. In addition, AIDSCAP has participated as a member of the State Scientific Commission for STDs and AIDS Prevention, which advises the State Secretary of Health on policies and scientific matters.

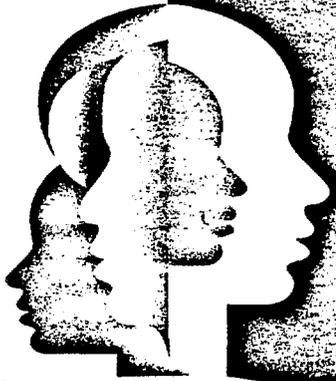
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AIDSCAP works closely with the World Health Organization and other multilateral and bilateral organizations to coordinate activities in developing countries and provide guidance to HIV/AIDS prevention programs worldwide. Examples include AIDSCAP's collaboration with:

- the World Health Organization's Global Programme on AIDS (WHO/GPA), to validate proposed guidelines for treating STDs in areas where laboratory services are not available or too expensive and to develop standard measures for evaluating HIV prevention programs around the world.
- UNICEF, to provide technical assistance in evaluation and information dissemination to UNICEF field offices.
- WHO/GPA and the Program for Appropriate Technology in Health to develop diagnostic tests to detect STDs, especially in women.
- WHO/GPA and the Center for AIDS Prevention Studies, to carry out a definitive study on the effectiveness of voluntary AIDS counseling and testing in preventing HIV transmission.



Leveraging Resources

AIDS prevention programs throughout the world are constrained by inadequate supplies of condoms and drugs for STDs. To overcome this limitation, AIDSCAP works with governments and the private sector to find new sources of funding. As a result of the efforts of PSI and its affiliate DKT International to generate condom donations, more than 30 percent of the condoms distributed or sold in AIDSCAP projects in 1994 came from non-USAID sources.

AIDSCAP leveraged a commitment of at least US \$7,500 a year from the National Railways of Zimbabwe (NRZ) for phase two of their HIV/AIDS prevention project. In phase one of the project NRZ developed an organizational HIV prevention policy, trained 26 coordinators and 69 peer educators, and started HIV awareness-raising activities at worksites. With technical assistance from AIDSCAP, 141 more peer educators will be trained and HIV prevention counseling and education activities will be expanded to all 60 railway sites.

AIDSCAP also works with private industry to convince business owners and managers that AIDS prevention makes good business sense. The Private Sector AIDS Policy Presentation (PSAPP) is one way in which AIDSCAP provides information and guidelines to help implement HIV/AIDS prevention policies and programs in the workplace. In a modular format, PSAPP presents guidance in all phases of workplace HIV/AIDS prevention program development, including training of trainers, developing presentations and organizational policy, and conducting one-day workshops and workplace needs assessments.

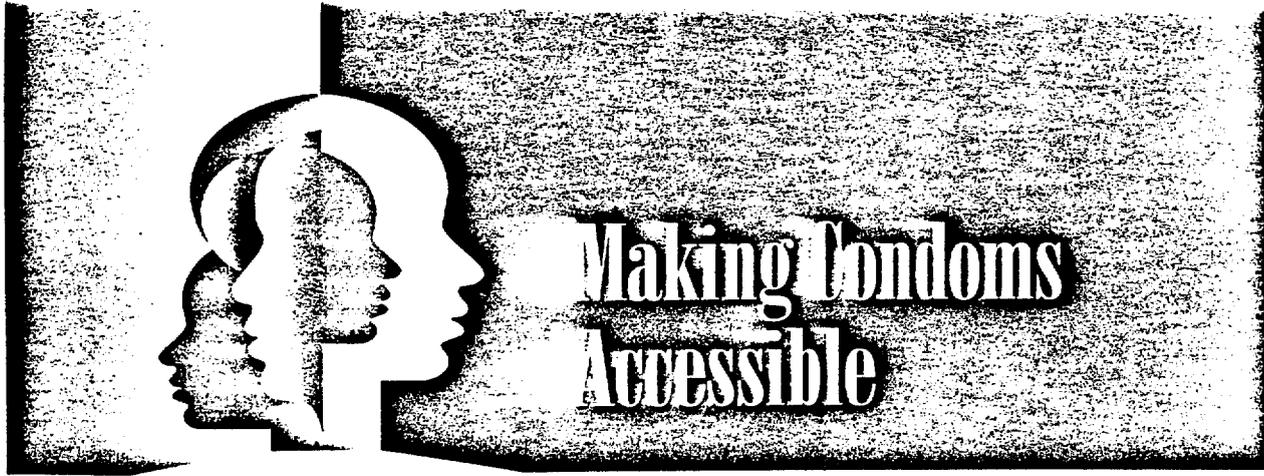
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AIDSCAP works with government officials and other decision makers to help them develop and sustain policies to support HIV/AIDS prevention.

- In Honduras, an AIDSCAP presentation of the projected social and economic impact of AIDS given to 350 government ministers, journalists, and business, community and religious leaders led to the creation of a senior-level AIDS advisory committee chaired by the First Lady of Honduras, to widespread media attention and to increased commitment from donors of resources for prevention.
- A similar presentation to decision makers in the Dominican Republic contributed to the passage of new legislation outlawing discrimination against people with HIV or AIDS and mandating that every ministry develop a plan to address the epidemic.
- Indonesian policy makers who participated in AIDSCAP policy tours in Thailand continue to meet regularly to discuss how they can use what they learned from the Thai approach to improve HIV/AIDS prevention efforts in their own country.
- In Brazil, the federal government eliminated a 15 percent import tax on condoms, making them more affordable for lower-income people. The decision to eliminate an import duty on condoms was the result of a lengthy process of analytical review with assistance from AIDSCAP and advocacy by the AIDSCAP resident advisor and other AIDS prevention activists.

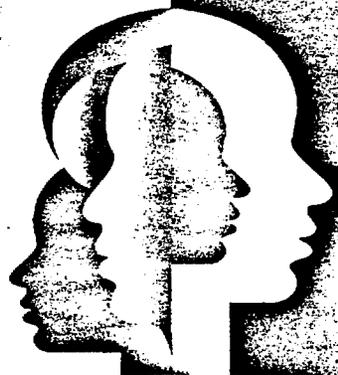
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AIDSCAP improves access to condoms and promotes their correct and consistent use through social marketing and by distributing free condoms in many of its community-based activities. Condom sales and distribution figures continue to rise. During the first five months of 1995, AIDSCAP distributed more than 24.9 million condoms.

- In Ethiopia, PSI began condom social marketing even before the fall of the communist government. In 1991, 3.8 million condoms were sold. With the addition of AIDSCAP support, as of April 1995 33.3 million condoms had been sold.
- In Haiti, despite difficult conditions and a history of opposition to condom use in the country, condom sales rose from 580,000 in 1991 to 4 million in 1993. By April 1995, 10.6 million condoms had been sold.
- In Rwanda, AIDSCAP/PSI social marketing efforts have continued in spite of civil strife. PSI was forced to leave Rwanda in April 1994 but returned in March 1995. A total of 1.2 million condoms have been sold and 1.1 million have been distributed to Rwandan refugees in camps in Tanzania.
- In the Dominican Republic, AIDSCAP and JSI have instituted a private sector leveraging program to complement the existing condom distribution program. USAID is providing 9 million condoms for this two-year activity.

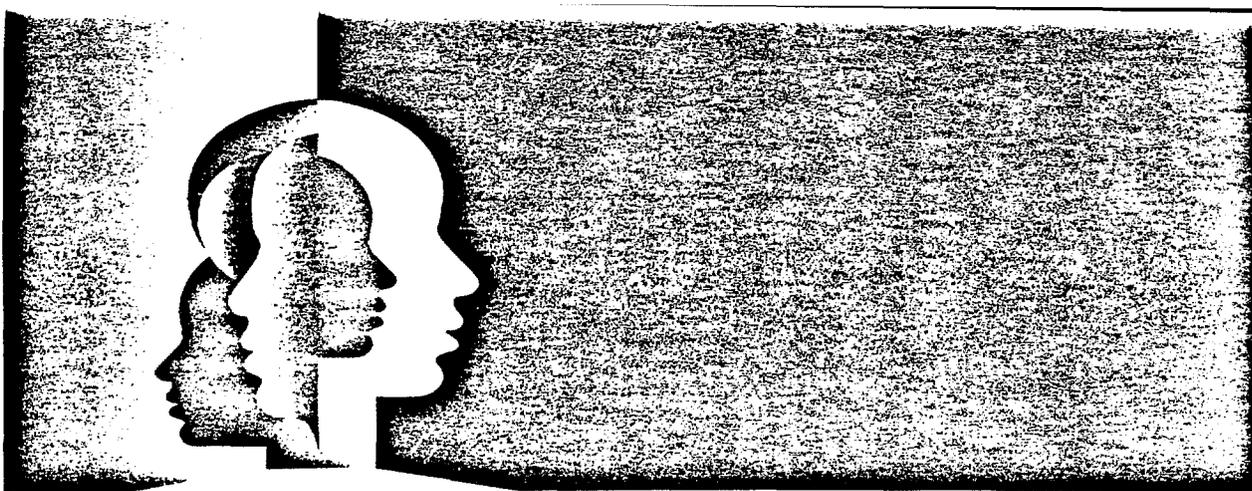
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Innovative Approaches

AIDSCAP pioneers innovative ways to reach people at risk of HIV infection through targeted prevention messages, helps to change social norms to support safer sexual behavior, and improves access to condoms and STD treatment. Examples include the following:

- AIDSCAP is the only internationally funded program that blankets large communities of hundreds of thousands of people with the three core prevention interventions (behavior change, condoms, and STD control) simultaneously. AIDSCAP's programs are being evaluated before, during and after implementation to assess the effectiveness of this strategy.
- Recognizing that AIDS does not respect national boundaries, AIDSCAP has identified "areas of affinity" in Asia that are related culturally, politically, economically, demographically or epidemiologically. This unique strategy allows AIDSCAP to design interventions that reach mobile populations, such as transport workers, business travelers, commercial sex workers and migrant laborers, who may be at higher risk of acquiring HIV infection than more stable populations. Multilingual, multicultural interventions at special sites (border crossings, hotels on both sides of a border, clandestine commercial sex establishments) also distinguish this strategy from conventional prevention programs.
- In Thailand, AIDSCAP is testing a community mobilization model for behavior change that targets sexually active young adults in the city of Bangkok and reaches them through their social networks at work and in the community. AIDSCAP supports an



AIDS Center for the Bangkok Metropolitan Administration, which serves as the focal point for all prevention activities. Here private- and public-sector organizations working in HIV prevention meet monthly to share information on successful interventions and changes in risk behavior and to coordinate governmental and nongovernmental efforts.

- In Cameroon, AIDSCAP designed and pilot tested an innovative but controversial strategy for improving access to STD treatment. Although this approach, which uses private-sector health services for STD diagnosis and sale of complete STD treatment kits, did not prove feasible in Cameroon, five other countries have expressed interest in adapting the model. These pilot projects could result in improved access to quality treatment for millions of people in developing countries, where most STDs go untreated.
- The project's Rapid Response Program enables AIDSCAP resident advisors to provide support quickly to local NGOs for small, community-based interventions. Funding of less than \$5,000 for Rapid Response activities can be awarded within a few weeks. Examples of the more than 131 activities funded by the Rapid Response Program include World AIDS Day AIDS-awareness activities, drama presentations and the production of educational materials. In Kenya, for example, AIDSCAP supported performances of a play, "All Positive," by the Rotaract Club of the University of Nairobi at 21 universities, colleges and training institutions.

Summary
FHI Technical Advisory Committee
June 19, 1996

**FHI's HIVNET INTERNATIONAL COHORTS:
PAST ACCOMPLISHMENTS, PRESENT STATUS, AND FUTURE POTENTIAL**

Willard Cates, Jr., M.D., M.P.H.
for the HIVNET International Investigators Group
Family Health International, Research Triangle Park, North Carolina

Background. Using FHI as the International Master Contractor, the NIAID's HIV Network for Efficacy Trials (HIVNET) is currently sponsoring projects in nine countries: five in Africa, two in Asia, and two in the Americas. Study participants include a range of high-risk populations, including commercial sex workers, military recruits, truck drivers, men who have sex with men, persons attending STD clinics, and infants born to HIV seropositive mothers.

Past Accomplishments. The HIVNET international cohorts of high-risk, seronegative individuals have already paid rich scientific dividends. These cohorts have helped elucidate biologic and behavioral cofactors of HIV transmission under conditions which would occur during typical efficacy trials of HIV preventive interventions. Past scientific contributions from these studies have documented 1) partial immunity provided by previous HIV-2 infection, 2) the association of hormonal contraception with acquisition of HIV, 3) the association of both ulcerative and inflammatory STDs with HIV seroconversion, 4) the lack of impact of vaginal washing on reducing perinatal HIV transmission, and 5) decreasing HIV incidence among male clients using condoms with commercial sex workers.

Present Status. These HIVNET international cohorts provide both an ongoing research infrastructure able to conduct, as well as a variety of study populations able to participate in, HIV preventive intervention trials. The current seroincidence among these cohorts ranges from 2% to 15%, and the follow-up rates range from 70% to 98%.

Future Potential. These HIVNET international cohorts are able to evaluate a wide variety of HIV interventions. Protocols are currently being finalized, and investigations are being initiated. These include an evaluation of low-dose nonoxynol-9 as a vaginal microbicide; a Phase I evaluation of acid buffer gel as an additional microbicide; a Phase I study of short-term oral nevirapine to reduce maternal-infant HIV transmission; an evaluation of behavioral interventions to increase the use of condoms in discordant stable sex partnerships; and a Phase I study of the safety and immunogenicity of live recombinant canarypox HIV vaccine. In addition, serum samples acquired and stored from these international cohorts are being evaluated for antigenic variability of HIV and early markers of HIV infection.

Conclusion. The HIVNET international cohorts provide a multi-center, collaborative, flexible research infrastructure able to implement large-scale HIV prevention efficacy trials. HIVNET's unique strength lies in its use of multidisciplinary collaborators, involving combinations of behavioral and biomedical (whether molecular or clinical) skills, to evaluate the mix of imperfect, though cumulatively-effective, interventions necessary to reverse the global HIV pandemic. Just as with combination chemotherapy for HIV-infected individuals, combination prevention approaches among high prevalence populations--evaluated through HIVNET--will be essential to reduce HIV transmission.

Table 1
HIVNET International Cohorts
Past Accomplishments

Country	Cohort	Selected Scientific Conclusion
<u>Africa</u>		
Kenya	Commercial Sex Workers	Hormonal contraception increased risk of HIV acquisition
	Truck Drivers	Educational intervention increased safer behaviors
Malawi	Pregnant Women	Vaginal washing did not protect against MIT
Senegal	Commercial Sex Workers	HIV-2 conferred partial immunity to HIV-1
Uganda	Military Recruits	Prophylactic vaccine perceptions were inaccurate
Zimbabwe	Factory Workers	Educational intervention increased condom use in stable partnerships
<u>Asia</u>		
India	STD Clinic Attendees	STD increased risk of HIV acquisition
Thailand	Royal Thai Army	Condom use with sex workers decreased HIV incidence in young Thai men
<u>Americas</u>		
Brazil	Men Who Have Sex With Men	CD4 models predicted HIV disease progression
Haiti	Pregnant Women	Utility of HIV IgA for diagnosis was demonstrated

HIVNET COHORTS
1996 Update

Site	Cohort	Number	1995		1-Year Follow-Up
			HIV Incidence	HIV Prevalence	
Uganda	Military	241	3.5%	16%	80%
	Antenatal	1000	3%	20%	94%
Senegal	CSW	618	2%	9%	98%
Kenya	CSW	300	12.4%	55%	85%
	Truck Drivers	559	4.2%	17%	70%
Malawi	Antenatal	700	5%	30%	81%
Zimbabwe	Factory Workers	1807	2.3%	19%	80%
Thailand	STD Clinic (Male/Female)	1368	3.2% male 3.7% female	11.9% male 6.1% female	92%
	Royal Thai Army	822	0.08%	7%	90%
India	STD Clinic (Male/Female)	1134	10.2%	21.5%	75%
Haiti	Antenatal	Early recruitment	1.5%	10%	---
Brazil	MSM	Early recruitment	2.4%	15%	---

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HIVNET RESEARCH AGENDA--FUTURE POTENTIAL

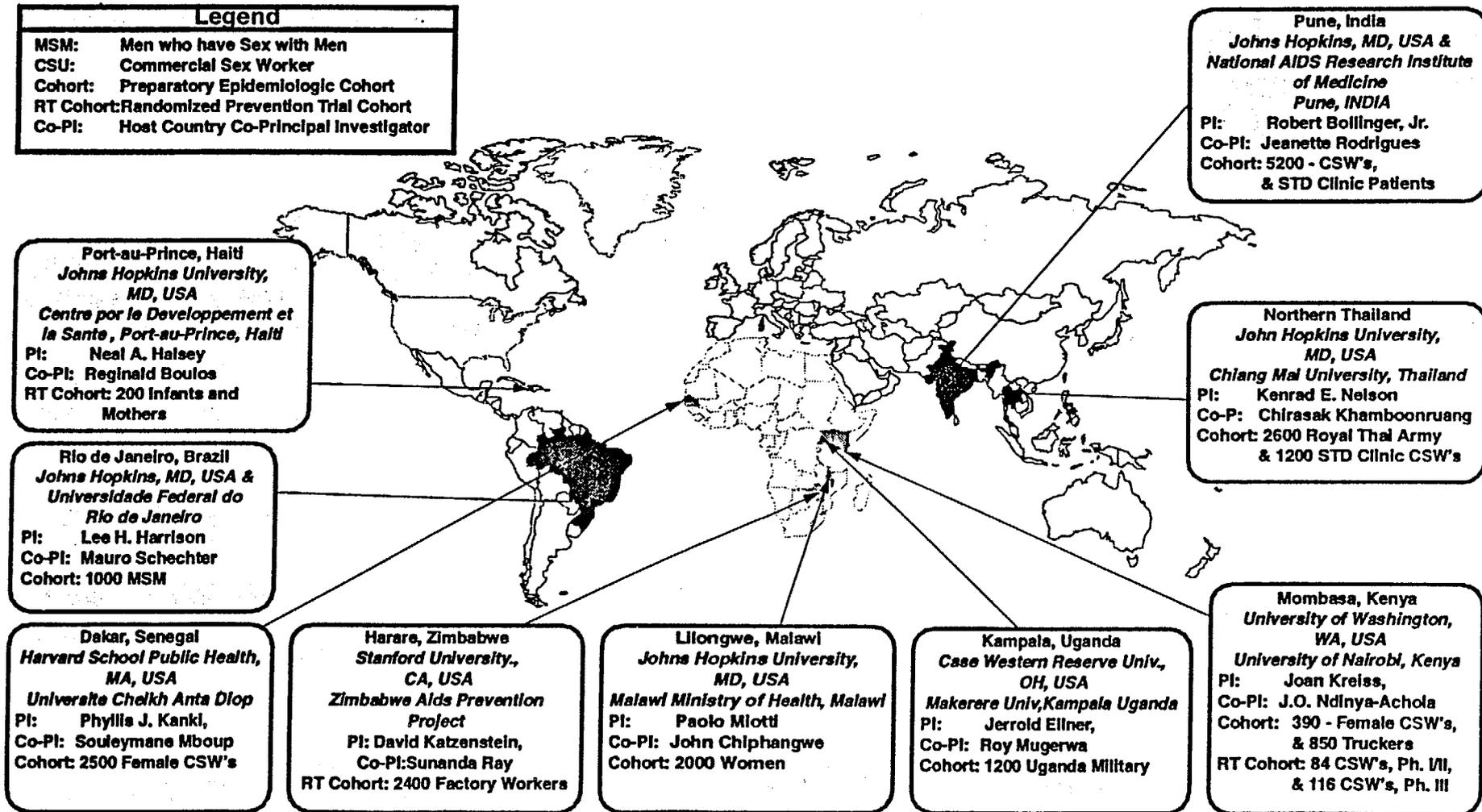
	Pretrial Prep	Phase I/II	Phase III
Vaccines	VPS: Domestic IPP/acute Exposed/uninfected Viral characterization	Phase I Live Recombinant Canarypox (Thai Gp 120)	(Phase III 98)
Behaviorial	VPS: Domestic International Risk assessment/informed consent R+A counseling Community study T-ACASI - Risk assessment ? ACASI: Domestic/International [NIDA/NIMH]	? Condom use Stable partners - Thailand/ India/Malawi/Uganda ? Syringe exchange - New York	Peer counseling - Zimbabwe
Microbicides/STDs	? HSV-2 prevalence - USA ? Viral load in semen - Malawi DAIDS Preclinical Development Program	Phase I Vaginal microbicides - Domestic Phase I/II Vaginal microbicides - International Phase I Rectal microbicides	N9 gel - Kenya N9 gel - WHO (N9 film - Cameroon) (Mass STD treatment - Uganda)
Perinatal/Peds	? STDs - Mother to Infant Transmission - Malawi, Zimbabwe ? HIV in breast milk - Haiti	Nevirapine mother/child - Uganda [ACTG] [AVEG]	Newborn HIVIG - Haiti Vaginal washing - Malawi Oral AZT mother/child - Uganda (Oral AZT - Haiti) (Maternal HIVIG - Uganda) (Formula intervention - Kenya) (AZT - Thailand, Ivory Coast) (Vitamin A - Malawi)

- Bold** = HIVNET protocols
? = Being revised per SG recommendations for further consideration
() = Ongoing studies outside of HIVNET resources

HIV Network for Efficacy Trials (HIVNET) International Study Centers

Legend

MSM: Men who have Sex with Men
 CSU: Commercial Sex Worker
 Cohort: Preparatory Epidemiologic Cohort
 RT Cohort: Randomized Prevention Trial Cohort
 Co-PI: Host Country Co-Principal Investigator



Women's Studies Project

Cooperating Agency: Family Health International
Project Number: 936-3060
Agreement Number: CCP-3060-A-00-3021-00
Duration: September 1993 - September 1998
Geographic Scope: Worldwide
Level of funding: \$8.6 million over five years

Purpose: To conduct a program of research and other activities on the impact of family planning on women's lives.

Strengthen Capabilities: Improve family planning and related reproductive health policies and programs through increased knowledge of the needs and perspectives of women.

Examples of Policy Activities:

This project is undertaking social science and behavioral research on the immediate and long-term consequences for women of FP programs and methods. Multiple research projects are under way in each of six emphasis countries: Bolivia, Brazil, Egypt, Indonesia, the Philippines and Zimbabwe. Single studies are being conducted in Jamaica and Mali as well as China (with funds from The Rockefeller Foundation). Secondary analysis of data has been completed in Bangladesh, Nigeria and Malaysia and numerous papers have already been published or have been submitted for publication. Secondary analyses from the Philippines will be completed in June, 1996.

Over twenty field research projects were initiated after needs assessment visits, which included visits with USAID Missions, government officials, NGOs, women's advocates, health providers and researchers. In-country Advisory Committees have been established in each emphasis country to guide research and plan for dissemination of project results. Among the topics being explored in the Women's Studies Project are the impact of family planning on women's work and income; the impact of family planning on women's roles within the household and family; the use and non-use of family planning by adolescents; the impact of sterilization on women's lives; women's roles as family planning providers; women's perceptions of male attitudes about family planning; and the psychosocial impact of family planning for women.

Research papers published as part of the project include "The Impact of Family Planning on Women's Lives: Toward a Conceptual Framework and Research Agenda" and "From Rhetoric to Reality: Delivering Reproductive Health Promises through Integrated Services." Forthcoming research papers include a conceptual framework for the impact of family planning on women's work, a study documentation manual, and a report on male involvement in FP programs. Three case studies on women-centered health programs are being done, highlighting programs in Jamaica, the Philippines and Bolivia. The Jamaica case study is

about to be published. The Women's Studies Project periodically publishes a newsletter, which provides an update on research and results.

The WSP has an international Technical Advisory Group which meets at least once a year. The FHI staff working on the WSP come from a wide variety of academic disciplines as well as a number of different divisions within FHI.

Contact:

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Agenda Item 7 – Reception and Dinner			
Wednesday, 5:30-8:00	Background Materials	Action from TAC	Coordinator
Reception and dinner at FHI	None	None	Bowden

Transportation to FHI:

At 5:15 p.m., TAC members and invited observers will be transported to FHI Headquarters from the Radisson Governors Inn by FHI staff volunteers (or Radisson shuttle--to be determined).

Reception and Dinner:

A reception and buffet dinner, catered by Eats of Eden, will begin at 5:30 p.m. in the Training Center, second floor, FHI Headquarters building.

Menu

*Assorted Cheeses and Fruit
 Breast of Chicken and Julienne Vegetables
 in Creamed Herb Wine Sauce
 Rice
 Garden Salad
 Homemade Chive Biscuits
 Belgian Chocolate Cheesecake
 Key Lime Chiffon
 Brown Sugar Pound Cake
 Iced Tea
 Lemonade
 Coffee*

Transportation to Hotel:

The Radisson Governors Inn will provide transportation from FHI to the hotel at 8:15 p.m.

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**Agenda Item 8 – Technical Discussion: New Directions in Contraceptive Technology:
Implications for FHI's Future**

Thursday, 8:30-10:30	Background Materials	Action from TAC	Moderator
<p>FHI Presenters: Robinson Sokal Cates</p> <p>TAC Discussants: Diaz Norsigian</p>	<ol style="list-style-type: none"> 1. "Rethinking FHI's Contraceptive Development Program" (B. Robinson and N. Williamson) 2. New Directions in Contraceptive Technology 3. Institute of Medicine. Contraceptive Research and Development. Looking to the Future. Washington, DC: National Academy Press, May 1996. 	<p>Recommend FHI Program Priorities</p>	<p>Grimes</p>

FHI's quarter century of contributions to reproductive health have focused on three main goals: 1) increasing contraceptive choices; 2) preventing STD/HIV; and 3) improving the quality of life. Our current Corporate Report (to be distributed at the TAC meeting) builds on these themes, and the background information for this technical discussion presents several views of how we can continue to advance contraceptive technology within a world of finite resources.

Because of the overlapping fields of family planning and STDs, safety and efficacy studies of contraceptives which help prevent *both* unplanned pregnancy and genital infections will be crucial. Female-controlled barrier methods of contraception, as well as ways to build in creative approaches to dual method use, have already been discussed on the TAC agenda. Other priorities include evaluating FHI's prototype twin-aperture plastic condom, as well as investigating the potential for non-prescription cervical barrier methods.

In addition, FHI will continue to use social sciences research to establish factors of acceptability and compliance (e.g., lower discontinuation rates). FHI will also use its expertise to communicate the noncontraceptive health benefits of hormonal contraception. By incorporating the views of consumers and women's health advocates earlier in the natural history of contraceptive development and evaluation, better methods (or combinations of methods) can be found.

Questions we would like TAC to consider include:

1. Are the criteria FHI is using for selection of new leads in contraceptive technology appropriate? What additional criteria, if any, should we be using?
2. Which of the categories of vaginal barrier methods should FHI emphasize for further research?
 - OTC diaphragm or diaphragm-like devices
 - New/better vaginal sponge
 - Improved vaginal spermicides/microbicides
 - Other
3. Is a continued focus on barrier methods, hormonal methods, and IUDs the most appropriate for FHI in meeting the contraceptive technology and reproductive health research needs of the next millennium?

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New Directions in Contraceptive Technology

Prepared for
Technical Advisory Committee Meeting
Family Health International
June 20, 1996

FHI staff have reviewed a large number of potential new contraceptive methods that have been proposed or are already under development (Table 1). Only partial information is available on some of these methods.

Based on the criteria presented in Table 2, the projects/products we consider most promising for FHI to pursue are described in Table 3.

For each method, we hope to demonstrate early in the development process some assurance of:

- 1) support from women's or men's health advocates and/or consumers for the development of this method, and
- 2) the potential for collaboration with a public or private sector partner(s) in the eventual production and marketing of a product, and
- 3) a demonstrated FHI capability or competitive advantage to conduct the work.

A few of the projects that we have identified are at a relatively early stage of development. FHI collaboration with researchers working on early phases of product development can help stimulate basic researchers to do more clinically relevant research. In addition, by providing appropriate advice on regulatory issues, FHI can help facilitate the process of product development.

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Table 1.
**Family Health International
 New Leads Strategic Planning Group**

Method	Description	Contact/Sponsor or Current Work
IUDs		
LNg IUD		?
Frameless IUD		D. Wildmeersch
ICD	LNg releasing intracervical device	T. Luukkainen
Immunocontraception: Active (Vaccines)		
Female:		
Live recomb. Salmonella vector		CONRAD
Zona pellucida		CONRAD
SP-10		CONRAD
TCTE		CONRAD
LDH-C4		CONRAD
Male:		
LHRH		Pop Council
Immunocontraception: Passive (monoclonal antibodies)		
Female:		
Anti sperm		John Herr
Anti HCG		AKZO N. V. Pharm.
Male:		
none?		
Male Systemic, nonhormonal		
Hexoseaminidase inhibitors		J. Hall, NC State
IOCD compounds		CONRAD
Female Systemic, nonhormonal		
PMPA	Nucleotide for post-exposure prophylaxis	Gilead Corp.

**Family Health International
New Leads Strategic Planning Group**

Method	Description	Contact/Sponsor or Current Work
Hormonals (female)		
Norplant 2		Pop Council
Capronor		RTI
Mifepristone		
Mesigyna	Monthly inject.	
Cyclofem	Monthly inject.	
Progesterone releasing vag ring		Pop Council/CONRAD
Progesterone microspheres		CONRAD
Natural steroid sustained release		CONRAD
NESTERONE transdermal gel		Pop Council
NESTERONE vaginal ring		Pop Council
NESTERONE implant		Pop Council
Progest. + mifepristone OC		CONRAD
Generic implant with LNG		CONRAD
Trimegestone		Roussel Uclaf
Dienogest		Jenapharm
Novel estrogenic and progestogenic pharmacophores	Nonsteroidal; selective/specific targets	Ligand; Ortho
Uniject	DMPA	PATH
"Uniject"-like disposable syringe	immunization uses	PATH?
Uniplant	Nomegestrol	South to South
Implanon	3-ketodeso-gestrel	Organon/AKZO w/ EVA
Vaginal Contraceptive Pill	Amorete	South to South / Ibfarma (Brazil)
Hormonals (male)		
Testosterone + LNG injections		CONRAD
Test. + desogestrel injections		CONRAD
Test. microcapsule injections		CONRAD
LHRH analogue + MENT implant		Pop Council
LHRH + T injection		CONRAD/NICHD
Sterilization (female)		
Quinacrine pellets	Follow up studies only, no clinical trials planned	FHI (surveys only)
Copper microcoil in Fallopian tube		Conceptus, Inc.
Ovablock	Formed in place silicone	HRP/AVSC
Sterilization (male)		
SHUG		CONRAD
Copper		CONRAD
Vasoclude		Pop Council
Vas Block	formed in place silicone	HRP/AVSC

**Family Health International
New Leads Strategic Planning Group**

Method	Description	Contact/Sponsor or Current Work
Barriers, physical		
Semina diaphragm	Silicone	Luisa Eluf/Brazil
Ortho diaphragm	Latex diaphragm	Ortho
Pharmatex sponge	BZK	Innothera/France
Protectaid sponge	Na cholate, N9, BZK	AXCAN/Canada
Avert* sponge	N9	Gynetech
Femcap	Cervical cap	CONRAD
Lea's Shield	Diaphragm-like device	YAMA, Inc
Novel silicone diaphragm		CONRAD
Barriers, chemical (spermicides/microbicides)		
New N9 vaginal films		CONRAD
New BZK vaginal films		CONRAD
Integra polysaccharide		CONRAD
Sulfated polysaccharides	Non-carrageenan compounds	Pop Council
Carrageenan	Not currently studied, enhances chlamydia in animal model	Pop Council
C31G	Mixture of 2 surfactants	BioSyn
EGB		CONRAD
Hemi-cholinium lipids		CONRAD
Anti-HPV spermicide	Screening various compounds	FHI/U Ark/Penn State
Advantage 24		Columbia Labs
Chlorhexidine		
Topical monoclonals	Secretory antibodies from plants	Johns Hopkins Univ
Hexoseaminidase inhibitors		J. Hall, NC State
Protegrins		UCLA
Lactobacillus crispatus	Once/month probiotic	S. Hillier, U Pittsburgh
Squalamine	Steroid-like structure, from shark liver	Magainan Pharm.
Acid buffer gel	Polymeric buffers	Johns Hopkins Univ
New N9 formulation	Slow release vaginal capsule	George Digenis (Univ. KY)
New N9 formulation	Slow release N9 w/ H2O2	BIOTEK
New N9 formulation	N9 + H2O2	Microbiological Consultants
New N9 formulation	N9 3% + H2O2	FEMCAP
New combination	Dextrin-2 sulfate + either N9, gramicidin or BZK	MRC (London)
N-docosonal	Straight chain alcohol (22-C)	Lidak Pharm.
Zinc salts	Genital lubricants w/ inorganic Zn	Patrick Kelly (private inventor)
Modified bovine lactoglobulin	Modified milk by-product	NY Blood Center

Table 2. Selection Criteria for Prioritizing New Contraceptive Methods Research

These criteria are adapted from those used by the World Health Organization's Human Reproduction Programme (WHO/HRP) at a meeting in December 1995. The major change made to the WHO list is a more explicit listing of user concerns; in particular, the inclusion of activity against STDs (the WHO list did not include barrier methods or microbicides). In parallel to these product-related dimensions, we also needed to consider FHI's capabilities (clinical trials, acceptability research, service delivery research, epidemiologic research). That said, we did not conduct a detailed feasibility analysis, as would be done by industry.

1. User's perspective
 - a. safety
 - b. efficacy against pregnancy
 - c. efficacy against STD transmission
 - d. other non-contraceptive benefits
 - e. acceptability
 - f. benefit to under served groups

2. Service delivery feasibility
 - a. policy issues
 - b. program issues
 - access
 - availability
 - quality of care
 - method mix
 - likely cost

3. Development feasibility
 - a. industrial collaboration
 - b. time and cost to develop
 - c. technical feasibility
 - d. collaboration with other organizations (e.g., CONRAD)
 - e. advantages compared to current methods
 - f. likelihood of regulatory approval

4. Commercial potential
 - a. market size
 - b. time and cost to market
 - c. market protection and profit

Table 3. Draft List of Promising Projects and Products

First Priority--Barrier Methods

1. **Non-fitted Diaphragm.** This project would involve the Semina diaphragm, a rose-colored diaphragm made of silicone, manufactured by Dr. Luisa Eluf in Brazil. The major objective would be to study the feasibility of non-fitted use of this diaphragm, using a single size. If feasible, FHI would seek U.S. Food and Drug Administration (FDA) approval for over-the-counter status. A possible U.S. manufacturer has been identified.
2. **Seek FDA Approval of a New Sponge.** Two sponges are presently approved in other countries. The Pharmatex® sponge contains benzalkonium chloride (BZK) and is made in France. Several years ago we (unsuccessfully) proposed a study of this sponge to NICHD, but circumstances for this project may now be more favorable. The Protectaid® sponge was recently approved in Canada as a device; it contains low doses of nonoxynol-9, BZK, and sodium cholate. The dosage may make it less irritating, but the combination of ingredients may be a regulatory hindrance, and few data are available on its contraceptive efficacy.
3. **Vaginal Microbicides--Part I.** FHI proposes to collaborate with Richard Cone, et al., Johns Hopkins University, in studies of monoclonal antibodies for vaginal use, which could be used for contraception and/or prophylaxis. The first preclinical goal of this project would be to assess the feasibility and safety of this approach. The first clinical goal, aside from addressing safety issues, would be to prepare a formulation which could be used as a gel or with a sponge. FHI would provide regulatory support for the preclinical work leading to development of a product for human use, at which time FHI would conduct clinical trials.
4. **Vaginal Microbicides--Part II.** FHI proposed to continue collaboration with Paul Hermonat, University of Arkansas, and John Kreider, Hershey, in selecting and screening agents for activity against papillomavirus. Iodine is effective but not acceptable; monoclonals might be effective; hydrogen peroxide is another possibility. Once again, our role would be advisory during pre-clinical phases.
5. **FHI Male Plastic Condom.** Development of this product is now mostly of a proprietary, confidential nature in collaboration with Mayer Laboratories, but USAID resources are being used to support further research.

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Table 3. Draft List of Promising Projects and Products (continued)

Second Priority

1. **Levonorgestrel-releasing Intrauterine Devices (IUD) or Intracervical Devices (ICD).** We have not included these as first priority projects, since FHI does not hold the rights to these devices and has not been involved in their development. However, if opportunities arise for appropriate collaboration, we would certainly wish to participate in studies toward FDA approval of these devices.
2. **Improving/Evaluating Emergency Contraception.** FHI has had limited involvement in studies of emergency contraception. However, FHI has developed a draft strategy that identifies potential research that could be conducted should resources become available.
3. **Improving Male Contraceptive Options.** Aside from development of plastic condoms, FHI has no immediate plans for work on male methods. However, time and resources permitting, we certainly would be open to projects for men.

Other Areas

1. **Nonsurgical Female Sterilization.** Due to its toxicologic problems and the low probability FDA approval, FHI is not planning any further clinical work on quinacrine. Other nonsurgical tubal occlusion methods will be considered on a case-by-case basis.
2. **Hormonal Implants.** We have not included development of any new hormonal implants. At present, work is already being done on such products by other groups. Additional work by FHI seems unlikely to result in new methods with advantages over products already available on in the pipeline (Norplant[®], Norplant-II[®], and Depo-Provera[®]), with the exception of lower cost. In addition, these methods do not provide protection against STDs. If new, "generic" implants become available we are prepared to evaluate them.

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Uncorrected Proofs

Contraceptive Research and Development

Looking to the Future

Polly F. Harrison and Allan Rosenfield, *Editors*

Committee on Contraceptive Research and Development

Division of Health Sciences Policy

INSTITUTE OF MEDICINE



NATIONAL ACADEMY PRESS
Washington, DC 1996

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Thursday, 10:45-11:30	Background Materials	Action from TAC	Speaker
a. Proposed Expert Meetings	None	Recommendation	King
b. Date/Site of 1997 TAC Meeting	Calendar	Date	Bowden

Lunch
Radisson Governors Inn

Airport Shuttle Service:

For your convenience, transportation to the Raleigh/Durham Airport will be arranged through the Radisson Governors Inn. Shuttle departures will be announced prior to adjournment on Thursday, June 20.

1997

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IMPORTANT DATES

JANUARY
 1 New Year's Day
 20 Martin Luther King, Jr. Day

FEBRUARY
 12 Lincoln's Birthday
 12 Ash Wednesday
 14 Valentine's Day
 17 Washington's Birthday - Obsvd.
 22 Washington's Birthday

MARCH
 17 St. Patrick's Day
 23 Palm Sunday
 28 Good Friday
 30 Easter Sunday

APRIL
 22 Passover

MAY
 11 Mother's Day
 17 Armed Forces Day
 19 Victoria Day (Canada)
 26 Memorial Day - Obsvd.
 30 Memorial Day

JUNE
 14 Flag Day
 15 Father's Day

JULY
 1 Canada Day (Canada)
 4 Independence Day

SEPTEMBER
 1 Labor Day

OCTOBER
 2 Rosh Hashanah
 11 Yom Kippur
 12 Columbus Day
 13 Columbus Day - Obsvd.
 13 Thanksgiving Day (Canada)
 24 United Nations Day
 31 Halloween

NOVEMBER
 4 Election Day
 11 Veterans Day
 27 Thanksgiving Day

DECEMBER
 24 Hanukkah
 25 Christmas Day

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FAMILY HEALTH INTERNATIONAL

June 13, 1996

Erin T. McNeill, Ph.D.
Technical Advisor, FHI
G/PHN/POP/R, SA-18
U.S. Agency for International Development
Washington, D.C. 20523-1819

Dear Erin:

The final agenda for the Technical Advisory Committee meeting on June 19-20 is enclosed. This version contains a variety of background materials developed to complement the presentations. However, the supply is limited, so please bring this copy with you to the meeting.

As mentioned in a previous letter, a room has been reserved (at the government rate) for you at the Radisson Governors Inn for the evenings of June 18-19. Sandi has negotiated with the hotel to hold this reservation until Monday, June 17. Please let her know if this meets your needs. The hotel also will provide airport shuttle service. If you wish to take advantage of their courtesy service, please call them at 549-8631.

We look forward to seeing you soon. Meanwhile, if you have any questions, need additional information, or should alter your itinerary, please give Sandi a call at 919/544-7040, ext. 541.

Sincerely yours,


Theodore M. King, M.D., Ph.D.
President/Chief Operating Officer

Enclosures



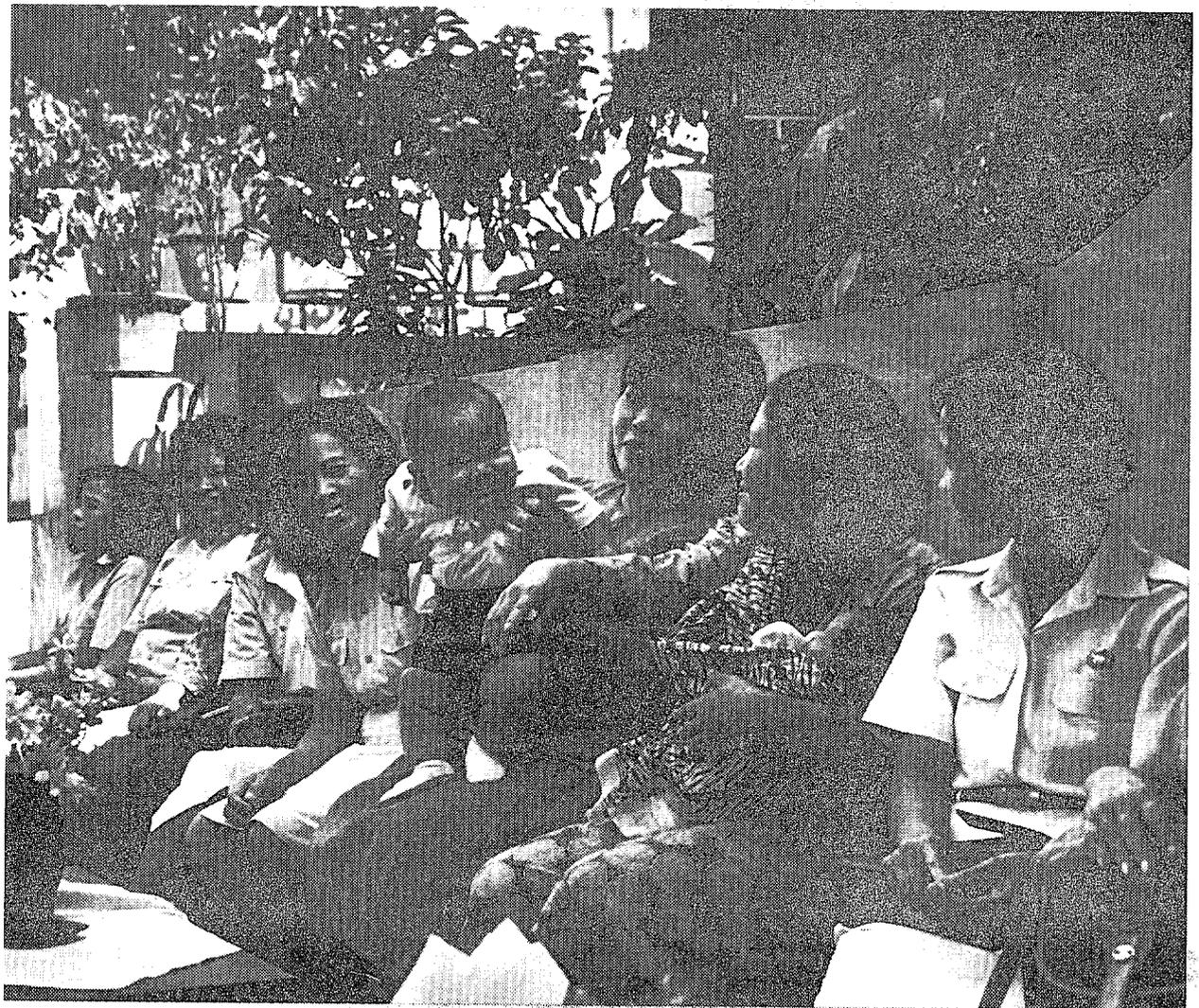
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Network

FAMILY HEALTH INTERNATIONAL, VOL. 16 NO. 2, WINTER 1996



News Briefs

NEW DRUG EXAMINED IN AIDS RESEARCH

A new drug called PMPA has protected monkeys from being infected by SIV, an HIV-like infection that occurs in monkeys. The drug also slows the onset of symptoms when administered after an SIV infection is established.

Dr. Che-Chung Tsai and colleagues at the University of Washington Regional Primate Research Center in Seattle, WA, USA tested PMPA in macaques against SIV (simian immunodeficiency virus). PMPA successfully protected 25 macaques against SIV without causing harmful side effects. Another 10 animals did not receive the drug and all became infected.

"The reason I believe this is very encouraging is because it also is very effective against HIV in the test tube," says Dr. Tsai. The research appears in the Nov. 16, 1995 issue of *Science*, the journal of the American Association for the Advancement of Science.

While the drug is promising, HIV is different from SIV. Human trials involving PMPA may begin in 1996, Dr. Tsai says, but it may be many years before a successful product

would be available for general use among humans. Also, the drug is not a vaccine, but chemotherapy. "A person may still have a chance to get reinfected" after a successful treatment, he says.

Both HIV and SIV rely on a special enzyme to multiply and spread infection inside their host. Like AZT, a widely-used drug that curtails AIDS symptoms, PMPA inhibits this enzyme.

FEMALE CONDOM SHELF LIFE EXTENDED

The female condom's shelf life has been extended from two years to three years by the U.S. Food and Drug Administration (FDA), a regulatory agency. Shelf life refers to the amount of time an unopened product is known to be effective and safe to use.

Users who have female condoms with expiration dates of 1997 or earlier may safely add another year. The FDA also approved using Reality, the brand of female condom marketed in the United States, for use with the spermicide nonoxynol-9. The U.S. Agency for International Development (USAID) recently provided a limited supply of Reality female condoms in 22 countries and will evaluate whether to continue supplying them.

MICROBICIDES RESEARCH BEGINS

Research to develop microbicides, chemicals that may prevent HIV and other sexually transmitted diseases, has begun at three medical centers in the United States.

The development of safe and effective microbicides is expected to take many years, says Pat Randall of the National Institute of Allergy and Infectious Diseases (NIAID), a U.S. government agency financing the research. Test tube studies have identified several compounds that can destroy HIV, chlamydia, gonorrhea, syphilis and genital herpes. The new research will examine the use of these microbicides in animals.

NIAID awarded three grants, totaling U.S. \$1.5 million during the first year, for research at the University of California at Los Angeles (UCLA), Children's Hospital Research Foundation in Cincinnati, and University of Pittsburgh and Magee-Women's Research Institute in Pittsburgh. "It should be possible to make

synthetic molecules patterned after a natural antibiotic which have excellent activity against STDs and have no adverse health effects on the user," says Dr. Robert Lehrer, principal investigator at UCLA.

HIV TEST TO BE AVAILABLE

An inexpensive test for HIV in blood samples will soon be manufactured in Cameroon and Zaire, according to the Program for Appropriate Technology in Health (PATH).

Manufacturers in Argentina, India, Indonesia and Thailand have produced more than two million HIV dipstick tests. The HIV dipstick, developed by PATH, requires little training or equipment, making it useful where laboratories are not readily available.

The test costs less than U.S. \$0.50 each and takes about 20 minutes to perform, says Milton R. Tam of the U.S.-based PATH. A recent World Health Organization evaluation showed the kits are 100 percent sensitive in detecting infection, and 98 to 99 percent specific in determining what strain of HIV is present.

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FAMILY HEALTH INTERNATIONAL, VOL. 16 NO. 2, WINTER 1996

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Intrauterine devices (IUDs) are among the safest and most effective contraceptives available, suitable for many women. Front cover photo, by Dr. Karen Hardee of FHI, shows women at a neighborhood family planning clinic in Bandung, Indonesia.



Women Deserve Accurate Information

By Dr. Aníbal Faúndes, M.D.
Universidade Estadual de Campinas, São Paulo, Brazil

Women in many countries are far from taking full advantage of modern intrauterine devices (IUDs), which are among the safest and most effective contraceptives available. Many women, for whom the IUD could be the ideal method, are using alternatives that are less convenient and may not be as safe.

A negative opinion toward IUDs among potential users and providers alike, based upon misconceptions or lack of current scientific information, is a major obstacle to IUD use. To be sure, many countries also have limitations within their health systems that make them poorly prepared to offer sufficient IUD services. Another serious obstacle in some countries is a lack of trained providers to handle IUD insertion and management. Adverse public opinion and the consequent weak social acceptance of this excellent method, however, are fundamental obstacles worldwide.

Uninformed opinions about IUDs can result in negative messages to potential users, thus reducing demand, and may discourage providers from offering the method. Negative messages also affect policy-makers, who will not provide the political support required for adequate supply of the method. As scientists, health-care providers and policy-makers, we have a solemn responsibility to help create the climate for a better-informed public opinion.

Scientists must play a vital role in correcting these misconceptions. It is obvious that researchers should report their findings without hiding any relevant information. The problem is that the public often does not comprehend the nuances of scientific data and is slow to understand that what seemed true yesterday may not be so today.

One example of this can be seen in the incorrect perceptions about safety, especially regarding the risks of pelvic inflammatory disease (PID) and ectopic pregnancy. Early reports of high PID risk, largely influenced by the Dalkon shield, remain in the public's mind. The Dalkon shield was discontinued more than 20 years ago, in 1975. In reality, research has shown there is no increased risk of PID among women in monogamous relationships using today's IUDs, but this finding has not been widely disseminated.

We have not been able to correct the wrong message and let the public know that the risk of PID depends more on the sexual behavior of the user or her partner than on the IUD, and that appropriate counseling, client selection, and IUD insertion technique should prevent complications. The result of our failure is that many women still believe that any IUD is a dangerous method to use, independent of their sexual behavior and of the quality of the services provided by the clinic.

Similarly, epidemiological analysis clearly shows that users of modern IUDs are at low risk of ectopic pregnancy, yet clinicians and the general public alike are often poorly informed about this risk.

Statements on efficacy can be misleading. It may be hard for the public to understand the meaning of published IUD pregnancy rates of 1 to 6 percent a year. Many people may not realize that rates as high as 6 percent correspond to old inert IUD models and to specific subsamples of younger women. In addition, those figures do not reflect the pregnancy rates of the newer copper IUDs, which have consistently been below 1 percent per year, even among women under age 30.

The lack of updated information on IUD effectiveness explains the commonly held, but incorrect, opinion that pills are more effective than IUDs in everyday practice. This is far from the reality in developing countries. Consequently, women for whom avoiding pregnancy is a very important issue are often discouraged from using the IUD, since they wrongly view it as a less effective method.

Another example of how misconceptions discourage use involves the IUD's mechanism of action. Decades ago, it was found that an intrauterine foreign body did not prevent fertilization in several species of rodents, and there were clear indications that implantation of the fertilized egg was prevented. From that information, it was incorrectly concluded that the mechanism of action of IUDs in women was the same. The lack of evidence that fertilization occurred during IUD use in humans and other primates did not change that concept. More recent studies have demonstrated mechanisms of action in women that clearly preclude and prevent fertilization.

In countries where there is a strong religious or political rejection of abortion, this kind of misconception has a dramatic

impact, since preventing implantation of a fertilized egg has been defined by some as interruption of pregnancy. Our current understanding of the mechanism of action for copper IUDs indicates that the primary mechanism is the prevention of fertilization.

Women deserve accurate information about all methods to make well-informed choices about their contraceptive use. Our current knowledge shows clearly that IUDs are safe, highly effective, affordable and convenient to use, provided they are offered by high-quality service delivery units. In many countries, however, use of this method is being discouraged by incorrect perceptions about its safety, effectiveness and mechanism of action.

LACK OF INFORMATION ABOUT IUDS OFTEN DISCOURAGES USE. ACCURATE INFORMATION ABOUT ALL METHODS HELPS FAMILIES TO MAKE WELL-INFORMED CHOICES ABOUT THEIR CONTRACEPTIVE USE. THIS COUPLE RECEIVES COUNSELING AT A CAMPINAS, BRAZIL CLINIC.



RICHARD LORD



Proper IUD Use Requires Training

Good training includes current scientific information, insertion practice, and counseling techniques.

Women must be fully informed about the intrauterine device (IUD) before choosing it, and health care workers must be adequately trained to insert the device, if the IUD is to be used properly.

"Many providers are not comfortable with the method," says Dr. Roberto Rivera, FHI corporate director for international medical affairs, who notes that good training can improve access to the method. "For wide-scale IUD use, providers need to have a commitment that they are doing something for the benefit of the client, to improve the health and life of the woman. Then they are willing to spend whatever time is necessary to help the client select the method of her choice and provide it under the conditions that are required."

Providing the IUD takes more time than do many other methods. Good IUD services require good client screening and counseling, a pelvic exam, assuring that no pregnancy or infection is present, good insertion technique, proper follow-up, and management of side effects.

The IUD is the most widely-used modern, reversible contraceptive method worldwide, with about 100 million users, although 70 percent are in China. In only four developing countries do as many as 15 percent of married women of reproductive age use IUDs: Vietnam (33 percent), Egypt (28 percent), Tunisia (17 percent) and Jordan (15 percent).

The number of IUD users "should increase by 25 percent or more in the coming decade, if due attention is given to keeping the medical, scientific, and programmatic communities informed about the characteristics of IUDs in comparison to other methods," write Drs. Parker Mauldin and Sheldon Segal, both of the Population Council, in proceedings from the latest international IUD conference.¹

IUDs will continue to be underutilized in many countries until health workers are trained in three essential aspects of IUD use: the latest scientific information on the device, proper insertion methods, and good counseling techniques. These areas overlap but necessary attention must be given to each.

Other factors also limit women's access to IUDs. These include national policies, restrictive protocols on who may do insertions and required number of follow-up visits, fear among potential users, and in some areas, maintaining a steady supply of IUDs.

SCIENTIFIC UPDATES

An IUD must be obtained through health care services. If a provider explains it fully, women are more likely to use it. To do this, health workers must understand how the method works, its efficacy rates, potential side effects, and how to insert and remove it.

Worldwide, two matters in particular have limited IUD use, says Dr. Rivera of FHI: Fears of infection and concerns about bleeding and pain. "These problems do exist, but the frequency and severity have been highly exaggerated," he says.

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The IUD devices in use today by most programs do not themselves cause infection and pelvic inflammatory disease. "Infections associated with the IUD are due to the actions of the provider, through improper screening of potential users and poor insertion technique," says Dr. Tapani Luukkainen, a visiting scholar at FHI from the University of Helsinki and a leading expert on IUDs. "Infection is not due to the IUD."

If a woman is at high risk for sexually transmitted diseases (STDs), she should not use the IUD. If she has a cervical infection, it should be cured before the IUD is inserted. It is very important that all insertions be done under strictly aseptic conditions.

The newer models of IUDs generally have lower rates of bleeding and pain than do the early models.² Also, insertions done well are less likely to cause pain and bleeding.

The first step in changing providers' views on the IUD is wide-scale dissemination of correct information. Various organizations are attempting to provide such information. FHI, for example, has recently developed a presentation on IUDs with slides, lecture script and resource materials that can be used in medical schools and training courses. (A copy of this IUD module is available at no charge to family planning trainers in developing countries who provide a written explanation of need to FHI.)

NEEDS VARY

Training efforts on IUD use are expanding, including a national project in Indonesia and a three-year program in four Central Asian countries. Training is also intensifying in Brazil and the Philippines, to name just a few countries. The emphasis varies from country to country, depending on many factors. These include the current

image of IUDs among providers and potential users, the needs of the national training structures and the health-care infrastructure, national policies, and supplies.

In the Central Asian countries, trainers are emphasizing the importance of giving the client the information she needs to choose the method. "Our biggest challenge is having the physicians recognize that women should be given information about IUDs and other methods currently available so they can make an informed choice," says Beverly Tucker of FHI. "Historically, physicians in the former Soviet Union would mandate what contraceptive method women used." Tucker is coordinating this UNFPA-funded project in Tajikistan, Kazakstan, Kyrgyzstan and Uzbekistan, all formerly part of the Soviet Union.

Where IUDs have been available in these countries, they have been well accepted. But until recently, contraceptive supplies have been very limited, and few family planning workers have received good training. The new training initiative covers counseling techniques and scientific information on several methods, but with clinical training only on IUDs. In Uzbekistan and Tajikistan, which border Afghanistan, obstetrician-gynecologists will be trained in IUD insertion, including postpartum and postabortion techniques. They will in turn train others. In Kyrgyzstan and Kazakstan to the north, a vast area about the size of India, midwives will be trained in IUD insertion as well.



A BANGLADESHI FAMILY PLANNING BOOKLET FOR CLIENTS FOLLOWS THE STORY OF FATIMA, WHO LEARNS ABOUT IUDS AND DECIDES TO HAVE ONE INSERTED.

BANGLADESH DIRECTORATE OF FAMILY PLANNING

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In Brazil, where only 2 percent of married women of reproductive age use IUDs, the government has recently made IUDs a part of the official family planning program. "For many years, IUDs were seen as a very bad method in this country," says Dr. Juan Díaz, who has worked with IUDs in Brazil for almost 20 years. The Catholic Church did not support the method, and many stories circulated about the IUD leading to infection.

Over the years, Dr. Díaz and his colleagues at the Centra de Pesquisas e Controle des Doencas Materno-Infantis de Campinas (CEMICAMP) have provided the IUD and trained other providers in IUD use. "Gradually, women began accepting IUDs, and these happy women began telling their friends," he says. "Word of mouth is extremely important for acceptance." But the increased use was localized. With the change in national policy, more physicians receive training at more locations, including two new centers in northern Brazil where the method was rarely used before.

"The work of convincing physicians is easier now," says Dr. Díaz. "Anywhere physicians obtain a certain amount of training, they begin offering it and demand increases. To improve access, we need training, training, training."

In Kenya, researchers recommend that training focus on improved quality of care, including motivating family planning workers to take a client's best interests to heart. Despite sharp increases in contraceptive use

in Kenya in the last 10 years, the number of IUD users has remained about the same. As a proportion of all modern contraceptive use, IUD use has dropped from 31 percent to 15 percent.

To assess the factors causing this decline in popularity, researchers conducted in-depth interviews with 24 providers and made 28 simulated client visits at 14 clinics. "Nurses posing as clients reported that many providers were rushed and unfriendly, and that many were not well informed about the IUD," reports John Stanback of FHI, who coordinated the study. Providers did not often mention IUDs as a choice available to clients, nor did they attempt to dispel common rumors.

The Kenya study concluded that several interrelated factors account for the stagnant level of IUD use, including poor quality of care, poor product image, provider bias or preference, and shifting client preferences. Accurate information can address some of these issues. For example, some Kenyans are reluctant to use copper IUDs that have tarnished in their packages, thinking that the greenish color can be dangerous. This oxidation process can occur in properly packaged and stored devices and does not affect IUD safety or effectiveness.

NATIONAL EFFORTS

Two ambitious national training efforts are under way in the Philippines and Indonesia. In the Philippines, IUDs had never been widely available until the government, with UNFPA assistance, recently began a

large-scale training project. Between 1990 and 1994, thousands of health workers were trained, and IUD use in the Philippines increased substantially, explains Cathy Solter, who worked on the project. In one region, for example, the number of new acceptors quadrupled in three years, from 4,000 in 1990 to 17,000 in 1992, says Solter, now with the U.S.-based Pathfinder International.

"There was resistance to the training and complaints that the IUDs were too large for Filipino women — complaints that were not correct," says Solter. The training had to address various myths about IUDs. For example, the IUD cannot circulate through the body if the uterus is perforated, as some say, nor can the IUD string get wrapped around a man's penis during intercourse. "Once they were trained, the providers' bias went the other way. They loved the method."

Many of those trained in the Philippines were midwives working in rural clinics. "They knew the women in the villages," says Solter. "They were constantly worried about the supply stream for pills. And there were few services for sterilization. With the IUD, once they put it in properly, they knew they didn't have to worry about these clients again. They really like it as a method."

In Indonesia, recent studies by the National Family Planning Coordinating Board (BKKBN) and others found that training for long-term methods needed improvement. A national five-year effort recently began to improve training, focusing on IUDs and Norplant. Funded by the U.S. Agency for International Development and coordinated by Pathfinder International, it involves government and nongovernmental organizations, professional associations and other groups.

Hundreds of clinicians will be trained as trainers in Indonesia. They in turn will train thousands of providers, about half of them midwives. Indonesia is already one of the world's largest users of the IUD, but

IRENE YACOBSON/FHI



DR. BAUYRZHAN AMIROV CONDUCTS A TRAINING WORKSHOP SPONSORED BY FHI AND UNFPA IN DUSHANBE, TAJIKISTAN.

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IUDS BLOCK FERTILIZATION

Intrauterine devices (IUDs) achieve their primary contraceptive effect by interfering with sperm motility and survival. They also prevent fertilization and, in rare cases, implantation.

Any IUD prompts an endometrial reaction that promotes the release of leukocytes and locally-acting substances, called prostaglandins. These act simultaneously in the oviduct, cervix, uterine cavity and genital tract to impede sperm and egg development.

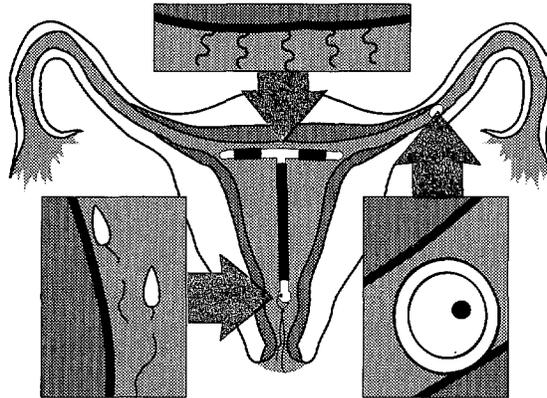
The presence of copper enhances this effect. Studies among women using copper IUDs have shown a reduced number of live sperm after intercourse when compared with nonusers. The interruption of sperm migration begins in the cervical mucus and continues in the uterus and oviducts. A California research team compared eight women 15 to 30 minutes after insemination. Sperm were detected in the oviducts of all four women not using IUDs, while no sperm were in the oviducts of copper IUD users.¹ Many studies have

shown copper to act as a spermicide. In a study of the Copper T 200, scientists observed that the sperm heads were detached from the tails in a majority of sperm cells.²

Fertilization is also interrupted through action on unfertilized eggs. A Chilean research team found few eggs in the tubes and uteruses of IUD-using women. They searched for ova by flushing the uterus on the second through the fifth day after ovulation. Eggs were found in one-third of 36 women using no contraceptives, while only one egg was recovered among 22 users

of inert IUDs that contain no copper and none in 43 users of copper IUDs.³ A comparison of copper IUD users and women using no contraception showed that none of the eggs from copper IUD users were fully

IUD promotes release of leukocytes and prostaglandins from endometrium.



This release interferes with sperm motility and impedes egg development.

developed or fertilized, in contrast to more than half of the eggs recovered from noncontraceptive users.⁴ Other data show the copper IUD slows the development and transportation of eggs. When screened for a hormone secreted just prior to implantation of a fertilized egg, one study found few IUD users who tested positive for the hormone. The study concluded that the IUD's prevention of implantation is very rare.⁵

FHI trials of 10,000 women in 23 countries conclude the annual pregnancy rate for the Copper T 380 is very low, 0.5 per 100 women (one pregnancy among 200 users). Copper accounts for this high degree of contraceptive efficacy, according to Irving Sivin, senior scientist at the Population Council, which developed the Copper T 380. "With the inert IUD, we know that sperm transport is interfered with," says Sivin. "But with copper, it is interfered with more. And the more copper, the more interruption."

Copper IUDs also function well as emergency contraception when inserted within five days after unprotected intercourse. Emergency contraception is used after unprotected coitus to avoid pregnancy.

— Sarah Keller

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IUD use has declined from 13 percent of married women of reproductive age in 1991 to 10 percent in 1994.

INSERTION AND COUNSELING

Regardless of the specific country's situation, training projects should include certain basic components and approaches. These involve three general areas — scientific and counseling knowledge, skills acquisition using anatomical models, and clinical practice.

"Providers have to obtain a certain level of competence in knowledge and skills before going on to clinical practice," says Patricia MacDonald of the Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO), a U.S.-based group that coordinates IUD training projects throughout the world.

Training health workers about the method covers scientific information, clinical skills, and techniques for counseling potential clients. For example, a provider must not only

understand the relationship between IUDs and STDs, but also how to discuss a client's history of STDs in a sensitive way so as to get accurate information. In the past, training has emphasized the medical aspects of IUDs more than the impact on the clients. But that is changing.

"Women need to be counseled on what to expect during insertion, what you're getting ready to do," says the Pathfinder's Solter, a nurse-midwife herself. "We need to let women know what to expect from IUDs, particularly extra bleeding during menstruation. It is also

important to encourage women to return to the clinic if they have any problems or questions." New training curricula are putting more emphasis on client behavior and attitudes, asking the trainees how they think clients would feel about particular steps in the process.

Studies have found that most women stop using the IUD because of personal, not medical, reasons. For example, a study of 2,748 users in 14 countries found that the most common reasons given for discontinuation were planned pregnancy (32 percent) and a husband or family opinion against IUD use (26 percent). Effective counseling about IUD use, especially among illiterate women, may encourage better continuation rates, concluded Dr. Carlos Petta of CEMICAMP, and his colleagues at FHI, who conducted the analysis.³

In the skills acquisition stage of IUD training, experts agree that the crucial element is having sufficient anatomical models with which to work. In the Philippines project, there were not enough models. Some trainees had to spend evenings to get their turn, says Solter. "It was extremely important for everyone to use the models. People have no business inserting IUDs in women without working with a model first."

Following skills acquisition, trainees get clinical experience under the supervision of an experienced clinician. Some of the most important practical elements are:

- screening the clients with a preliminary pelvic exam to rule out pregnancy, pelvic inflammatory disease (PID) and endocervical infection

- STD screening by personal history and sociodemographic risk factors, such as having multiple partners or a partner with multiple partners

- counseling that emphasizes changes in menses, heavier bleeding with copper-bearing IUDs, and situations that would require a return visit to the clinic, such as abdominal pain, pain with intercourse, abnormal vaginal discharge, pelvic pain with fever, or a change in the IUD string (missing, shorter or longer).

Training must emphasize aseptic conditions. IUD insertion should not be done unless aseptic procedures can be followed, including handwashing by the inserter, careful preparation of the cervix, sterile IUDs and equipment, and correct decontamination of the instruments.

Midwives and nurses can insert IUDs safely with appropriate training. Studies have found that they are at least as careful as doctors in performing insertions.⁴ "Often, nurses or midwives are better at insertion because they are not as rushed and approach it more conscientiously," says Dr. Pouru Bhiwandi, a former FHI medical director who recently conducted insertion training in the Central Asian republics on the FHI-UNFPA project.

An appropriate follow-up schedule should be encouraged. One follow-up visit one month after insertion is sufficient unless there is a problem. Thereafter, there is no need for a fixed follow-up schedule. Research has found that multiple follow-up visits take time away from serving more clients and result in discovering only a very small number of problems that would not have caused women to return on their own.⁵ Users, however, must understand which symptoms require a return visit to the clinic.

Finally, after providers have gained knowledge, acquired skills and demonstrated competence in clinical practice, each individual should consider listing the specific problems he or she will face and ways to overcome these barriers. "These might be a lack of equipment and supplies for infection prevention, problems with client flow or clinic overcrowding, or the attitude of other providers," explains MacDonald of JHPIEGO.

— William R. Finger

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RICHARD LORD



A FAMILY PLANNING CONSULTANT ADVISES A WOMAN ABOUT CONTRACEPTIVES AT A CLINIC IN HUE, VIETNAM.

Key Precautions Minimize PID Risk

Client screening and aseptic insertion can greatly reduce the risk of infection.

Understanding the relationship of the intrauterine device (IUD) to sexually transmitted diseases (STDs), pelvic inflammatory disease (PID) and infertility has improved in recent years.

Studies have shown that the risks of infection associated with IUD use are greater for certain clients (those at high risk of acquiring a sexually transmitted disease) and at certain times (within the first few months after insertion). This new knowledge has enabled family planning programs to develop criteria to determine who is an appropriate candidate for IUD use, and who is not.

Numerous studies have shown that IUDs by themselves do not cause PID, and for most IUD users, fertility returns quickly after the device is removed. However, IUD use does carry some risk of infection for some women, primarily due to nonsterile insertion techniques or the clients' STD exposure.

"The screening of the client is important. The skills of the provider are important," says Dr. O.A. Ladipo, director of the South to South Cooperation for Reproductive Health in Brazil, who has studied IUD use in developing countries. "If the insertion is performed properly and the client is well-screened, the risk of infection is very low. Consequently, the risk of infertility also will be low."

Providers can minimize risks by following these important guidelines:

- screening clients carefully to determine their probability of being currently infected with STDs
- counseling clients about STD risks and any future symptoms of lower and upper genital tract infection
- practicing aseptic techniques when inserting IUDs
- encouraging clients to return for a follow-up visit approximately one month after insertion to determine if infection is present.

The Technical Guidance Working Group, a panel of family planning experts from around the world organized by the U.S. Agency for International Development, recommends that clinicians not insert IUDs unless they can follow basic infection prevention measures, including handwashing, preparation of the cervix, use of sterile IUDs and equipment, decontamination of instruments and safe disposal of contaminated materials.

In addition, the working group recommends that IUDs not be inserted if there is evidence of PID, abnormal vaginal discharge, or infection of the cervix or the vagina. If the client has an STD but is no

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A WOMAN RECEIVES COUNSELING AT A FAMILY PLANNING CLINIC IN MURANGA, KENYA. GOOD COUNSELING SHOULD INCLUDE INFORMATION ABOUT PID SYMPTOMS AND SHOULD ENCOURAGE CLIENTS TO RETURN FOR A FOLLOW-UP VISIT ONE MONTH AFTER INSERTION.

longer at risk of a new infection, the infection should be treated and the IUD inserted when the infection is gone. When the client has acute PID, PID should be treated, and providers should wait three months after successful treatment before inserting an IUD. If the client has an STD and continues to be at risk of reinfection, she should be advised to consider another contraceptive method and to use condoms to protect against STDs.¹ Clients at high risk of STDs include those with multiple partners, or whose partner has multiple partners.

The World Health Organization (WHO) also has recently developed guidelines for contraceptive use. WHO recommends that IUDs not be used by women who currently have or in the three months prior to insertion have had PID or STDs. For women who are not in mutually monogamous relationships or women who are HIV-positive, IUD insertion usually is not recommended unless no other contraceptive method is available or acceptable.²

GREATER RISK?

Pelvic inflammatory disease — an inflammation of the upper reproductive tract, including the uterus, fallopian tubes and ovaries — can be fatal if not treated promptly. In addition, PID can cause scarring and blockage of the fallopian tubes and result in infertility.

Controversy over IUD use began in the 1970s, when epidemiologic studies reported a greater risk of PID among IUD users, compared with users of other contraceptives. In the late 1980s, researchers learned that the sexual behavior of a woman or her partner played an important role in PID risk. A reanalysis of data in the United States found that IUD users at low risk for acquiring STDs (women in mutually monogamous relationships) were unlikely to develop PID. Those at higher STD risk had higher risks of developing PID.³

A study published by WHO analyzed clinical trial data from 13 studies in Africa, Asia, Europe and the Americas and found that the incidence of PID was greatest within the first 20 days following IUD insertion. Afterward, the risk of PID dropped and

remained low throughout the eight-year study.⁴ Other research has found that risks of infection are high during the first four months following insertion, but decline afterward.⁵

The reason for the increased risk of infection after insertion is that microorganisms in the vagina can be transported through the cervix and into the uterine cavity during insertion. Even organisms that occur naturally in the vagina can lead to PID if they ascend into the upper genital tract. STD pathogens, specifically *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Mycoplasma hominis*, are a cause of PID and can also be transferred from the cervix and vagina to the uterine cavity during IUD insertion.

In reviewing the methods used to collect data on IUDs in the 1970s, scientists now believe that methodological flaws may have affected early study results. For example, IUD users were compared with women who used oral contraceptives and barrier contraceptives, both of which have a protective effect against PID. Also, early studies did not consider factors such as sexual behavior or the time between insertion and onset of PID. Many IUDs in use during the 1970s are no longer made. Newer copper IUDs are considered safer and more effective.

Provider concerns about pelvic inflammatory disease and infertility are major barriers to IUD use in Asia and Latin America, according to comments at workshops sponsored by FHI.⁶ In Jamaica, when 367 private physicians were asked their reasons for not recommending certain contraceptive methods, more than 35 percent said they opposed the IUD because they believed, incorrectly, that it caused infections.⁷

While bacterial STDs and pelvic inflammatory disease can nearly always be treated with antibiotics, the health and socioeconomic consequences for infected women can be severe. In cultures where women's roles are defined by childbearing and childrearing, infertility resulting from PID can have devastating results, including abandonment, divorce, and community ostracism.

"This is why women's health advocates are so passionate about reminding us that we cannot just look at the scientific data on a contraceptive method," says Karen Beattie of AVSC International. "We also must look at the culture, the health care system and the

IUD NOT FIRST CHOICE FOR YOUNG, NEVER PREGNANT WOMEN

program in which that method may be offered, and the individual who may use the method."

While provider training can minimize the risks of PID during IUD insertion, counseling women about STD risks can be more difficult. Providers may be reluctant to question women about their sexual practices or the behavior of their partners. Women may not know their partner's behavior. Women with STDs are often asymptomatic, which makes it difficult for providers to diagnose a disease.

"We know now that women exposed to STDs are not good candidates for IUD use," says Dr. Roberto Rivera, FHI's corporate director of international medical affairs. "What we don't have is a good, easy-to-use instrument to assess whether a woman or a couple is at high risk." Family planning experts, including members of the Technical Guidance Working Group, are considering simple, inexpensive ways to determine risk for STDs.

AVSC International, in collaboration with the Population Council, the International Center for Research on Women and the Pacific Institute for Women's Health, is conducting a four-year study to examine the use of IUDs in poor communities where laboratory tests are not available. Researchers will examine different approaches for screening IUD clients for STDs, including self-assessments by clients. This approach would avoid interviewing a client about her sexual behavior and might be useful for women who have no STD symptoms.

Young women and women who have not yet had children can generally use intrauterine devices (IUDs), but providers should be cautious. Because these groups face increased risk of IUD expulsion and pelvic inflammatory disease (PID), the IUD generally is not recommended as the first method of choice.¹

For adolescents who need family planning, the IUD does have distinct advantages: It is nonhormonal and requires minimal compliance after insertion. The risks of infertility, however, should be considered before recommending this method to younger women.

"Age by itself is not a contraindication for IUD use," says Dr. Roberto Rivera, FHI's corporate director of international medical affairs. "There is no biological reason to say a young woman is at higher risk than an older woman. An older woman and a younger woman with the same sexual behavior have the same risks."

While there is no medical rationale against IUD use by adolescents, demographic studies show that women under age

25 have a higher incidence of sexually transmitted diseases (STDs) than older women, who are more likely to be married or living in union. Younger women are not biologically more susceptible to STDs; however, lifestyles and sexual behavior, such as multiple sexual partners, may put them at greater risk.

For the majority of IUD users, fertility typically returns immediately or soon after the device is removed, and duration of use does not appear to affect a woman's ability to conceive. One study in New Zealand found that within 48 months of IUD removal, 91.5 percent of women, who had never before been pregnant, had conceived, while 95.7 percent of those who had been pregnant before IUD use had conceived.²

Family planning providers should help clients understand how contraceptive use may affect their risks of PID and their future fertility. In spite of risks of infertility to young women and nulliparous women, the decision about which method to use ultimately should be made by the woman.

— Barbara Barnett

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BERYL GOLDBERG



A YOUNG COUPLE AND CHILD IN SANTO DOMINGO, DOMINICAN REPUBLIC.

The study also will analyze client-provider interaction when clients come to family planning clinics for IUDs, the costs of family planning and STD treatments, and the acceptability of using two methods — IUDs for contraception and barrier methods for STD prevention.

In the meantime, local family planning clinics also are considering ways to screen IUD clients for STDs. Providers at the Asociación Pro-Bienestar de la Familia de Guatemala (APROFAM) clinic explain to all IUD clients that their risks of PID and infertility increase if they are exposed to STDs. “We do not ask if they have more than one partner, but we explain that if they do, they have increased risks,” says Dr. Carlos Contreras, medical director.

As part of client screening, Dr. Ladipo of South to South Cooperation for Reproductive Health encourages providers to ask about both PID symptoms and STD risks. Clients may not know if they have had an episode of infection, because their ailment may not have been diagnosed, but they will remember if they have had symptoms, such as vaginal discharge, painful intercourse, or tenderness in the pelvic area. A pelvic examination prior to insertion is essential. A pelvic exam can identify conditions that would contraindicate use, such as pregnancy, PID or endocervical infections.

In addition, providers should question clients about their age at first sexual intercourse and about their current sexual behavior. Ideally, the provider should question both partners about these issues.

ANTIBIOTICS

Since microorganisms in the vagina may be introduced into the uterine cavity during insertion, scientists have debated the use of antibiotics as a prophylaxis before insertion. Studies on the preventive use of these drugs have not shown effectiveness in lowering the occurrence of PID.

FHI has sponsored two studies to evaluate antibiotic use. A study at Kenyatta National Hospital in Nairobi, Kenya investigated the effects of doxycycline on users of four types of IUDs — Lippes Loop, Copper T, Nova T, and Multiload. Half of the group of more than 1,800 study participants received 200 mg of doxycycline before IUD insertion, and the remainder received a placebo. Screenings for gonorrhea and chlamydia were performed before insertions. Findings showed the number of return visits to the hospital for lower abdominal pain, a symptom of PID, and bleeding were reduced by 40 percent among the antibiotic recipients.⁸ The study in Kenya and a study of nearly 1,300 IUD users in Ibadan, Nigeria found PID rates were lower than expected among all women. However, the Kenya study found that doxycycline reduced

the likelihood of PID, while the Nigerian study found antibiotics had no significant effect on PID.⁹

The use of prophylactic antibiotics remains controversial. Some scientists speculate that use of antibiotics prior to IUD insertion could result in drug-resistant strains of bacteria. “Antibiotics might provide some benefit, but the evidence does not support it as a global treatment procedure,” says Gaston Farr, associate director of FHI’s clinical trials division and one of the authors of the Nigerian study. “If you screen clients for STDs and follow aseptic insertion procedures, you could limit risks essentially as much as if you followed a course of antibiotic treatment.”

In the past, researchers have speculated that the IUD strings might play a role in the development of PID by allowing the ascent of bacteria from the vagina into the uterine cavity. Studies found that users of the Dalkon shield, an early IUD no longer available that had a multifilament tail, had an increased risk of PID when compared with users of other IUDs, such as Lippes Loop and copper IUDs with single-filament tails. In subsequent studies comparing IUDs with single-filament tails and no tails, researchers concluded that strings do not play a role in PID. This reinforced the findings that PID is due primarily to nonsterile insertion techniques or exposure to STDs.¹⁰

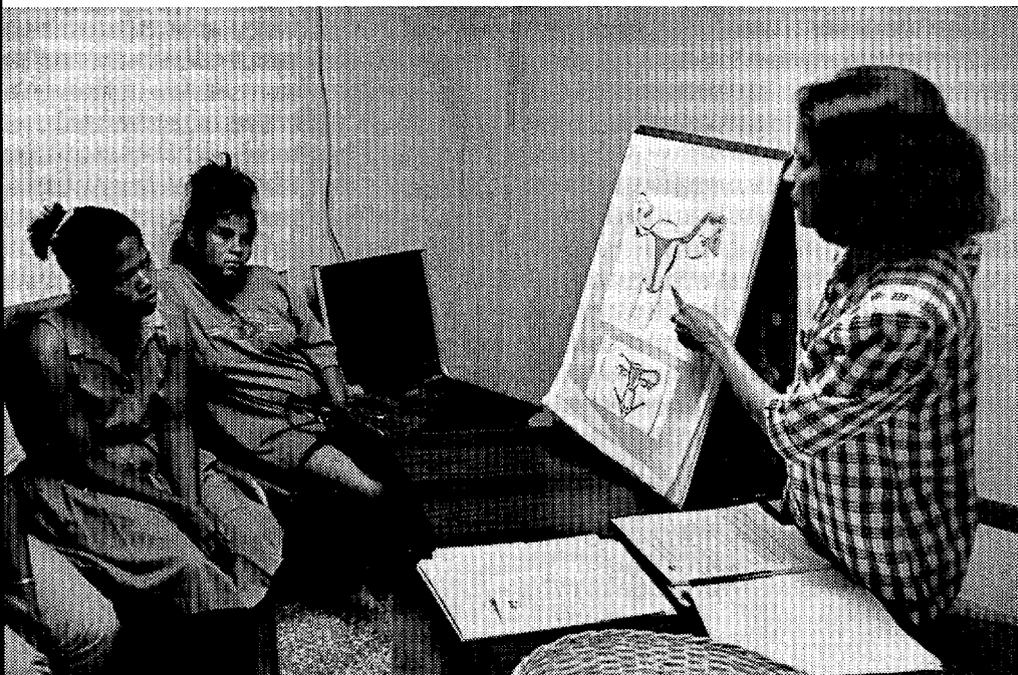
IUDS AND HIV

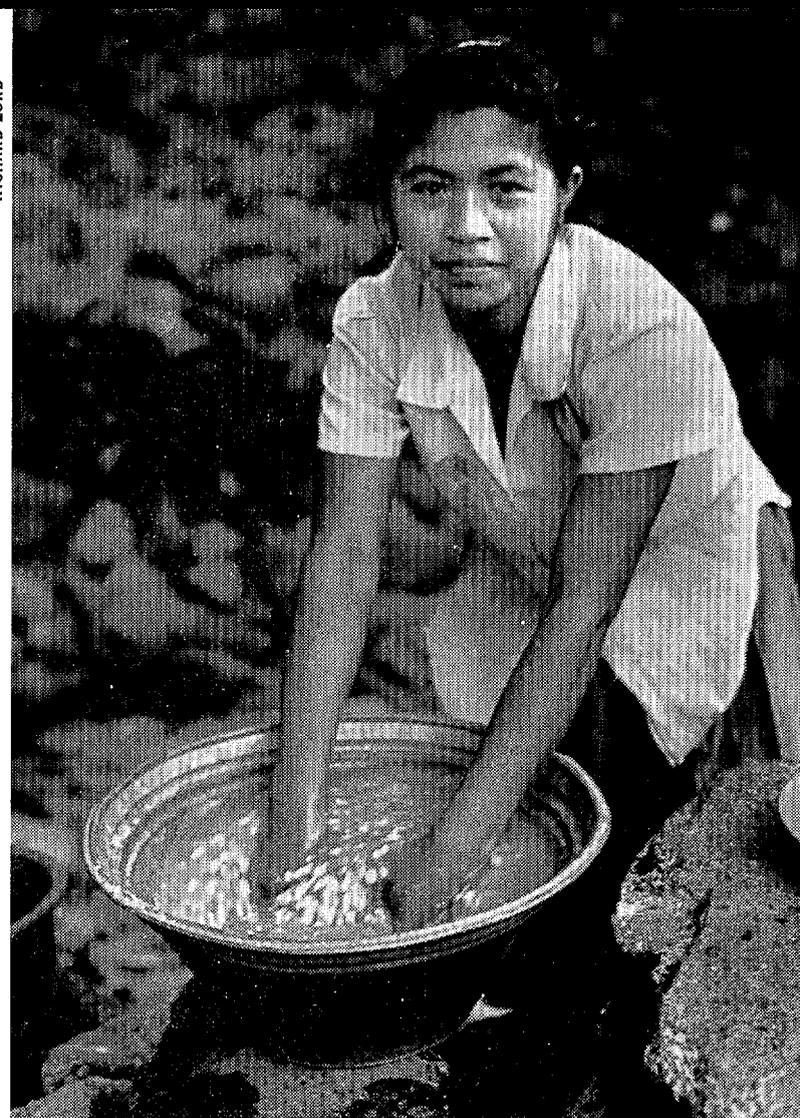
As AIDS becomes more prevalent, family planning providers are raising questions about IUDs and HIV infection. An FHI-sponsored study in Kenya found that providers feared they would transmit HIV to clients by using nonsterilized or contaminated equipment or dirty gloves. Providers also worried they would contract HIV from clients. “The fear of HIV seems to prompt providers to be more rigorous in the sterilization of instruments and other aspects of aseptic technique,” says a summary of the study. “However, this fear may also contribute to the current situation in which providers do not encourage clients to accept the IUD.”¹¹ In Zimbabwe, a study of provider attitudes of long-term contraceptive methods found that nurses who performed IUD insertions also feared contracting HIV from clients.¹²

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A COUNSELOR EXPLAINS FAMILY PLANNING PRACTICES AT A CLINIC IN THE DOMINICAN REPUBLIC.

RICHARD LORD





IUDs ARE CONVENIENT TO USE, MAKING THEM POPULAR WITH MANY WOMEN. A WOMAN PREPARES FOOD IN LOS HORCONES, HONDURAS.

Currently, FHI is collaborating with researchers in Nairobi to examine the short-term effects of IUD use among HIV-positive women. Researchers are following 150 HIV-positive women and 450 HIV-negative women for four months after IUD insertions to determine if side effects and complications are different for the two groups. Researchers will look for evidence of PID, uterine perforations, IUD expulsions and the incidence of removal due to pain and bleeding.

Women who wish to participate in the study are being counseled about family planning methods and HIV risks, including the use of condoms to prevent STD transmission. Women are excluded from the study if they have a history of ectopic pregnancy, active PID, reproductive cancers, or high risk for STDs. If a woman chooses an IUD and consents to participate in the study, HIV testing is conducted and she is counseled about the results. "The primary objective of this study is to determine if HIV-infected women have a different risk of short-term complications following insertion than women who are not HIV infected," says Dr. Charles Morrison, an FHI epidemiologist who designed the study. The study will also explore whether IUD use increases the infectiousness of HIV-infected women by comparing the presence of HIV in cervical secretions before and after IUD insertions.

— Barbara Barnett

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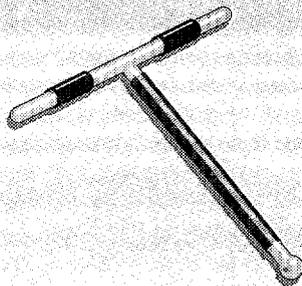
WIDELY-USED COPPER IUDS

Copper T 380

Effective for 10 years

Available in about 70 countries

Has 380 square millimeters of copper distributed on all arms of the T

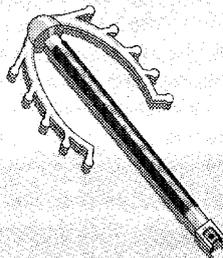


Multiload 375

Effective for five years

Available in about 50 countries

Horseshoe-shaped arms theoretically resist expulsion

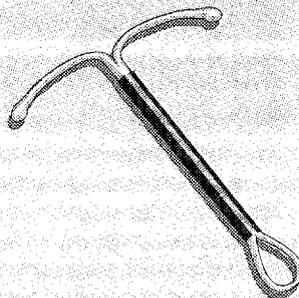


Nova T

Effective for five years

Available in about 60 countries

Flexible horizontal arms and loop on lower end make removal easier



LNG-RELEASING IUD

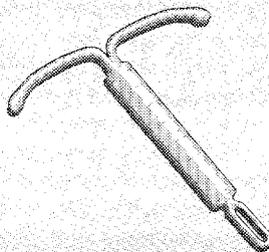
Mirena and Levonova

Effective for five years

Available in six countries

Releases a synthetic progestin hormone, levonorgestrel, 20 micrograms daily

As effective as copper IUDs with less bleeding as a side effect



THE COPPER IUD:

When should an IUD be inserted?

An IUD may be inserted anytime during the menstrual cycle when reasonably sure the woman is not pregnant. IUD use during pregnancy greatly increases risk of spontaneous abortion. There is no need for a separate visit before insertion; if at all possible, counseling, screening and a pelvic exam should be done the same day as the insertion.

What age woman can use an IUD?

There is no age restriction, but young women have a higher incidence of sexually transmitted diseases because of lifestyles and sexual behavior. Hence, younger women should be carefully counseled about the potential risk of pelvic inflammatory disease (PID) and infertility that could result.



Can nulliparous women receive IUDs?

Yes. However, IUDs should not be the first choice of contraception for these women because of higher risk of expulsion. Also, a nulliparous woman is typically young and may have sexual behavior that increases her PID risk, making her a poor candidate for IUD use.

Should women with irregular menstrual bleeding pattern use IUDs?

With proper counseling, menstrual irregularities should not affect IUD use. Menses are normally heavier with the IUD, and intermenstrual bleeding may occur; this decreases over time with IUD use. Oral iron supplements can improve hemoglobin levels if bleeding is heavy or the woman is anemic. A woman in pain in the first month after insertion can receive a short regimen of a nonsteroidal, anti-inflammatory agent other than aspirin. If a woman wants the IUD removed or if pelvic infection is diagnosed, remove the IUD.

Should a woman with a sexually transmitted disease (STD) use an IUD? Can she in the future?

A woman who has an STD, or has had one in the last three months, should not receive an IUD. Any STD, purulent cervicitis or PID should be treated. If a woman will be at low risk of STD infection in the future, and she gets careful counseling, an IUD may be inserted after an STD infection is treated and resolved; for acute PID, wait three months after PID is resolved before inserting an IUD.



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PICAL QUESTIONS

Should a woman at risk of STDs use an IUD?

Women using an IUD should be at low risk of STDs, especially young women. A woman at low risk of STDs does not need a lab test prior to IUD use. If other more appropriate methods are not available or acceptable, even women at high risk of STDs could use an IUD, according to the World Health Organization (WHO), as long as the woman is monitored closely for infection during the first six weeks after insertion.



If the cervix is red, can the IUD be inserted?

Yes, if the redness is due to cervical ectopy/ectropion, which is not an infection, or cervical erosion (a small trauma); if the woman is not at risk of STDs; and if the pelvic exam is normal (no cervicitis). Cervical ectropion is a normal condition in many women (the presence on the ectocervix of columnar epithelial cells from the endocervix).

Should a woman with past PID but no current risk of STDs use an IUD?

If she has had a subsequent pregnancy, previous PID does not affect IUD use, says WHO. If there has not been a subsequent pregnancy since PID, there may be some added risk of PID, but advantages generally outweigh risks.

When can an IUD be inserted postpartum?

Immediately postplacental; during or immediately after a cesarean section (with special training); prior to hospital discharge (up to 48 hours after delivery); four weeks postpartum for the Copper T IUDs and six weeks postpartum for other types of IUDs. Special training is needed for insertions done before the woman leaves the hospital because of increased risk of uterine perforation or expulsion.



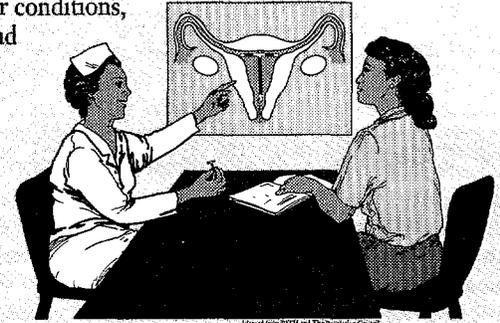
Can an IUD be inserted immediately postabortion?

Yes, for a spontaneous or induced abortion, except when the uterus is infected or at risk of infection; there is serious trauma to the genital tract; or there is hemorrhage or severe anemia — conditions that must be resolved before insertion. Postabortion IUD insertion after 16 weeks (the second trimester) may have an increased risk of expulsion and should only be done with special training, as the uterine cavity is too enlarged for routine insertion techniques.

WHO SHOULD USE COPPER IUDS?

No restrictions for a woman who has:

- given birth and is 20 years old or older
- begun breastfeeding
- undergone a first trimester abortion
- any of these gynecological conditions: irregular menstrual pattern without heavy bleeding; past PID with a subsequent pregnancy; past ectopic pregnancy; cervical intraepithelial neoplasia; cervical ectropion; history of pelvic surgery
- any of most cardiovascular conditions, including hypertension and uncomplicated valvular heart disease
- any of these metabolic conditions: diabetes; obesity; goiter
- any of these liver problems: biliary tract disease; neoplasia; cirrhosis; viral infection
- breast disease, epilepsy, headaches, or who smokes or uses antibiotics



Advantages generally outweigh risks for a woman who has:

- not given birth and is under age 20
- recently given birth (but IUD should not be inserted between 48 hours to four weeks after delivery)
- undergone a second trimester abortion
- these gynecological conditions: severe dysmenorrhea; irregular menstrual patterns with heavy bleeding; past PID without a subsequent pregnancy; vaginitis without purulent cervicitis; uterine fibroids or cervical lacerations not distorting uterine cavity or interfering with insertion; endometriosis
- sickle cell disease, iron deficiency anemia, or complicated valvular heart disease

Not recommended, unless other more appropriate methods are not available or acceptable, for a woman who has:

- multiple partners, or whose partner has multiple partners
- benign gestational trophoblastic disease
- HIV infection, or high risk of HIV infection
- heavy irregular vaginal bleeding, if anemia is noted clinically

Should not be used by a woman who has:

- a pregnancy
- cervical cancer awaiting treatment, endometrial cancer, or ovarian cancer
- infection after childbirth or abortion
- malignant gestational trophoblastic disease
- had an STD, PID or purulent cervicitis within the previous three months
- unexplained vaginal bleeding
- uterine cavity distortion or is otherwise incompatible with insertion



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IUD Safety Can Be Appealing

In countries where IUDs are not widely used, unfounded health concerns can be a reason.

Intrauterine devices (IUDs) have no systemic health effects or harmful side effects except an increased risk of anemia, making them among the most attractive of all contraceptive methods.

"Copper IUDs are popular in many countries because they are safe, in addition to being convenient and effective," says FHI's Gaston Farr, who has coordinated multicountry clinical trials involving the Copper T. In countries where the IUD is not widely used, misinformation about health concerns can be a significant barrier to use.

Copper-bearing IUDs are not a direct cause of pelvic inflammatory disease (PID), although users face some risk of PID when the device is inserted under unsterile conditions. Also, women at high risk of a sexually transmitted disease (STD) usually are not good candidates for IUD use because of a correlation between STDs and PID. (See related article, page 11.)

There is no evidence that IUDs increase the risk of cervical, uterine or endometrial cancer. However, women with known or suspected cancer of the uterus or endometrium, or undiagnosed vaginal bleeding, are not good candidates for the IUD.¹ IUDs, like some uterine cancers, may cause uterine bleeding between menstrual periods. Bleeding abnormalities could be attributed to the IUD in error, and the real reason for bleeding overlooked.

Other health concerns usually are not serious or occur very infrequently. These include pregnancy during IUD use, intermenstrual bleeding or increased menstrual bleeding, perforation during insertion and expulsions.

PREGNANCY

If a client with an IUD misses her period, providers should determine if she is pregnant, and whether the pregnancy is ectopic. If the egg is implanted in the uterus correctly, the client should choose whether to continue the pregnancy. There is no evidence of birth defects when conception occurs with a copper IUD in place.

If the IUD is still in place, it should be removed in order for the pregnancy to proceed safely. Removal should be done carefully. If the pregnancy is less than 13 weeks along and the strings are visible, removal can be done by a trained health care provider. If the strings are not visible, or if the pregnancy has advanced beyond 13 weeks, the client should be examined by a physician. If the IUD cannot be removed, the woman should be told she is at an increased risk of miscarriage, premature labor and uterine infection. If she still wishes to continue her pregnancy, she should be examined frequently for complications, such as infection.²

The high degree of contraceptive effectiveness from copper IUDs results in protection from all pregnancies, including tubal implantation or ectopic pregnancy. Irving Sivin of the Population Council, a leading expert on IUDs, analyzed 42 IUD

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studies published between 1970 and 1990. Ectopic pregnancies occurred in less than 0.02 percent of women using the Copper T 380 IUD, according to the pooled analysis.³

If an ectopic pregnancy does occur, immediate medical attention is needed since an ectopic pregnancy endangers the mother's life. The client should be referred to a hospital with surgical facilities. Ectopic pregnancy can be detected by ultrasound, hormonal tests, or by noticing symptoms, which include abdominal pain.

BLEEDING

Irregular menstrual bleeding among IUD users is not usually a sign of a health problem. Bleeding can, in fact, be a sign that the IUD is working properly. The copper released by the IUD interrupts the normal reproductive cycle and causes the endometrium to shed more frequently than during a woman's normal menses.

However, due to the possibility of increased bleeding with IUD use, women should be carefully screened for risk of anemia prior to insertion. An Israeli study looked at 34 women using copper IUDs other than the Copper T 380: the Multiload 250 or the Nova T. Menstrual bleeding increased from 3.9 to 7.1 days after four months of use, and the ferritin levels — an indicator of anemia when levels are low — dropped by more than half (from 24 ng/ml to 9.3 ng/ml).⁴ Other indicators, hemoglobin and iron, remained the same. But since menstrual bleeding decreases over time, users may experience a slight increase in hemoglobin levels with extended IUD use.⁵

During the first year of FHI's multicountry trials, nearly half of all Copper T 380 users complained of bleeding and pain. However, only a small fraction of the women, 5.6 percent, had the device removed for this reason.⁶

Rarely was the removal medically necessary; for most of the women studied, the choice of removal was a personal preference. In addition, FHI's Farr found the acceptability of irregular bleeding varied from place to place. In Egypt, removals for bleeding were more common than elsewhere in Africa, at 17.3 per 100 users. By contrast, in Nigeria and Cameroon, irregular menses caused only 1.3 and 1.0 removals per 100 women using IUDs.⁷

Side effects of irregular bleeding, spotting, or heavy bleeding decrease with time. Once women are accustomed to IUD use, removal rates go down. A four-year study of

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IUDs ARE CONVENIENT, EFFECTIVE AND SAFE TO USE, MAKING THEM APPEALING TO MANY WOMEN. A WOMAN PEELS POTATOES AT A FARM NEAR HUANCAYO, PERU.

two brand-name Copper T 380s, the Gyne T 380 and Slimline, conducted from 1988 to 1992, showed that women who had previously used IUDs were one-third as likely to have their IUDs removed because of bleeding or pain, compared with women without previous IUD experience.⁸

INSERTION, PERFORATION

Improper insertion can be harmful, since it can result in partial or total perforation of the uterine wall. However, this happens very infrequently. "Perforation is a very rare event in the hands of a skilled provider," says Dr. Barbara Rojnik of Slovenia, who chairs a World Health Organization steering committee on IUDs and is currently at

FHI on a fellowship. The risk of uterine perforation by Copper T 380 IUDs is only 0.4 per 1,000 women and the risk of cervical perforation is 0.6 per 1,000, making a total perforation rate of approximately 1.0 per 1,000, or one woman in 1,000 insertions.⁹

When perforations do occur, the IUD may injure or puncture surrounding organs. A woman whose uterus has been perforated should have the IUD removed as soon as possible. If a client feels a sharp pain during insertion, the provider should terminate the procedure, provide an alternate contraceptive method, and wait at least a week before attempting another insertion. The cervix may also be perforated when an IUD is being expelled. Copper-bearing devices are made with a rounded tip at the bottom to reduce this risk.

Providers should always insert the IUD gently. A good time to insert is during menses when the cervix is dilated and

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irregular spotting will go unnoticed. However, IUDs can be inserted at any time in a woman's cycle, provided she is not already pregnant. The preference for menstrual insertion should not be used to refuse access to the method. The provider need not be a physician, but all providers should be well-trained to insert IUDs.

The sterilized IUD package should be opened just prior to insertion, not in advance. If left too long in the loading tube used for insertion, a Copper T IUD may lose its shape and become less effective. If a copper IUD has become tarnished in its sterile package (turns green or black), it is still safe to use and will be just as effective.

EXPULSION, REMOVAL

Because IUDs require only one visit for insertion and few follow-up visits, correct use by the client is easy. She needs only to check for a marker string, also called the IUD's tail, to make sure the device has not been expelled.

While there is no health risk involved, a partially expelled device can leave a woman believing she is protected from pregnancy

when she is not. Because expulsions are not always felt by the user, it is important for women to check routinely for the IUD string attached to the bottom of each device, to make sure the IUD is still in place.

Providers may use a syringe-like suction device to extract the IUD. A new IUD can be inserted if there are no complications from the removal, or if there are no indications that replacement would be problematic.

In the multicountry FHI study that compared the Copper T 380 with other IUDs, Copper T 380 IUDs had the lowest rate of expulsion. The risk of expulsion was greatest with the Lippes Loop, an inert IUD that does not contain copper. The Copper T 380 had an expulsion rate of 3.1 per 100 women for one year, compared with 6.4 per 100 for the Lippes Loop.¹⁰

Partial or complete expulsion usually occurs during the first few months after insertion, when the uterus is reacting to the presence of a new object. After the first three months, the risk decreases substantially. The provider's skill in insertion is the single most

important factor in avoiding expulsion. Expulsions are also more common among young women who have not been pregnant.

The protection IUDs offer can be long-term. In the absence of complications, copper devices may be left in for 10 years or more. Those inserted after age 40 may be left in until menopause, unless a woman becomes pregnant. An IUD should be removed one year after menses stop, but no ill effects have been reported among women who have not had them removed more than a year after menopause.

— Sarah Keller

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BERYL GOLDBERG

A WOMAN MILLS GRAIN IN BURKINA FASO.

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IUD Insertion Timing Vital in Postpartum Use

Because of expulsion risks, insertion ideally should take place soon after delivery, or delayed for weeks.

As a contraceptive used during the postpartum period, the IUD has a distinct advantage: It does not affect breastfeeding, as do many systemic contraceptive methods. The postpartum period may also be a convenient time during a woman's life to have an IUD inserted, since it may be one of the few times she is in contact with medical services.

In addition, IUDs do not require regular user compliance. Coital-dependent methods may be used inconsistently during the postpartum period by couples who think conception is less likely during this period. Also, if a woman says she wants no more children but has not had time to consider sterilization carefully, an IUD offers a reversible alternative.

Timing of insertion, counseling, provider training and programmatic support are critical factors for IUD use during the postpartum period.

The timing of insertion is important primarily because it influences the risk of expulsion. Expulsion can leave a woman unprotected from pregnancy without her realizing it. Ideally, postpartum insertion should take place within 10 minutes of placental delivery (immediate postplacental) or at about six weeks after birth, when a woman returns for a routine postpartum care visit.

Postpartum insertion can be done before hospital discharge (up to 48 hours after delivery), but it should not be done between 48 hours and about six weeks postpartum because of an increased risk of expulsion and

perforation. Special training is required for immediate postplacental insertions and for insertion within the first 48 hours. Copper T IUDs may be safely inserted as early as four weeks postpartum, but for other IUDs, one should wait until six weeks postpartum. This is because the so-called "push insertion technique," used for some types of noncopper IUDs, might result in higher perforation rates.¹

Immediate postplacental insertion should only be done if there is adequate prenatal counseling. Ideally, choices of methods should be discussed during routine prenatal visits, allowing women to choose the most appropriate method at that point. In some cases, a woman in the early stages of labor could receive enough information after arriving at the clinic to decide to have a postplacental insertion. Likewise, a woman could decide after delivery to have an IUD inserted before leaving the hospital. A woman should never receive an IUD immediately after delivery without having received adequate counseling and giving her informed consent. Counseling should be done once the emotional and physical stresses of labor have ended.

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RICHARD LORD

PRENATAL COUNSELING SHOULD INCLUDE CHOICES OF CONTRACEPTIVE METHODS, ALLOWING WOMEN TO CHOOSE THE MOST APPROPRIATE METHOD. A PREGNANT WOMAN GAZES FROM HER WINDOW IN LOS MINAS, DOMINICAN REPUBLIC.

Good postpartum IUD programs in hospitals need national and regional support. Clinicians need specialized insertion training, and prenatal clinics must give priority to contraceptive counseling. A variety of methods should be available to potential users. Also, the obstetric unit of the health-care center must work in close coordination with the family planning or maternal and child health unit. Only a few countries, including Mexico and Colombia, have committed major resources and programmatic attention to postpartum IUD programs.

SAFE AND EFFECTIVE

Studies have shown that postpartum IUD insertions, including those done immediately after placental delivery or cesarean section, are generally safe and effective.

Compared with interval insertions, postpar-

tum insertions do not increase the risk of infection, bleeding, uterine perforation or endometritis, nor do they affect the return of the uterus to its normal size.² ("Interval insertions" are those that are done after the postpartum period of six weeks following delivery.)

Research shows that with the Copper T 380A IUD, breastfeeding women have less pain at insertion, and have lower removal rates due to bleeding or pain than nonbreastfeeding women.³

An IUD can also be safely inserted immediately after a spontaneous or induced abortion except when the uterus is infected or at risk of infection, there is serious injury to the genital tract, or there is hemorrhage or severe anemia. If the abortion occurs after 16 weeks of pregnancy, IUD insertion should only be done by someone specially trained in correct fundal placement. Otherwise, the insertion should be

delayed for six weeks after abortion because the uterine cavity is too enlarged for using routine insertion techniques.

The main problem with postpartum insertions is that they generally result in higher expulsion rates than interval insertions. Risk of expulsion is lower for insertions done within 10 minutes of delivery than for those done between 10 minutes and hospital discharge.⁴ One multisite study found that after six months, the cumulative expulsion rate was 9 percent for immediate postplacental insertion, or nine of every 100 women, compared with 37 percent for insertions done between 24 and 48 hours after delivery, or about one out of three women.⁵ The risk of expulsion can be reduced substantially with appropriate training in postpartum insertion techniques.

For interval insertions, the rate of expulsion after 12 months is about 6 percent, or six out of 100 women.⁶ Expulsion rates for insertions following cesarean deliveries are about the same as for interval insertions, according to studies conducted in Mexico, Belgium and China. Expulsion rates can vary extensively, depending on the timing of insertion, the technique used, skill of the person doing the insertion, and the type of IUD used. These factors are especially important in postpartum insertions. A study of immediate postplacental insertions reported three-year cumulative expulsion rates of 28 percent for the Lippes Loop compared to 11 percent for Copper T's.⁷

High fundal placement by hand or with forceps during the postpartum period reduces the risk of expulsion. The provider should feel the IUD against the fundus both internally and through the abdominal wall. An inexperienced person might tend to place the IUD too low in the uterus.⁸

A recent FHI study in Africa showed the importance of training and experience. The study evaluated postpartum IUD programs at the Provincial General Hospital of Nyeri, Kenya and the Maternité Hamdallaye of Bamako, Mali. All women who received an IUD during a seven-month period were interviewed. In Kenya, 224 IUD acceptors were interviewed at six weeks, three months and six months after insertion along with 185 nonacceptors. In Mali, a similar approach involved 110 acceptors and 273 nonacceptors.⁹

The six-month cumulative expulsion rates in Kenya were 1 percent for immediate insertions and 5 percent for insertions done before hospital discharge, rates comparable to or even lower than interval insertions. These low rates might be attributable to the extensive training and experience of the Kenyan providers.

In Mali, the six-month expulsion rates of 15 percent (immediate postplacental) and 27 percent (before leaving the hospital) were skewed by the high rates for one of the three providers, who had far less training and experience than the other two. All of the providers were midwives. Removals for medical reasons and pelvic infections were rare in both countries, and no uterine perforations were reported.

DELAYING ACCESS RISKS UNWANTED PREGNANCY

Before providing any method of contraception, family planning practitioners should be sure a woman is not pregnant.

Traditionally, family planning clinics without laboratory facilities have used menstrual bleeding as an indicator that a woman is not pregnant. This had led, in many instances, to policies that prohibit clients from receiving intrauterine devices (IUDs) and other family planning methods unless they are menstruating.

Yet, these policies are medically unnecessary and may result in an unplanned pregnancy if a woman must wait weeks before she is allowed to begin using contraception. Providers can take other steps to make sure family planning clients are not pregnant, including client interviews, physical examinations, or laboratory tests.

Postponing a woman's access to contraception to coincide with menses may even discourage her from using family planning, says Dr. Roberto Rivera, corporate director for international medical affairs at Family Health International. "It requires an extra visit to the family planning clinic. It may mean a sense of frustration for the client. The woman made the decision and took the time to get family planning, and her expectations have not been met. She may not come back, and she may get pregnant during the waiting period."

In a study of IUD use in Kenya, researchers found that usually the first question asked of a client during the registration process dealt with menstruation. "Only one client was told that she could have an IUD inserted if she had refrained from sexual intercourse since her last menses," the study found.¹ In Ghana, three-fourths of providers surveyed delayed giving oral contraceptives to nonmenstruating clients who had requested the pills.²

The Technical Guidance Working Group, a committee of practitioners and family planning experts from around the world organized by the U.S. Agency for In-

ternational Development, has developed the following recommendations for screening clients for pregnancy.³

A clinician can normally find out whether a woman is pregnant by asking the client if she has had any symptoms of pregnancy, such as absent or altered menses, nausea, persistent fatigue, breast tenderness or enlargement, increased frequency of urination, or the perception of movement of the fetus.

Providers also can be reasonably sure a woman is not pregnant if any of the following is true:

- she has not had sexual intercourse since her last normal menses
- she has been correctly and consistently using a reliable contraceptive method
- she is within the first seven days of onset of normal menses
- she is within four weeks postpartum (for nonlactating women); or within seven days after an abortion; or, is correctly practicing the Lactational Amenorrhea Method (is amenorrheic and fully or nearly fully breastfeeding a baby younger than six months).

To determine if a woman is pregnant, providers also may conduct a physical examination, but this is seldom necessary. At or around 18 weeks, providers can hear

the fetal heartbeat with a stethoscope and can detect fetal movements.

Laboratory tests can also be used to detect pregnancy. However, tests often are not available or affordable and are often unnecessary.

— Barbara Barnett

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POSTPONING A WOMAN'S ACCESS TO CONTRACEPTION TO COINCIDE WITH MENSES MAY DISCOURAGE HER FROM USING FAMILY PLANNING, SINCE IT MAY BE DIFFICULT FOR HER TO MAKE ANOTHER CLINIC VISIT. THIS MOTHER AND HER CHILDREN LIVE IN AN ISOLATED AREA OF GUATEMALA.



ROGER LEMOYNE/UNICEF/5482

A WOMAN SMILES AS SHE RECEIVES HER BABY IMMEDIATELY AFTER BIRTH. THE TIMING OF IUD INSERTION AFTER DELIVERY IS IMPORTANT BECAUSE IT INFLUENCES THE RISK OF EXPULSION.

COUNSELING CRITICAL

In the Kenya and Mali programs, women who had received counseling in the prenatal period or during the first stage of labor at the hospital were eligible for an immediate insertion. Women who were counseled about IUD insertion after delivery could choose to have an IUD inserted before hospital discharge, generally within 72 hours of delivery. "Prenatal counseling is important because it allows for immediate postplacental placement, which is associated with lower expulsion rates," says Dr. Charles Morrison of FHI, study coordinator.

Few studies have examined counseling issues and other service delivery questions regarding postpartum IUD use. Often, providers discuss the method choice only with the woman. But later, a husband or other family member such as a mother-in-law may object to the choice. Ideally, a couple would receive thorough prenatal counseling together about contraceptive choices, including IUDs. Such a counseling approach would better prepare the family for the method and encourage longer continuation rates. In the Africa postpartum study, for example, husbands' desire for IUD removals

was a significant reason for removal, emphasizing the importance of involving the husband in prenatal counseling.

Because most expulsions occur in the early months, it is particularly important to give clear instructions about recognizing expulsion through the string length. The Copper T device has a string 12 cm long that can easily move into the enlarged postpartum uterus and therefore can no longer be felt by the woman.

"A number of relevant questions with regard to missing strings need to be answered," says Dr. I-cheng Chi of FHI, an IUD specialist. "Do the missing threads indicate expulsions or retraction of the strings into the uterus? Should the IUDs be removed when the strings are missing, and is this removal difficult? Should follow-up visits for immediate postpartum insertion be scheduled earlier than for interval insertions so as to discover the missing threads in time?"

Characteristics of successful postpartum contraceptive programs were identified at a 1990 worldwide meeting sponsored by FHI, the Mexican Ministry of Health and the Instituto Mexicano del Seguro Social (IMSS). Among the important characteristics are good training in counseling, quality of care, and clinical issues for personnel at all levels.

— William R. Finger

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LNg IUD Offers Less Bleeding

A new IUD available in a few countries uses a synthetic hormone to achieve a high rate of long-acting contraception, typically with less bleeding than any other type of currently available IUD.

Menstrual bleeding is reduced in all women who use the levonorgestrel (LNg)-releasing device, in some by so much that they hardly bleed at all. The LNg IUD can be inserted early in a woman's reproductive life and its contraceptive effect is reversible. The device combines the high efficacy of modern hormonal contraceptives, such as injectables, with the convenience of intra-uterine contraception.

The device is available in Europe and Singapore. Since it has not yet been approved by the U.S. Food and Drug Administration for use in the United States, it is not available through the U.S. Agency for International Development, which provides contraceptive commodities to many developing countries. The LNg IUD, also known as the LNg-20 IUD because it releases 20 micrograms of levonorgestrel daily, is manufactured by Leiras Pharmaceuticals in Turku, Finland. It received approval for use in Finland in 1990 and in Sweden, Norway and Denmark in 1992, where it is marketed under the brand name Levonova, and in Singapore and the United Kingdom in 1995, where it is sold as Mirena.

Worldwide, one other hormonal IUD is on the market, and it is available only in the United States. Progestasert, made by

ALZA Corporation in Palo Alto, CA, USA, uses the natural hormone progesterone, but is approved for only one year of use. Since it was first marketed in 1976, demand has been limited.

A related approach, the intra-cervical device (ICD), is in the early stages of development at the University of Helsinki, Finland. This product also contains LNg, but has a slightly smaller size than the LNg-20 IUD and is placed in the cervical canal instead of the uterus. Because of this, insertion may be easier and may require less training.

FIVE YEARS OF USE

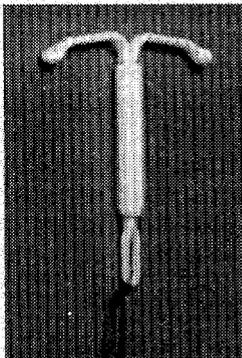
The LNg IUD is currently approved for five years of use in countries where it is available and indications are promising that it may be highly effective for longer. It is shaped like a copper-bearing Nova T IUD, but contains no copper. Instead, the vertical portion of the "T" bears a small rubber sleeve containing 52 milligrams of the synthetic hormone levonorgestrel. Research shows it still contains 40 percent of its original steroid load after five years. Because of its long-acting effect, some experts consider the LNg IUD an alternative to surgical female sterilization, the most widely-used modern contraceptive method.

Finnish researchers compared the opinions of 61 LNg IUD users with 44 users of the copper-bearing Nova T at several clinics in Helsinki. About half (48 percent) of the LNg users expressed high satisfaction compared with 23 percent of women using the copper IUD.¹ The high level of satisfaction may be due to the LNg IUD's reduction of menstrual bleeding and its high efficacy rates, even among young women.

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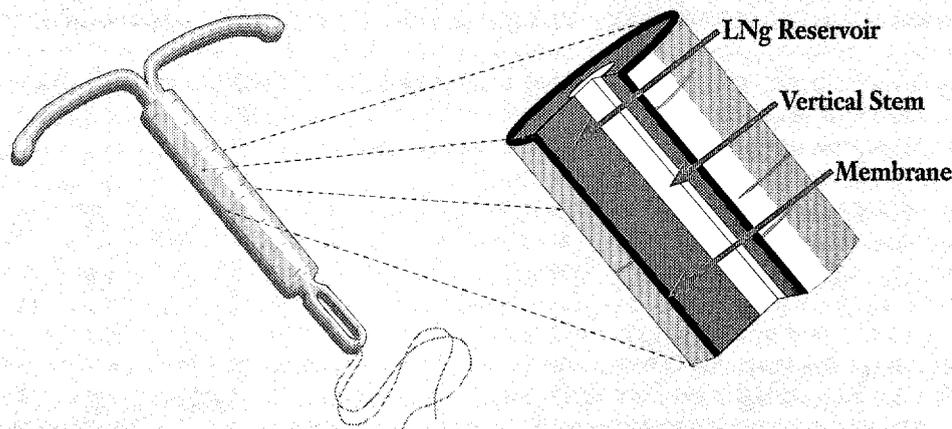
LNG-20 INTRAUTERINE DEVICE

The LNG-20 IUD contains 52 milligrams of a synthetic progestin hormone, levonorgestrel (LNg), releasing 20 micrograms daily.



Characteristics:

- Long-lasting (at least five years)
- Very effective contraception
- Less bleeding than other IUDs
- Lower risk of myoma (benign muscle tumor)
- More amenorrhea (a disadvantage in some cultures)



Manufacturer: Leiras Pharmaceuticals, Turku, Finland

Brand names: Levonova in northern Europe, Mirena in the United Kingdom and Singapore

Approved for use: Finland, 1990; Sweden, Norway and Denmark, 1992; United Kingdom and Singapore, 1995

Combined results from three international trials and one national trial involving 7,393 women in 17 countries show the LNG-20 IUD has a long-acting contraceptive effect, similar to copper-bearing devices. The pregnancy rate for the LNG IUD was 0.2 per 100 users (two pregnancies per 1,000 women during the first year), compared with 0.9 per 100 for the Nova T and 0.4 per 100 for the Copper T 380.²

Unlike many other methods of contraception, the LNG IUD is highly effective among younger users. Copper devices, oral contraceptives and other methods have higher failure rates for women under 30, who are more prone to accidental pregnancy because they are more fecund and have more frequent sexual intercourse than older women. In a study that tracked 338 LNG users under the age of 25 for five years, none became pregnant.³

Many users are attracted by the LNG IUD's ability to reduce menstrual bleeding and pain. In contrast to copper IUDs, which tend to increase monthly blood loss by an additional 20 ml, the LNG IUD usually reduces or eliminates the normal monthly blood flow.⁴ This reduction is particularly important for women who suffer menorrhagia, or excessive bleeding. By using the LNG IUD, these women can significantly reduce their bleeding. LNG is so effective in reducing menses that it can be used as a therapeutic treatment for menorrhagia and dysmenorrhea, excessive and painful bleeding.⁵

Levonorgestrel renders the endometrium unresponsive to estrogen, the body's natural hormone responsible for growth of the uterine lining in preparation for pregnancy or monthly shedding. Without this periodic growth, the lining remains thin and causes less bleeding.⁶ The endometrium returns to its normal cycle soon after the IUD is removed.

For most women, the first two to three months after LNG IUD insertion are accompanied by lighter menstruation and some irregular spotting. Thereafter, up to 30 percent of LNG IUD users become completely amenorrheic, with no spotting at all.⁷ A majority of women stop their periods but may continue to have occasional spotting. This provides relief to

women for whom menses are painful, inconvenient or excessive. In cultures where amenorrhea may worry clients, counseling can reassure women that reduced bleeding is

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not harmful and may be beneficial to their health. The manner of insertion can affect the amount of bleeding. If the LNG IUD is placed correctly at the fundus of the uterus, spotting is minimized.

Reduced blood loss, including amenorrhea, increases hemoglobin and iron levels. This aspect of the LNG IUD may be advantageous among women with anemia.⁸ Given the appropriate counseling, women in many cultures may prefer amenorrhea. Continuation rates increase when women are told to expect initial spotting, reduced menses, and the possibility of amenorrhea.⁹ Women should be informed that the reduction of bleeding is not harmful to their health.

Removal rates for bleeding disturbances appear to be about the same for LNG and copper-releasing devices during the first year, at 8.7 and 7.5 percent respectively.¹⁰ After five years of use, removal rates for bleeding were significantly lower among LNG users compared with copper IUD (Nova T) users. Heavy flow is rare among LNG IUD users while it is the most common cause of menstrual-related removal for copper IUD users. However, the LNG IUD did have more removals due to amenorrhea.¹¹

PID, ECTOPIC PREGNANCIES

The reduced amount and duration of menstrual bleeding makes the genital tract less hospitable to infection. In addition, levonorgestrel keeps the cervical mucus thick and less penetrable by either sperm or bacteria. Consequently, pelvic inflammatory disease (PID) may be less common among women using the LNG device, in comparison with users of copper IUDs. A three-year study showed 0.5 cases of PID per 100 LNG IUD users, compared with 2.0 per 100 copper IUD (Nova T) users.¹² Other studies show PID rates among different modern IUDs to be indistinguishable. The LNG device also decreases the risk of myoma (benign uterine tumor).¹³ Rates for ectopic pregnancy and expulsion appear to be the same for the Copper T 380 and LNG IUD.¹⁴

Rare hormone-related side effects, such as acne, hair loss, weight change, headache, breast tenderness and depression, are other reasons some women stop using the LNG IUD. These infrequent side effects, however, account for only 2.7 removals per 100 users.¹⁵ In a multicenter study in Finland and

Brazil involving 484 women, no change in body weight was detected among LNG users after one year.¹⁶

Persistent follicles, a phenomenon commonly associated with other progestin-only contraceptives, such as Norplant, the injectable DMPA, and progestin-only pills, have also been detected among LNG IUD users. While persistent follicles are more common among LNG IUD users than among copper IUD users, the health effects are slight. These follicles prompted only three removals from 1,821 women using LNG-20 IUDs for 12 months.¹⁷ Other studies have shown that this device has no detectable effect on blood pressure, carbohydrate metabolism, and blood coagulation.¹⁸

Once the LNG-20 IUD is removed, fertility returns promptly, as it does with the Copper T 380. Ninety percent of women using either device become pregnant within the first year after their IUD is removed.¹⁹

Currently, the LNG IUD costs approximately U.S. \$250 in Europe. A copper IUD costs about U.S. \$50 when bought in Europe, U.S. \$280 when purchased in the United States.

— Sarah Keller

Continued on page 32

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FDA CONSUMER



THE LNG IUD IS HIGHLY EFFECTIVE EVEN AMONG YOUNG WOMEN, WHO ARE MORE PRONE TO ACCIDENTAL PREGNANCY BECAUSE THEY ARE MORE FECUND AND HAVE MORE FREQUENT SEXUAL INTERCOURSE THAN OLDER WOMEN.

Newer OCs and Blood Clot Risks

Recent news reports in Europe and elsewhere have mentioned a possible link between the use of oral contraceptives (OCs) containing the newest formulations of progestins and the development of blood clots. Family Health International recently provided background materials to scientists and health providers worldwide to help clarify this relationship. The following is from a "Question and Answer" sheet circulated by FHI.

Question: Oral contraceptives (OCs) have been studied for years. Why have concerns about cardiovascular risks been raised now?

Answer: A large epidemiological study, designed to gain more information on contraceptive use and cardiovascular disease, has been conducted by the World Health Organization (WHO). While study results are preliminary, some results were published in British newspapers.

According to a news release from WHO, these preliminary study results suggest that users of combined oral contraceptives containing estrogen and the newest synthetic progestins, desogestrel and gestodene, appeared to have twice the risk of venous thromboembolism (blood clots) than users of pills containing the older progestins, levonorgestrel and norethindrone.

This information prompted the British Committee on the Safety of Medicines, the country's regulatory agency, to issue a warning about contraceptives containing the newest progestins. The government has said women may continue using the new progestin pills if they accept the higher risk.

Question: Which brands of pills contain desogestrel and gestodene?

Answer: The pills are marketed under the following brand names: Desolett, Femodeen, Femoden, Femodene, Femodene ED, Femovan, Frilavon, Ginoden, Gynera, Gynovin, Marvelon, Marviol, Mercilon, Microdosis, Microdiol, Minulet, Minulette, Moneva, Myvlar, Planum, Practil, Prevenon, Securgin, Segurin, Tri-Minulet, Triadene, and Varnoline. The names of contraceptives vary from country to country.

Question: Does the U.S. Agency for International Development (USAID) supply these brands?

Answer: No. None of these brands are distributed by USAID.

Question: Should women who are using pills containing the newest progestins, desogestrel and gestodene, stop taking these pills? Should they switch to another brand of pills?

Answer: It is important to remember that the new study results concern only the newest synthetic progestins, desogestrel and gestodene. The results do not apply to the older progestins, levonorgestrel and norethindrone.

Healthy women who use pills containing the newest progestins desogestrel and gestodene have a very, very low risk of developing blood clots. However, women who have questions or who may be interested in switching to a different brand of oral contraceptives should be advised to see their family planning provider.

To help put risks in perspective, both the World Health Organization and the International Planned Parenthood Federation (IPPF) have issued statements regard-

ing the recent reports. The organizations agree that because the incidence of venous thromboembolism in women of reproductive age throughout the world is very low, an excess risk from using combined oral contraceptives would affect a relatively small number of women.

WHO states that "current users of oral contraceptives containing desogestrel or gestodene appear to be at higher risk of venous thromboembolism compared to users of pills containing levonorgestrel or norethindrone." WHO, however, has noted that "the possibility that these results are due to chance or bias cannot be excluded entirely and the results should be confirmed by further studies."

WHO advises "that until further information becomes available, low estrogen dose oral contraceptives containing progestins other than desogestrel and gestodene may be preferred."

The IPPF statement says that women wishing to use pills containing desogestrel or gestodene should be counseled about the possibility of increased risks for thromboembolic disease. If women already using these pills wish to switch to a brand without desogestrel or gestodene, they should complete their present cycle of pills before beginning a new brand.

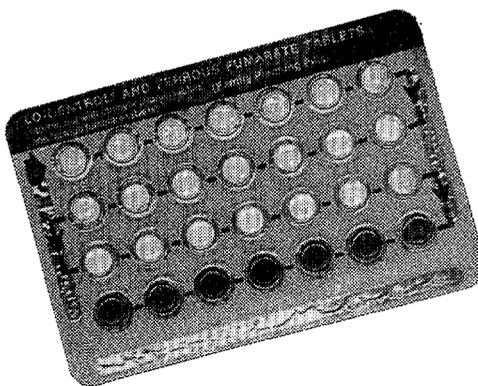
Dr. Olav Meirik, chief of WHO's Task Force for Epidemiological Research in Reproductive Health, said in a WHO written statement that "it should be understood that health risks from pills containing the progestogens desogestrel or gestodene are very low. The risks from an unplanned pregnancy or unwanted pregnancy are far greater in comparison."

Question: What do we know today about contraceptive use and cardiovascular disease?

Answer: When oral contraceptives were first introduced more than three decades ago, they contained high doses of the hormones estrogen and progestin. Since then, the amount of these hormones has been significantly reduced in combined oral contraceptives. Older oral contraceptives contained 75 to 100 µg of estrogen. Newer formulations of oral contraceptives contain 20 to 50 µg of estrogen. Also, researchers have developed an oral contraceptive that contains no estrogen, only progestin (the mini-pill, progestin-only pill or POP).

Early scientific research on the relationship between cardiovascular disease and oral contraceptive risks studied women using high-dose pills. Scientists found that estrogen promoted blood coagulation; consequently, blood clots were more likely to develop in oral contraceptive users than in nonusers.

Because newer combined pills contain smaller amounts of estrogen, they have less effect on blood coagulation, so the risks of heart disease are very rare with these pills.



PILLS CONTAINING LEVONORGESTREL.

However, because estrogen can still affect blood coagulation as well as blood pressure and lipids, these methods are not generally recommended for women who have a history of heart disease or blood clots or women who are at risk for heart disease. (These studies did not include pills containing desogestrel and gestodene.)

Modeling studies at Family Health International have examined the risks of death for women who use low-dose oral contraceptives. These studies have found that among users of low-dose OCs, the risk of cardiovascular death exceeds the risk of death due to pregnancy only among women who smoke 25 or more cigarettes a day and who are over 30 years of age.

Question: Are there guidelines or recommendations that health care providers can follow when counseling women about oral contraceptives and cardiovascular disease?

Answer: The World Health Organization has prepared a document entitled *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Initiating and Continuing Use of Contraceptive Methods*. The criteria were prepared after discussions among international health experts, including physicians from Family Health International.

According to these recommendations, use of low-dose oral contraceptives presents an unacceptable health risk in:

- women with high blood pressure (a systolic level greater than 180 and a diastolic level greater than 110)¹
- women with blood vessel disease (vascular disease)
- women with a history of deep venous thrombosis (blood clot) or pulmonary embolism (blood clot in the lung), or women who presently have these conditions²
- women with current ischemic heart disease, or a history of ischemic heart disease
- women with a history of stroke
- women with complicated heart valve disease
- women who are planning to undergo major surgery and will be immobile for a long period of time
- women who have severe headaches accompanied by disturbances in vision
- women who are both over age 35 and are heavy smokers (more than 20 cigarettes per day).

In addition to these women who should not use OCs, the WHO guidelines say the use of combined oral contraceptives is generally not recommended for women who have certain conditions that might increase their risks of heart disease, since the risks of using the method usually outweigh the benefits of pregnancy protection. Unless more appropriate methods are not available or acceptable, OCs are generally not recommended for the following women:

- women who are over age 35 and are light smokers (20 or fewer cigarettes per day)
- women who have a history of high blood pressure with a systolic pressure of 159 to 179 and diastolic pressure of 99 to 109
- women who have had vascular disease or diabetes for more than 20 years.

FOOTNOTES

1. High blood pressure or hypertension is a risk factor for heart disease. Women who are using combined OCs and develop a blood pressure level of 160-179 (systolic) over 100-109 (diastolic) should discontinue using combined oral contraceptives. Women with mildly elevated blood pressure can use combined oral contraceptives.

2. Healthy women face little risk of developing deep venous thrombosis or pulmonary embolism; however, women who already have these conditions should consider another family planning method.

Beijing: Commitment To Improve Women's Lives

By Dr. Karen Hardee
FHI Principal Research Scientist

BEIJING, China — From my perspective as a reproductive health scientist observing the United Nation's Fourth World Conference on Women, the September conference in Beijing was about our commitments to improve women's lives. Past U.N. conferences in Mexico (1975), Copenhagen (1980), and Nairobi (1985) outlined a number of issues facing women around the world. In Beijing, country delegations focused on the policies and programs necessary to create equality for the world's women.

The Beijing conference themes were consistent with those at the U.N.'s International Conference on Population and Development, held in Cairo in 1994, which stressed the need to view family planning in the context of reproductive health. Beijing emphasized the need to view reproductive health in the

broader context of women's lives. The themes from the Beijing conference reflected those of FHI's Women's Studies Project, designed to assess the impact of family planning on women's lives.

FHI

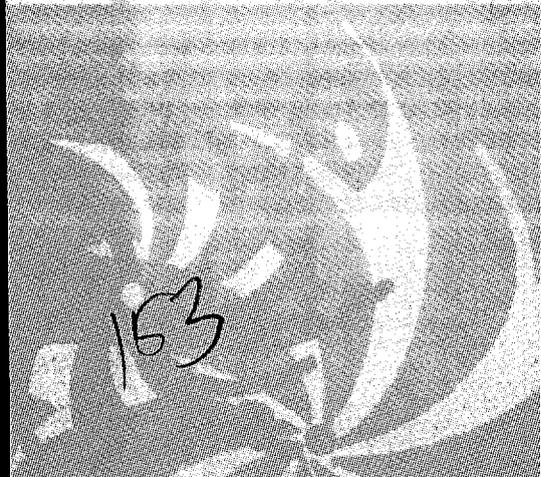


DR. KAREN HARDEE

Women's reproductive decisions are often affected by other aspects of their lives. Women facing domestic violence view their reproductive choices differently than women who live free from the fear of violence. Women prohibited from inheriting property, who have no choice in old age but to rely on children for support, might view their children in a different light than women who are free to inherit.

NGO SESSIONS

As with other recent U.N. conventions, the Beijing conference was held concurrently with a Nongovernmental Organization (NGO) Forum. Representatives from FHI's AIDSCAP Project took part in workshops involving women and AIDS, while I participated in two FHI cosponsored workshops at the forum. "Reproductive Health: A Requisite





KAREN HARDEE/FHI

WOMEN FROM MANY COUNTRIES GATHER AT THE NGO FORUM, HELD CONCURRENTLY IN BEIJING WITH THE UNITED NATIONS' FOURTH WORLD CONFERENCE ON WOMEN.

to Women's Empowerment" was cosponsored with the Washington-based Centre for Development and Population Activities (CEDPA). This session highlighted women's lack of access to even rudimentary reproductive health services around the world. A participant from Cambodia, for example, described the difficulties faced by pregnant women in rural areas, many of whom would need days of travel to obtain trained obstetric care during an emergency. Another workshop, cosponsored with the American College of Obstetrics and Gynecologists (ACOG), entitled "Contraceptive Methods and Users' Perspectives," emphasized the need for balanced information on methods of contraception, especially for providers and clients. Many sessions at the forum focused on contraception but not always in a positive light. At one session, there was a drawing of a woman being looked at by a man with a magnifying glass. The woman was being jabbed by needles, and pills were scattered around. A caption read: "No more unethical

medical research on women!" Family planning providers must be aware of these negative perceptions, so they can appropriately and accurately address women's concerns.

Women's groups discussed contraceptive safety and the need to develop women-controlled methods that protect against pregnancy and sexually transmitted diseases, including HIV. A study on women's views and practices in negotiating reproductive rights, conducted by the International Reproductive Rights Research Action Group (IRRRAG), drew considerable attention. The three-year study documented how women in seven countries consider themselves entitled

to make decisions regarding their reproductive health and childbearing but often lack social, cultural or institutional support to achieve those rights.

185 COUNTRIES

At the conference, government delegates from 185 countries reached agreement on a declaration calling on governments to improve the economic conditions of women, protect them from increasing levels of violence, and improve the status of girls. Language on reproductive health and reproductive rights from the Cairo conference remained intact within the Beijing Declaration and Platform

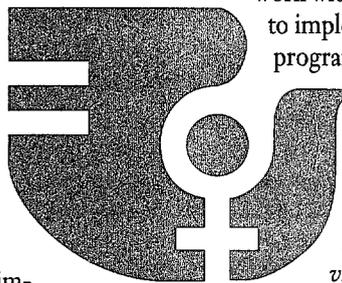
for Action. Key points from the platform regarding reproductive health and reproductive rights include the following:

- Women should be guaranteed inheritance rights, although they may not necessarily inherit the same amount as their sons.
- Women should have the right to decide freely all matters related to their sexuality and childbearing.
- The family is the basic unit of society and should be strengthened, protected and supported. Women must not suffer discrimination because they are mothers.
- Marital rape, genital mutilation of girls, attacks on women because their dowries are too small, domestic battering and sexual harassment are all forms of violence against women and violations of their human rights.

U.S. First Lady Hillary Rodham Clinton told the NGO Forum that the success of the conference rests with NGOs, whose representatives should return to their countries and hold their governments accountable for implementing the Beijing platform. More than 35,000 NGO delegates met in Beijing and returned to their countries determined to take on the challenge of implementing the promises of the conference. While the conference failed to win sizable financial commitments from governments to pay for new programs, some governments did pledge to redirect national budgets and resources.

For reproductive health, the goals of the Cairo conference were reinforced and ratified in Beijing. It is now our job, as family planning and women's health NGOs, to

work with governments to continue to implement reproductive health programs, always keeping in mind the complex and varied contexts of women's lives.



Dr. Karen Hardee, deputy director of FHI's Division of Service Delivery Research and principal research scientist, represented FHI at the NGO Forum.

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Resources

FHI MATERNAL HEALTH WORKING PAPERS

Recent working papers on maternal health are available from Family Health International. *Reproductive Morbidity: A Conceptual Framework* addresses obstetric, gynecologic and contraceptive morbidity; nonreproductive morbidity; and the measurement of maternal morbidity. *Maternal Mortality and Morbidity in sub-Saharan Africa* looks at the reproductive health of women in sub-Saharan Africa, including childhood and adult factors influencing women's reproductive health. To request free copies, write: Publications Coordinator, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709 USA. Telephone (919) 544-7040, or fax (919) 544-7261.

WALL CHART ON THE WORLD'S WOMEN

A wall chart produced for the United Nations Fourth World Conference on Women, held in Beijing in September, provides information on the life of women around the world by country and region. The chart, titled *The World's Women 1995*, includes information on life expectancy, fertility, literacy, contraceptive prevalence and related statistics. The chart is free to people in developing countries and costs U.S. \$3.50 for others. To request a copy, contact Population Reference Bureau, 1875 Connecticut Avenue NW, Suite 520, Washington, DC 20009 USA. Telephone (202) 483-1100, or fax (202) 328-3937.

HEALTH CARE FOR WOMEN AND CHILDREN

The second edition of *Health Care of Women and Children in Developing Countries* discusses the status, roles, and special needs of women and children, including child survival and adolescent health. The

book is available for U.S. \$39.95 from Third Party Publishing Company, P.O. Box 13306, Montclair Station "E", Oakland, CA 94661-0306 USA. Telephone (510) 339-2323, or fax (510) 339-6729.

REPRODUCTIVE LAWS AND POLICIES

The laws and policies of six countries concerning health, population, family planning, contraception, abortion and safe motherhood are reviewed in *Women of the World: Formal Laws and Policies Affecting Their Reproductive Lives*. The 40-page book, which covers Brazil, China, Germany, India, Nigeria and the United States, is designed to inform policy-makers, donors, service providers and human rights activists about existing legal and policy models in these fields. For a free copy of the book, write: Center for Reproductive Law and Policy, 120 Wall St., New York, NY 10005 USA. Telephone (212) 514-5534, or fax (212) 514-5538.

LNg IUD

Continued from page 27

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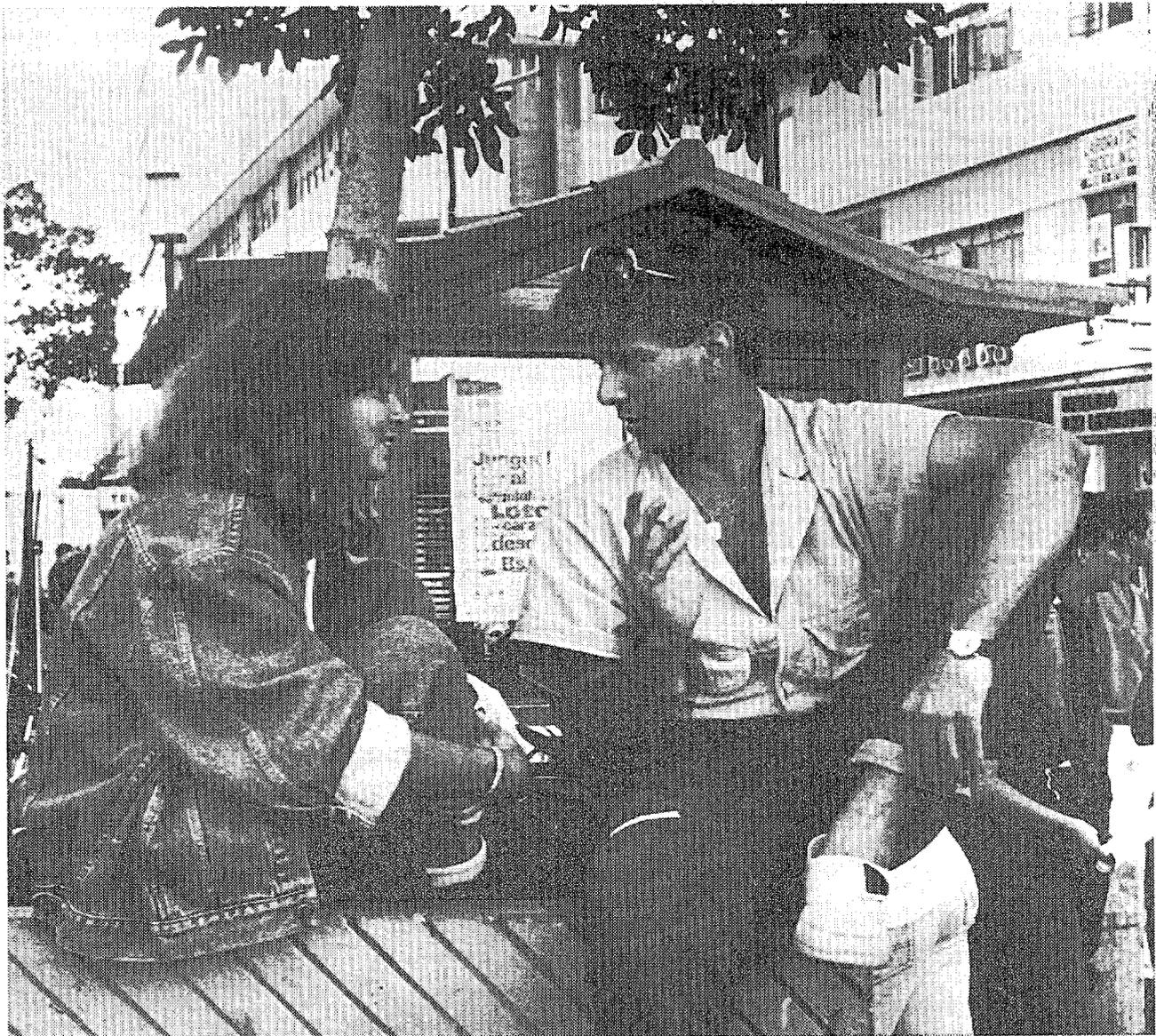
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Network

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ENTREPRENEURS



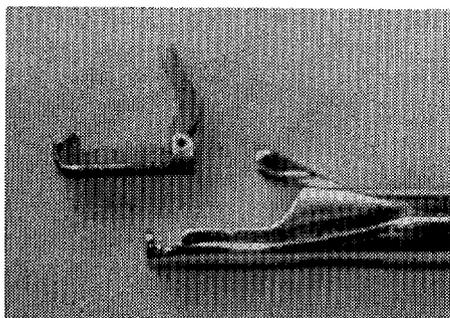
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News Briefs

FILSHIE CLIP

PASSES FDA PANEL

An advisory panel of the U.S. Food and Drug Administration (FDA) has recommended that the FDA approve the Filshie Clip, a device used in female sterilization. Manufactured by Femcare Limited of the United Kingdom, the clinical trials used to support the panel's decision were conducted by FHI.



FILSHIE CLIP AND APPLICATOR

Sterilization, the most widely used birth control method, is achieved in women by cutting or blocking the fallopian tubes, thus preventing a woman's egg from becoming fertilized. The Filshie Clip, about the size of a small fingernail, blocks the fallopian tube by clamping. It is designed to cause less damage to the tube compared with other widely-used sterilization procedures.

Because of this, it is hoped that the clip will improve the prospects for surgical reversal among women who later regret their sterilization and want to become pregnant. However, no data on reversal were submitted to FDA. Sterilization should be considered permanent since reversal operations are expensive, difficult and do not guarantee success.

In a February hearing before the advisory panel, FHI scientists said their studies show the Filshie Clip is both a safe and effective method for voluntary female sterilization. FHI began clinical trials on the clip in 1984 and has completed 11 studies in 20

countries involving more than 6,000 women who volunteered to be sterilized with Filshie Clips. They were compared with nearly 4,000 women using other sterilization techniques, including two other devices that block tubes: the Tubal Ring (also known as the Falope or Yoon Ring) and the Wolf Clip (also known as the Hulka Clip).

Femcare, based in Nottingham, England, distributes gynecological and urological devices to more than 40 countries. The FHI studies were supported in part by the U.S. Agency for International Development (USAID). Because of USAID assistance, the Filshie Clip will be available at a lower price to governmental and intergovernment agencies, as well as to national and international humanitarian aid organizations.

SIX-DAY WINDOW OF FERTILITY

A recent study shows women can only conceive if they have sexual intercourse during the six days that lead up to ovulation (including the day they ovulate).

Although scientists have known for some time that the period of fertility is limited, the new research more precisely identifies when a woman can get pregnant. Previously, estimates ranged from two days a month just prior to ovulation, to a total of 10 days before and after ovulation.

Women attempting to avoid this short period of fertility as a means of preventing pregnancy will need to know precisely when they ovulate each month — something that is still hard to predict.

"We came one step closer to understanding the fertility window," says Dr. Allen Wilcox, chief of epidemiology at the National Institute for Environmental Health Sciences (NIEHS), a U.S. government agency, located in Research Triangle Park, NC.

"For that to be translated into couples' practices, they'd have to have a very good measure of when ovulation occurs," he says. "Couples trying to avoid pregnancy by abstinence or natural family planning should still abstain for longer than six days, because we have no good way to predict ovulation accurately."

Dr. Wilcox, who headed the study, analyzed the menstrual cycles, urine samples, and sexual behaviors of 221 U.S. women who volunteered for a pregnancy

study. By comparing women's reports of when they had sex with hormonal evidence of ovulation and pregnancy, his team was able to identify when most women got pregnant. All 192 conceptions experienced by women in the study occurred during the six-day period ending on the day of ovulation. The study was published in the December 1995 issue of *The New England Journal of Medicine*.

NEW AIDS THERAPY DRUGS

The U.S. Food and Drug Administration (FDA) has approved three AIDS therapy drugs to reduce symptoms and increase the lifespan of people afflicted with the disease.

The new class of drugs, called protease inhibitors, attack the AIDS virus by blocking the enzyme, protease, which is crucial for the maturation and spread of the virus. Most previously available AIDS therapy drugs work by inhibiting a different enzyme, called the reverse transcriptase enzyme, which the human immunodeficiency virus (HIV) needs to reproduce itself.

The new drugs are saquinavir, made by Hoffman-LaRoche Inc., zidovudine, produced by Abbott Laboratories, and didanosine, made by Merck & Co., all U.S.-based pharmaceutical companies. The relatively expensive drugs are not expected to become widely available in developing countries.

Saquinavir, sold under the brand name Invirase, was approved by the FDA in December 1995. Trials showed that Invirase alleviated symptoms of AIDS when prescribed in combination with a more commonly used AIDS therapy, zidovudine (AZT).

In a ritonavir clinical trial involving 1,090 AIDS patients at 67 hospitals in the United States, Canada, Europe and Australia, the death rate after six months was 5.8 percent among patients receiving ritonavir, and 10.1 percent in a comparison group receiving a placebo. Ritonavir was approved by the FDA in February.

Indinavir, marketed as Crixivan, was approved by FDA in March. In clinical trials lasting 24 weeks, indinavir reduced HIV in blood levels by 90 percent in all 58 patients taking indinavir in combination with AZT, compared to a 45 percent reduction in 62 patients taking AZT alone.

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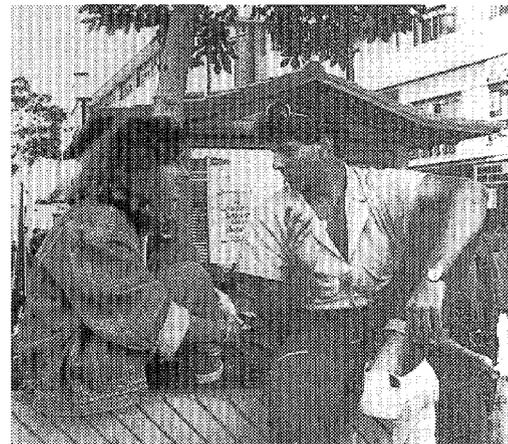
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Cover photo of a couple in Caracas, Venezuela by Beryl Goldberg



The Dual Goals of Reproductive Health

By Willard Cates Jr., MD, MPH
FHI Corporate Director of Medical Affairs

In today's global health village, the term "reproductive health" involves preventing not only unintended pregnancy, but also sexually transmitted diseases (STDs). The specter of HIV infection has made protection from genital tract infection a high priority on the world's reproductive health agenda.

As awareness of HIV and other STDs has grown, decisions about contraceptive use have begun to involve the need to prevent STDs. This became most obvious at the United Nations 1994 International Conference on Population and Development in Cairo, which defined a reproductive health agenda that encourages family planning programs to add STD prevention services. However, the only contraceptives currently recommended for STD/HIV prevention are barrier methods, making them important for ensuring one's reproductive health.

Nonetheless, many in family planning programs are hesitant to recommend barrier methods because their record in preventing unintended pregnancies is less reliable than other contraceptives. Some family planning clinicians worry that reliance on barrier methods alone will produce higher rates of both unintended pregnancy and STD/HIV. Are their fears justified?

What do we currently know about the efficacy of barrier methods in preventing STD/HIV? Four key questions dominate the barrier contraceptive method research agenda. Let us consider them in order.

Question: Do condoms (male and female) really work to prevent STD and unplanned pregnancy?

Answer: The simple answer is yes, if used consistently and correctly. When used consistently, condoms are effective in preventing both STDs and unplanned pregnancy. Thus, the method itself is effective against both conditions.

Several convincing studies demonstrate the effectiveness of condoms when used consistently. One intriguing study involved U.S. Navy seamen on shore leave in a "high-risk" port city: None of the 29 men who reported using condoms with commercial sex workers became infected with gonorrhea or nongonococcal urethritis, but 14 percent of the nonusers became infected (71 of the 499 nonusers). A second excellent study of condom use occurred among HIV-discordant couples in Europe. None of the 123 seronegative partners prospectively reporting consistent condom use became infected. Thus, used regularly and correctly, condoms work effectively.

The problem is that condoms — whether male or female devices — are typically used sporadically or incorrectly. Effectiveness rates must take this into account. Using a public health model, sexual abstinence will obviously prevent all of the risk of unprotected sex. However, intercourse using barrier methods of contraception, while not perfect, also provides a large measure of protection against the risk of STD or unintended pregnancy. In fact, plotting both abstinence and condom use on the same curve, sex protected by barrier methods reduces 70

percent of the total risk between unprotected sex and complete sexual abstinence. Thus, at the policy level, condoms must continue to be emphasized and made available.

Question: How effective are spermicidal nonoxynol-9 (N-9) agents against HIV and the other STDs?

Answer: Based on data from well-conducted randomized controlled trials, spermicides containing N-9 show a measurable protective effect against specific STDs — gonorrhea, chlamydia, trichomoniasis, and bacterial vaginosis. In Cameroon, Thailand and the United States, the regular use of N-9 by women attending either STD or family planning clinics reduced cervical gonorrhea and chlamydia infections by 20 percent to 50 percent.

However, the effect of N-9 agents on HIV transmission remains uncertain. Despite the *in vitro* activity of N-9 against HIV, and its protective effect against the simian immunodeficiency virus in Rhesus monkeys, published data are unclear about the impact of N-9 on humans *in vivo*. Among commercial sex workers in Nairobi, women who were randomly assigned to use a contraceptive sponge with N-9 had higher levels of vaginitis, genital ulcers, and HIV infection than those using a placebo. However, other observational studies in Africa and Asia show more favorable results — HIV infection was reduced among N-9 users. Thus, these data inconsistencies mean the jury is still out on the scientific verdict regarding N-9 and HIV.

Carefully controlled studies are also needed to assess the relative value of the different formulations of N-9 in preventing the transmission of STDs, especially HIV. Ongoing studies of N-9 film in Cameroon, and N-9 gel in Kenya and other parts of the world, will help resolve the question of which formulation, if any, works best.

Question: How close are we to having another female-controlled chemical barrier method?

Answer: Because of the uncertainties about N-9, and the desire to have a microbicide without spermicidal properties, developmental research is under way to discover new microbicidal agents (see article on page 15). Research is addressing not only new chemical methods, but also new physical barrier methods that protect the cervix.

New chemical methods under study include a buffer gel that maintains a low vaginal pH and does not disturb the normal vaginal flora; sulfated polysaccharides

designed to prevent adherence of HIV and chlamydia to cells in a woman's reproductive tract, yet are not spermicidal; N-docosanol, an antiviral product that works by inhibiting lipid-enveloped viruses; C31G, an amphoteric surfactant that disrupts cellular membranes but causes less irritation to the epithelium than N-9; and squalamine, a steroid-based compound that affects cell growth. These and other agents will undergo phased clinical studies over the next several years.

Question: Why not emphasize two methods, one for preventing unintended pregnancy and the other for preventing STD/HIV?

Answer: Clinicians promoting dual contraceptive use must weigh the interacting factors of extra cost and effect on user compliance. Clients usually attach different priorities to preventing either pregnancies or infections, and these priorities may change over time and among relationships.

Studies on dual-method use are limited and have focused on the use of the male condom added to the mix of other methods of contraception. In general, based on investigations where participants were using primary methods other than the condom, the more effective the primary contraceptive was in preventing pregnancy, the lower the level of consistent condom use. For example, a study in the U.S. city of Baltimore showed only 6 percent of the women who were sterilized were also using condoms consistently to prevent STDs.

Several reasons can explain why condom use may be low among people already using an effective contraceptive method. First, many people — even those with sexual behaviors putting them at risk of STD — see pregnancy as a greater immediate threat. Thus, having taken precautions against unintended pregnancy, they may be less motivated to undergo the extra effort and expense of using condoms.

Second, those who are sterilized or who are using implants, injectable contraceptives, or IUDs do not have frequent reminders to use contraception. People who depend upon barrier methods or the daily schedule

of taking oral contraceptives may be more aware of, and prepared for, prophylactic needs. Without regular reminders of the need to protect against both pregnancy and STDs, individuals may be less likely to have condoms available.

The way in which counselors and clinicians encourage dual methods can influence whether the message is effective. With spermicides as the primary contraceptive method, the percentage of consistent condom users varied dramatically among three small clinic-based studies in Mexico, the Dominican Republic, and Kenya. This indicates factors other than the method itself affect levels of concurrent use.

In addition, among Colombian commercial sex workers, women counseled to use spermicides as a backup method if their

clients were unwilling to use condoms were less likely to use condoms consistently than women encouraged only to use male condoms. More research is clearly needed on the best mix of contraceptives. Studies that examine the use of the female condom, diaphragm, or spermicides in conjunction with long-term methods will help clarify this issue.

What are the key messages regarding use of barrier contraceptive

methods to achieve better reproductive health? First, encourage correct and consistent use of condoms. Second, maintain hope (albeit with appropriate scientific skepticism) that research will show N-9 can be used effectively against HIV. Third, support developmental research of other female-controlled contraceptive barrier methods and microbicides. Fourth, evaluate ways to increase dual-method use to prevent both unplanned pregnancies and STD/HIV.

Dr. Cates, FHI's corporate director for medical affairs, is an epidemiologist. He previously directed the Division of STD/HIV Prevention at the U.S. Centers for Disease Control and Prevention.



DR. WILLARD CATES

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Barrier Methods Require Consistent Use

Correct, consistent use improves contraception and is essential for achieving good STD protection.

For barrier methods to be most effective against both pregnancy and disease, they should be used during every act of intercourse and be used correctly.

Barrier methods are the only contraceptive methods that have been shown to protect against sexually transmitted diseases (STDs). The best scientific data available suggest that the level of STD protection from condoms or spermicides is closely linked with consistent use.

Two recent studies found that condoms must be used with every act of intercourse to achieve dependable protection against HIV from an infected partner. The studies tracked monogamous couples in which one partner was infected with HIV and the other was not.

One study followed couples an average of 20 months. Among 124 couples who used condoms during every act of intercourse, covering some 15,000 episodes of intercourse, no new HIV cases occurred. Among the 121 couples who used condoms inconsistently, there were 12 new HIV cases, a yearly rate of 4.8 per 100 person-years. Moreover, the study found that the couples who used condoms more than half the time had about the same number of new HIV cases as did those couples who used condoms less than half the time.¹

A study of 343 steady partners of infected men found similar results, with a new HIV incidence rate of 7.2 per 100 person-years among those who did not always use condoms, compared to a rate of 1.1 per 100 person-years among those who always used condoms.²

"In these studies, because one partner was infected, every act of intercourse involved the possibility of HIV transmission," explains Dr. Paul Feldblum of FHI, an epidemiologist who studies barrier methods. "That's why even using condoms half of the time did not make a significant difference over time. Similarly, during a woman's fertile period, the condom must be used every time for pregnancy prevention. In these situations, inconsistent condom use does not provide protection."

However, people who have multiple sexual partners, a minority of whom are HIV infected, will achieve some protection even with inconsistent condom use. For these people, "50 percent condom use will reduce the probability of contact with an infected partner by half," Dr. Feldblum and his colleagues wrote in a review of the effectiveness of barrier methods in preventing HIV.³

Incidence rates of gonorrhea and chlamydial infection, two STDs that can enhance the possibility of HIV transmission, have been found to decrease as spermicides are used more consistently.⁴ Hence, there could be less chance of HIV transmission. Using hypothetical scenarios involving multiple factors, an FHI computer analysis also

predicts that HIV infections in a high-risk group would be reduced if the overall proportion of coital acts protected by condom or spermicide use increased.⁵

"The key is the proportion of unprotected coital acts," explains Dr. Feldblum. "We must reduce that proportion. A method of limited efficacy, such as spermicides or the diaphragm, may offer some protection against HIV for women in situations where men do not use condoms consistently."

COUNSELING

Counseling can help people assess their own risk of STD infection or unintended pregnancy, as well as gain the necessary skills to assure consistent and correct use of barrier methods. Just saying "use it every time" does not help a client to understand the problem or help alter his or her behavior.

The risk of STD transmission varies depending on the number of partners involved (including partners of partners), prevalence rates of STDs in the region, demographic issues and other factors. To avoid unintended pregnancy while using barrier methods, a woman needs to understand her fertile period.

While most family planning associations offer barrier methods, many providers feel that they are not as effective as other methods and they should promote injectables or IUDs or some other highly effective contraceptive method. "At the same time, there has been more emphasis on counseling in the clinic for all methods," says Marc Okunnu, African regional director for the International Planned Parenthood Federation. "Counseling is seen as very important, and the trend to emphasize counseling will increase."

In most cases, using a barrier method consistently requires a change in sexual behavior. As with other personal matters, such as changing a diet, this involves moving through several stages: a

person considers making the change, may use the new behavior on a sporadic basis, and finally may continue the change over time.

To sustain behavior change, counseling needs to help people assess the stage they are in and move toward the maintenance stage. "The main point of counseling is to bring into cognitive awareness the specific behaviors needed to begin and maintain their contraceptive intentions; not to say, 'use a condom every time,'" explains Dr. Deborah Oakley of the University of Michigan, who has studied the effectiveness of counseling on barrier method use.

"The user, not the counselor, has responsibility for the behavior change," she says. "Counseling should go beyond the traditional notion of simply providing information. The main messages need to be: What is important in your life? How do you solve a problem? What behaviors do you want to use for your life? For people at risk, the most important counseling message is to bring them into awareness of how they even know that they have a problem."

In a study of consistent condom use for contraceptive purposes, Dr. Oakley and her colleagues identified groups of women who needed intensive counseling to achieve consistent use.⁶ "People who use condoms as a

backup method — for example, when a pill was missed — are highly motivated," says Dr. Oakley. "However, those who choose condoms as their contraceptive method may have underestimated how hard it is to use them every time."

Counseling appears to increase condom use when being done with both partners in a monogamous situation and when focusing on skill building. In a project that counseled heterosexual HIV discordant couples every six months over six years, there were no HIV seroconversions. Over time, condom use and abstinence increased.⁷ Another study compared women who received four, 90-minute group sessions and a one-month follow-up session in skill training with women who received only general health prevention messages. Three months later, the group receiving the training had increased condom use from 26 percent to 56 percent while the control group only increased marginally, from 26 percent to 32 percent.⁸

A less intensive approach did not prove successful. In 1991, a study in Kenya informed all HIV-infected women of their HIV test results and counseled them about the potential risks of transmission to future

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RICHARD LORD



A FAMILY PLANNING COUNSELOR VISITS A SHOP IN HO CHI MINH CITY, VIETNAM, TO EXPLAIN THE CORRECT USE OF BARRIER METHODS.



A PROVIDER IN THE DOMINICAN REPUBLIC EXPLAINS THE CORRECT WAY TO USE CONDOMS.

FHI

children, giving special emphasis to using condoms. A year later, the same group was surveyed and compared to an HIV-negative control group. "Counseling women did not seem to influence their decisions on condom use and family planning," the researchers found. "More effective ways of informing and counseling women are urgently needed."

To assess risk for STD infection, a counselor must ask confidential questions about sexual behaviors. Risk assessment checklists can help guide a counselor. Another approach is self assessment, in which the client is given materials to help evaluate his or her own risk.

Family planning agencies might consider using strategies that AIDS prevention campaigns have found successful. For example, rather than relying on professionals for counseling, a clinic could use peer counseling, where members of a group work with their peers.

Successful AIDS prevention projects have used peer education widely, especially among adolescents, commercial sex workers, truck drivers and other targeted groups. In Abidjan, capital of Côte d'Ivoire in West Africa, Population Services International (PSI) sponsors about 20 kiosks where young men and women sell condoms, hand out information and demonstrate correct condom use. Kiosks are located at high traffic areas such as taxi stands and market areas, and can be moved for use at community events.

COMMUNITY FACTORS

Consistent use of barrier methods is influenced by a variety of cultural or community factors. "Two of the most important predictors of condom use in the developing world are availability and affordability," says Michael Sweat, who works with FHI's AIDS Control

and Prevention (AIDSCAP) project. "If people can't afford condoms they will not use them no matter what interventions you design."

From the beginning of the AIDS epidemic, promoting condoms and their use has been a primary strategy. Social marketing projects, which use mass media, entertainment and other commercial marketing approaches,

"DUAL-METHOD" APPROACH AFFECTS CONSISTENT USE

Consistent use of barrier methods may decline when clients employ the "dual-method" approach, using a barrier method for protection against sexually transmitted diseases (STDs) but another method for contraception.

In an analysis of dual-use studies, Dr. Willard Cates of FHI found that "the more effective the primary contraceptive method was in preventing pregnancy, the lower the level of consistent use of the male condom."¹ For example, a U.S. study in Baltimore, MD found that among 92 adolescent women who were using oral contraceptives and were at high risk for STDs, only 10 percent used condoms consistently.²

But factors other than the method itself appear to affect levels of concurrent condom use, says Dr. Cates, FHI's corporate director of medical affairs. In a multisite study where spermicides were the primary contraceptive method, wide variations were found in the degree of consistent condom use, from 75 percent in Mexico to only 4 percent in the Dominican Republic.³

FHI is conducting a study of dual method acceptability, where women using oral contraceptives are given the choice of spermicide film or male condoms for disease protection. "Preliminary data indicate that giving the women a choice for disease prevention increases the degree of consistent use," says Markus Steiner of FHI, study coordinator.

— William R. Finger

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have led to large-scale changes in condom use, particularly in Africa. Just a few years ago, there were less than a million condoms used annually in all of Africa. Today, there are nearly 20 million condoms sold a year in Ethiopia alone, with similar levels in several other African countries. "This pattern in condom sales across sub-Saharan Africa indicates a major behavioral change among African men," says Dr. Godfrey Sikipa, African regional director for AIDSCAP.

For counseling condom use among women to be effective, men have to be willing to use condoms. "Because women in many countries are not in a position to insist on condom use for cultural and economic reasons, men should be specifically targeted in AIDS prevention programs," concluded a study on condom promotion in Africa.¹⁰

"You've got to get to the men," says William Schellstede, FHI executive vice-president, who has worked with condom distribution for more than 20 years. "Counseling is a good, worthwhile thing. But the mass media approach is much more cost effective in reaching people who need to be using condoms but are not. You've got to do what the toothpaste industry did. 'Brush your teeth twice a day.' That jingle is what sells toothpaste, not individual counseling."

When possible, social marketing projects promote condoms for both disease and pregnancy prevention. "This double message allows women to bring up pregnancy prevention as a reason for using condoms, hence avoiding the issue of disease prevention or unfaithfulness," says Judith Timyan of PSI, the world's largest social marketing condom distributor. Entertainers, rock groups and others get people talking about condoms, helping to remove the stigma, she says.

PSI and other AIDS prevention efforts have used many tools to take the mass media message to a personal level. Illustrated brochures on correct condom use are usually distributed with condoms. Some programs have wooden penis models and demonstrate

proper condom use. Ideally, various barrier methods would be available for people to see and handle, at a clinic or from a community-based provider. Drawings, flipcharts, and wallcharts can be used to show correct placement of female methods. Also, women should have the opportunity to practice putting the diaphragm or cervical cap in place while at the clinic. Informational pamphlets or booklets to take home can be helpful.

Political decisions can affect condom use. In Thailand, political leaders approved a nationwide "100 percent condom" program, which has led to a sharp decrease in STD rates as condom use increased. "We concentrated the program on a limited goal, the use of condoms in commercial sex," explains Dr. Wiwat Rojanapithayakorn of the Thailand Ministry of Health. If a man came to an STD clinic with an infection, the clinic asked him which sex establishment he has used and enforced the rule at that establishment, closing it if necessary. Condom use has increased from about 14 percent when the program began in 1989 to 90 percent in 1994, and STDs in the country have decreased by 85 percent.¹¹

— William R. Finger

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FHI AIDSCAP PROJECT



AN AIDS PREVENTION POSTER FOR NEPAL, PRODUCED BY FHI'S AIDS CONTROL AND PREVENTION (AIDSCAP) PROJECT, PROMOTES CONDOM USE.

Methods Work Better when Couples Talk

Communication between partners about sexual concerns, risks and fears leads to better contraception and safer sex.

Communication between partners is a key factor in achieving correct and consistent use of barrier methods. Yet, in many societies, few couples ever talk to each other about reproductive health issues.¹

The couples who do not talk are at a greater risk for sexually transmitted disease and unintended pregnancy.² Providers who counsel clients on how to negotiate with partners and how to talk openly about sexual fears, risks and concerns will help clients achieve better contraception and safer sex.

While many AIDS prevention programs have explored ways to improve couple communication in order to promote effective condom use, family planning clinics have focused less on this issue.

"Most family planning programs offer methods women can use without involving their partners — such as pills and injectables," says Laurie Fox, who specializes in family planning and STD integration research at FHI. "The issue of correct and consistent barrier contraceptive use can be difficult because it requires something new — teaching partner cooperation." Some family planning providers criticize barrier methods because they are less effective in typical use than many other contraceptive options. The effectiveness of barrier methods would probably improve, however, with greater emphasis on couple communication.

"If family planning programs can counsel which method is best and how to use it, why can't they counsel clients on how to talk to their partners?" says FHI's Carol Joanis, who conducts research on the acceptability of contraceptive methods. "Certainly, we have enough experience with AIDS to know that communication is needed. Why is it such a radical notion? You ask if your client feels comfortable talking to her partner about condoms. Very simple questions lead to talking."

BUILDING CONFIDENCE

Ultimately, the effectiveness of communication about sexual issues depends on a person's self-esteem and sense of self-worth, says Joanis. The more confidence a woman has, the more she will be able to communicate about her needs, about sex, and her feelings, even in cultures where such communication is considered taboo.

Strengthening a woman's confidence in being able to manage her own sexual relationship may improve condom use, according to FHI's Dr. Priscilla Ulin, who conducted focus groups on safe sex in Haiti. Discussion groups among women, or among women and men, can promote a dialogue about sex, barrier methods and sexual risks.

Some women prefer gently encouraging a man to wear a condom, while others think they should convince a man rationally and appeal to his sense of duty to protect the family from AIDS. If communication does not work, women sometimes withhold sex, although

such a tactic can be risky.³ Counselors should consider asking clients what types of threats, reactions, and consequences they face.

In 1993 and 1994, the Washington-based International Center for Research on Women, an independent research group, organized 240 female factory workers into small discussion groups in Chiang Mai, Thailand, in collaboration with Chiang Mai University. After the sessions, the number of women who said they felt confident talking to a partner about STD risks increased from 60 percent to 90 percent. The portion of women who said they would not be embarrassed to give a partner a condom jumped from 36 percent before the sessions to 82 percent.⁴

Educational background may improve prospects for couple communication and contraceptive use, suggests a survey of 1,022 Nigerian men. The survey showed that among educated men who communicated about family planning with their partners, 60 percent used contraceptives. Among the educated men who did not discuss sexual matters with partners, only 10 percent used contraception. Among uneducated men in the survey, 27 percent who talked about family planning were using contraception, compared with only 4 percent who did not communicate with partners.⁵

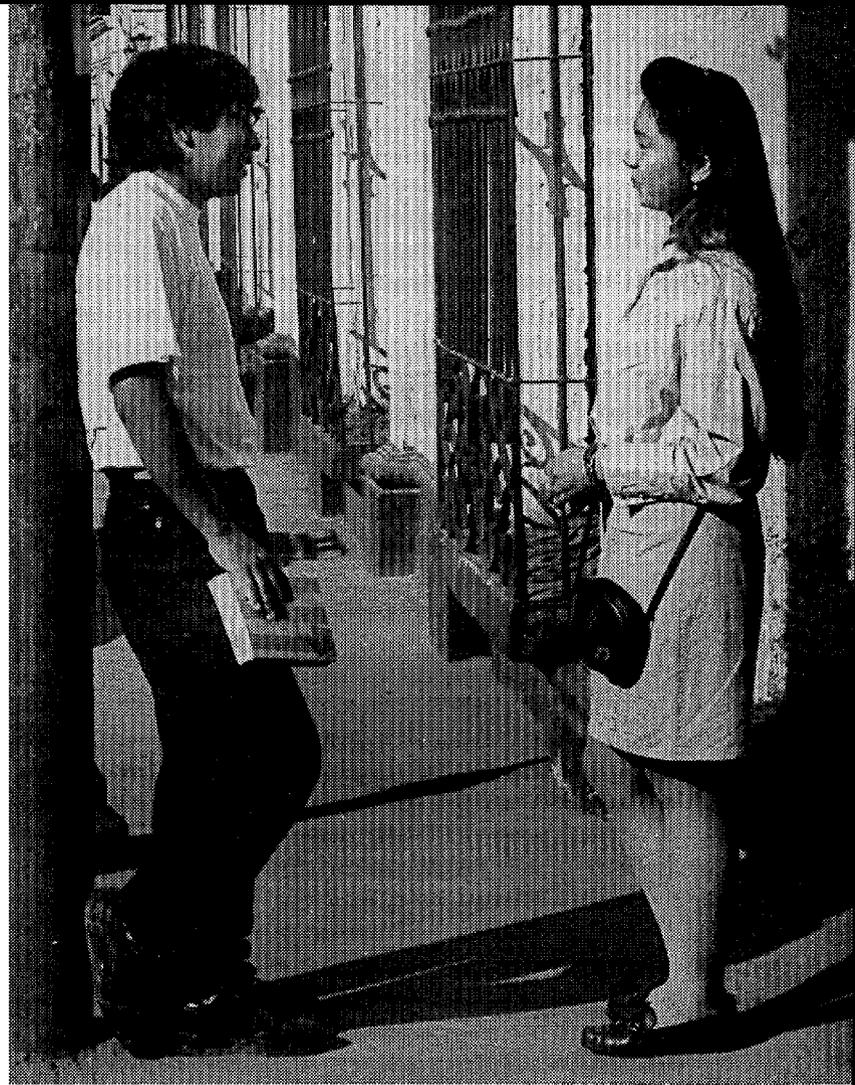
Couple communication among adolescents should be encouraged. A University of Minnesota study looked at 550 adolescent women in the United States who used school and community-based clinics. Women who said they communicate openly with their partners had the lowest risks of pregnancy and sexually transmitted diseases (STDs). Nontalkers were five times more likely to have multiple partners and twice as likely to have sex with a partner infected with an STD.⁶

Among married couples, communication seems to improve contraceptive use. The U.S.-based Demographic and Health Surveys (DHS) analyzed reports from 7,150 married women in its 1988 Kenya survey, finding that 36 percent of couples who communicated frequently about sex used contraception, compared with only 12 percent of women who did not communicate with their spouses.⁷

LEARNING TO TALK

Teaching women to talk about STD risks with their partners may require approaches that are different from the interventions used with men.

BERYL GOLDBERG



STUDENTS IN AVEQUIPA, PERU TALK AFTER CLASSES.

An STD education campaign in the Dominican Republic in 1995 improved condom use among men, but failed to address the needs of women. When surveyed, women said they did not like the idea of discussing sexual issues with men present. Consequently, the Coordinadora de Animación Socio-Cultural (CASCO), a non-profit STD prevention organization in Santo Domingo, and FHI's AIDSCAP project, revised their approach. In female discussion groups, women felt more comfortable talking about the challenges of encouraging condom use.

"We needed to think of a new strategy exclusively for women," said Betaña Betances, a CASCO social psychologist. The Santo Domingo discussion groups involved 185 young women, ages 15 to 24. Women said they understood condoms would help protect them from HIV and other STDs, but they feared insisting on condom use. They thought condoms would make them look promiscuous. Women with

multiple partners were more likely to use condoms, while those with monogamous relationships were less likely to do so.

When asked what type of sexual education they would most like to receive, the women were divided about whether they preferred talking to peers or experienced counselors. The women suggested having a resident female counselor in their communities with whom they could discuss sexual matters at any time.

In 1993, Brazil's family planning organization, Sociedade Civil Bem-Estar Familiar no Brasil (BEMFAM), began offering peer discussion groups to women attending BEMFAM clinics for routine medical services. By 1996, more than 2,500 women across the country had participated in the one-hour discussions, designed to teach communication

Continued on page 14

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Typical One-year
Contraceptive
Effectiveness*

Effect on STDs

Health and
Other Concerns

Male Condom

88%

Latex condoms provide substantial protection against STDs including HIV, if used consistently and correctly and are the recommended method for STD protection

Irritation and allergic reactions to latex (rare); may interrupt sexual activity and may reduce sensation

Female Condom

79%

Probably protects against STDs, including HIV, if used consistently and correctly; under study

Irritation possible (very rare); can be inserted prior to sexual activity; may be difficult to learn to insert; relatively expensive

Spermicides

79%

Some protection against bacterial STDs such as gonorrhea and chlamydia; effect against viral STDs such as HIV is uncertain

Can cause irritation with frequent use; may cause minor discomfort or allergic reaction; can lead to yeast infections

How to Use
Correctly

Used correctly, condoms rarely break or slip. Studies have found that only a small portion of condom users break them during use, and these people can be identified by good screening.

To use correctly:

- open package carefully to avoid tearing condom, especially with sharp objects like fingernails, teeth or scissors
- roll condom directly onto the erect penis all the way to the base of the shaft (do not unroll before putting it on)
- pinch the end of the condom while unrolling it to leave room for the semen
- after ejaculation, hold rim of condom and pull penis out of vagina before penis gets soft, to prevent condom from slipping off
- slide condom off penis without spilling semen
- dispose of properly after use

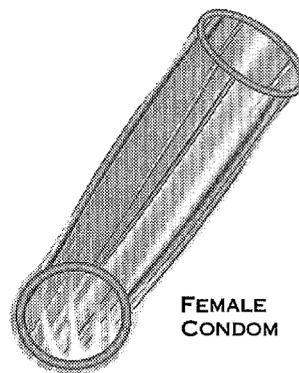
Other considerations:

- avoid genital contact before condom is put on
- use a separate condom for each act of intercourse, never reuse a condom
- use only water based lubricants such as K-Y jelly, spermicidal gels or creams or saliva; oil-based lubricants such as hand lotions and mineral or vegetable oils weaken condoms in just a few minutes, making them more likely to break
- if the package has been torn or damaged or if the condom feels brittle or dry or has changed color, do not use the condom

To avoid tearing the female condom, the package should be opened carefully, especially when using sharp objects like fingernails, teeth or scissors.

To use correctly:

- insert inner ring high in the vagina, against the cervix
- place the outer ring properly outside the vagina
- during intercourse, be sure the penis is placed inside the female condom



FEMALE
CONDOM

Other considerations:

- avoid genital contact before condom is put in and after it is removed
- can be used by a woman who is pregnant or menstruating, but not by a woman who has a tampon inserted
- is pre-lubricated with silicone, and a vial of lubricant is provided to allow adding more lubrication to meet a couple's preference; adding lubricant also reduces noise during use
- dispose of properly after use

Spermicides should be placed high in the vagina near the cervix shortly before intercourse, and reinserted for each act of intercourse. Foams, jellies and creams are effective as soon as inserted. Suppositories, tablets and films require five to 15 minutes to dissolve before intercourse.

To use correctly:

- use clean hands and a clean applicator when inserting
- for foams, shake container vigorously just before insertion
- for jelly or cream, fill applicator and insert far into vagina (near cervix); push applicator plunger to release spermicide; after each use, wash applicator with soap and water
- film must be folded in half and inserted with dry fingers near the cervix, or the film will stick to the fingers and not the cervix



Other considerations:

- once inserted, spermicides are effective for one to two hours
- for maximum effectiveness, a spermicide should be used with another barrier method, such as a diaphragm or condom
- after intercourse, wait at least six hours before douching

* Methods are more effective if used correctly during every act of intercourse — about 97 percent for the condom and 94 percent for spermicides. "Typical use" includes people who do not always use the method correctly, or who use it inconsistently.

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Barrier Methods and Disease Prevention

Diaphragm

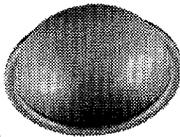
82% (with spermicide)

Some protection against bacterial STDs such as gonorrhea and chlamydia; effect against viral STDs, such as HIV, is uncertain

Not recommended for those with allergy to latex or spermicides or history of toxic shock syndrome; may lead to urinary tract infection

A diaphragm must be fitted initially by a trained provider and is not recommended for women with cervical or vaginal abnormalities or during the first six weeks after childbirth.

DIAPHRAGM



To use correctly:

- before inserting, check for holes or tears by holding it up to the light; if defective, use a backup method
- spread spermicidal jelly or cream on the inside portion of the dome and rim with clean, washed hands
- put the device all the way back against the cervix with the cavity containing the spermicide covering the cervical opening; feel around the edge to be sure the cervix is completely covered
- if intercourse occurs more than an hour after inserting a diaphragm, or if multiple acts occur, spermicide should be added without removing the diaphragm
- leave in place for at least six hours after the last act of intercourse, but no more than 24 hours
- after use, wash with soap and water, dry it, and store it in a cool, dry, dark place

Other considerations:

- after intercourse, wait at least six hours before douching
- when removing, care should be taken not to damage it with fingernails
- refitting may be necessary following weight change, full-term pregnancy or late-term abortion

Cervical Cap

82% (nulliparous women)

May protect against gonorrhea and chlamydia, but not studied

Not recommended for those with allergy to latex or spermicides or with history of toxic shock syndrome

Cervical caps are inserted before intercourse and can remain in place up to 48 hours. They are effective for multiple acts of intercourse.

They must be fitted initially by a trained provider and are not recommended for women with cervical or vaginal abnormalities or during the first six weeks after childbirth.

To use correctly:

- before inserting, check for holes or tears by holding it up to the light; if defective, use a backup method
- fill one-third to one-half of cap with spermicidal jelly or cream
- insert by squeezing cap between thumb and index finger, sliding into vagina and pressing rim around cervix; feel around the edge to be sure the cervix is completely covered
- to remove, press on rim until seal on cervix is broken, tilt cap, then hook fingers under rim and pull sideways out of vagina
- after use, wash with mild soap and water, and dry thoroughly; store in a cool, dry, dark place

Other considerations:

- although it can stay in place for up to 48 hours, this may lead to a bad odor
- after intercourse, wait at least six hours before douching
- when removing, care should be taken not to damage it with fingernails
- refitting may be necessary following weight change, full-term pregnancy or late-term abortion

Sponge

82% (nulliparous women)

Probably protects against bacterial STDs, such as gonorrhea and chlamydia; only study done on HIV did not show any protection

Irritation and allergic reactions (rare); limited availability; may be less effective among parous women

A sponge is effective for multiple acts of intercourse and, depending upon brand, may be used up to 12 hours or up to 24 hours. It should be left in place for several hours after intercourse.

Specific instructions vary by product. The sponge is currently marketed only in France (benzalkonium product) and Canada (a product containing sodium cholate, benzalkonium chloride and nonoxynol-9). A U.S. nonoxynol-9 product, the Today sponge, is no longer manufactured.

To use properly:

- insert deep into the vagina so it rests against the cervix
- check placement before and after intercourse
- follow other brand-specific instructions provided in the labeling
- dispose of properly after use

Other considerations:

- use only once
- no fitting needed
- consider using with condom to increase effectiveness

CERVICAL CAP



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A COUPLE AT A FAMILY PLANNING CLINIC IN LIMA, PERU. BETTER COMMUNICATION BETWEEN PARTNERS HELPS ACHIEVE CORRECT AND CONSISTENT USE OF BARRIER METHODS.

Continued from page 11

skills about safe sex. Comic strip stories about HIV risk were used to open up the group conversations, and penis models were used to teach women how to use condoms.⁸

In 1994, International Planned Parenthood Federation (IPPF) helped train counselors at the Jamaican Family Planning Association on partner negotiation and how to prompt clients to think about partners' sexual habits and STD risk. Training included role plays in condom negotiation strategies with a reluctant partner. The role playing helped counselors appreciate the complexity of trying to convince a partner to do something in the middle of a sexual act, says IPPF's Julie Becker.

A project by AIDS Technical Support: Public Health Communication Component (AIDSCOM) in Brazil, Tanzania and Indonesia asked women to talk about the reactions or consequences they might encounter if they tried to talk to their partners about sexual risks, or insisted on condom use. In

focus groups of 40 women in each country, women were asked to indicate the advantages and disadvantages of discussing safe sex.

Advantages included protection from AIDS and other STDs, protection from pregnancy, convincing a partner to have only one partner, and strengthening the relationship. But several disadvantages also were listed, including the potential for instilling distrust and suspicion.⁹

"It's a really tricky issue," says FHI's Donna Flanagan, who specializes in behavior change communication to help prevent AIDS. "You have to teach someone how to convince somebody else to do something, like wear a condom. That requires skills. Not only skills in communication, but it also requires self-confidence and assertiveness."

— Sarah Keller

FOOTNOTES

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Microbicide Research Aims to Prevent STDs

Polysaccharides, buffer gels and a variety of plant and animal extracts are among promising candidates.

One of the newer areas of barrier method research is the development of microbicides — substances that destroy or incapacitate infection-causing organisms, including bacteria, viruses and parasites.

Microbicides may offer a female-controlled method of STD prevention that does not require partner knowledge or cooperation. Also, microbicides may or may not have spermicidal properties, allowing women to prevent disease but not pregnancy — an option that is not available to condom or spermicide users.

While couples may want to prevent pregnancy at certain times in their lives, “the desire to prevent infection is consistent throughout your life,” says Dr. Penelope J. Hitchcock, chief of the STD branch of the National Institute of Allergy and Infectious Diseases (NIAID) in the United States. “Program managers have been focusing on family planning and limiting the number of children, but we also have to realize that preservation of fertility is an important component of reproductive health.”

NIAID is one of several organizations working to develop microbicides. With NIAID funding, the University of Pittsburgh will soon begin safety and efficacy studies of microbicides containing lactobacilli, bacteria that occur naturally in the vagina. Lactobacilli produce hydrogen peroxide, which scientists believe prevents the spread of infections. The University of Pittsburgh study will examine the use of lactobacilli suppositories among adolescents.

“Adolescents have typically been excluded from research,” says Dr. Sharon L. Hillier, the study’s principal investigator. “If we are going to think of solutions that will work in preventing STDs, we will have to target the group that is most at risk. We have to determine whether they will use an intervention, and how they will use it. We can benefit from knowledge of their behaviors.”

The study will follow more than 900 adolescent women at an urban health clinic for one year. Researchers will try to determine whether use of the lactobacilli suppositories alters microorganisms that normally occur in the vagina, whether the suppositories decrease the incidence of bacterial vaginosis and gonorrhea compared to use of a placebo, and whether use of the suppository has any effect on acquisition of other STDs.

The U.S.-based Population Council also is conducting research to develop new microbicides and has completed safety trials among women on microbicides containing sulfated polysaccharides. These substances occur naturally in the human body, coating the cells and connective tissues. Scientists believe that polysaccharides, which have been shown *in vitro* to inhibit HIV, may coat the epithelial surface of the vagina with a film that repels HIV and HIV-infected cells. Polysaccharides, which are used as food additives, are non-detergents and may produce less irritation than currently available spermicides.

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SPERMICIDE RESEARCH EXAMINES HIV PREVENTION

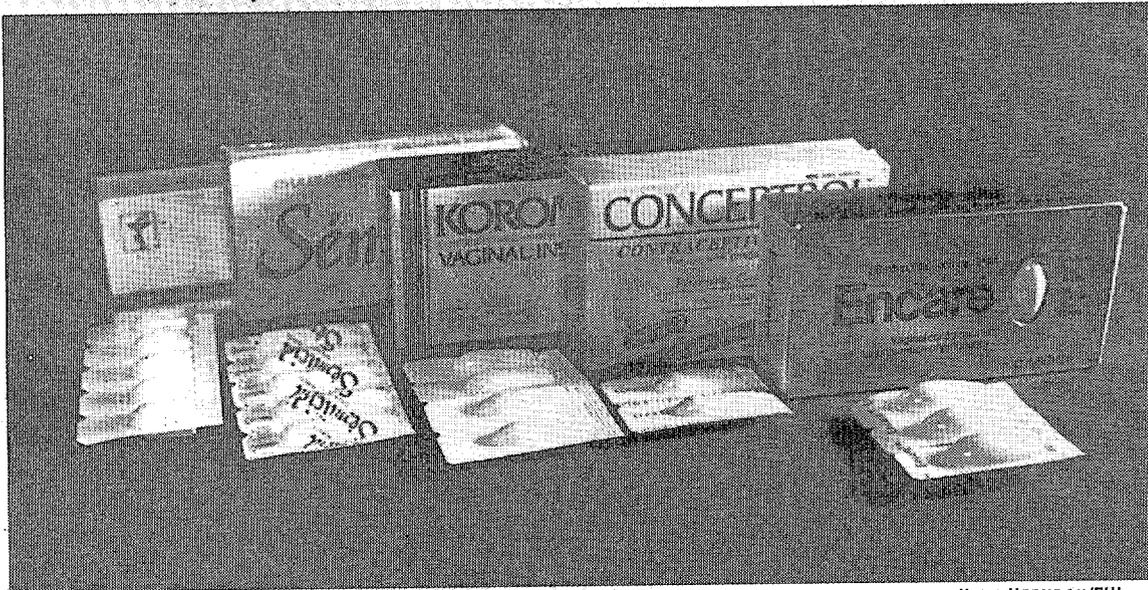
Spermicides, already available for contraception without prescriptions in many countries, are being studied for their ability to prevent HIV. FHI researchers, for example, are working with the Ministère de la Santé Publique in Cameroon to examine the effects of the vaginal contraceptive film containing the spermicide nonoxynol-9 (N-9) in preventing HIV.

Study participants include approximately 1,300 female sex workers in Yaoundé and Douala, who are HIV-negative. Participants are divided into two groups — those who use male condoms and N-9 film and those who use condoms and a placebo film. They will be followed for one year.

decrease in HIV infection, gonorrhea and genital ulcers.¹ A second analysis of the Cameroon data, which separated the effects of condom use and N-9 use, found HIV incidence declined as N-9 use increased.² FHI research in Zambia found that among 110 HIV-discordant couples who consistently used N-9 spermicide, there was a slightly lower incidence of seroconversion than among couples who did not use N-9 consistently. However, the study is not conclusive, and it remains unclear whether N-9 reduces HIV risks.³

The conflicting findings may be due to different doses of spermicide. FHI studies in Thailand and the Dominican Republic have

HIV, and because studies in humans demonstrate that spermicides reduce the incidence of gonorrhea and chlamydia, some health organizations have recommended spermicides as a choice for STD protection. In the United States, the New York State Public Health Department recommends a hierarchy of protective measures women can use against STDs. Male latex condoms are the first choice, followed by female condoms with spermicide, diaphragm with spermicide, and spermicide alone. "This is risky," a health department brochure says about using spermicide alone for protection, "but it's better than doing nothing."



NASH HERNDON/FHI

Researchers will also examine the effects of N-9 use on genital ulcers, as well as its effects on normal microorganisms in the vagina. The study is funded by the National Institutes of Health (NIH) in the United States.

Previous studies have shown that low levels of nonoxynol-9 inactivate HIV *in vitro*. But studies in humans have shown conflicting results. One study of female sex workers in Kenya found that sponges containing N-9 did not protect against HIV, while an FHI study of N-9 suppository use among sex workers in Cameroon showed a

shown that high, frequent doses of N-9 cause irritation and disrupt the cell surface of the vagina.⁴ The World Health Organization (WHO) conducted a study on effects of the spermicide menfegol, and found similar results.⁵ These effects on the vaginal mucosa may enhance the transmission of HIV and bacterial STDs.

Because *in vitro* studies show that the detergent spermicides N-9, benzalkonium chloride (BZK) and menfegol can inactivate

In addition to studies on the ability of current spermicides to prevent STDs, research is under way to develop new spermicides and delivery systems. Advantage 24, a spermicide that may be effective for 24 hours, is being studied for its microbicidal properties. Researchers have investigated the spermicidal effects of mandelic acid,

which is extracted from peach leaves and has been shown *in vitro* to kill both sperm and trichomonas; crassulaceae, a family of herbs used by rural women for contraception; carrageenan, a component of seaweed; synthetic magainins, peptides isolated from the skin of the African clawed frog; and extract from seeds of *Abrus precatorius*, commonly called Indian licorice.

ACCEPTABILITY

Researchers are examining ways to improve acceptability, including evaluations of the systems used to deliver spermicides and microbicides. An FHI-sponsored study of family planning clients in Kenya and Mexico found that women preferred spermicides delivered in contraceptive film rather than foaming tablets.⁶ Another FHI-sponsored study among STD clients in Zambia found that foam was the least popular delivery system while suppositories and foaming tablets were more acceptable.⁷ A study of 260 women in Scotland examined the acceptability of the diaphragm with contraceptive film and found that many women preferred the film but experienced some irritation and discharge not common among users of spermicide gel.⁸

PROFAM in Mexico has studied the delivery of spermicides through soft capsules that dissolve in the vagina. The University of Kentucky in the United States is exploring the use of slow-releasing pellets for spermicides and microbicides, and Biotek, a U.S. company, is working on a spermicide that turns into a gel when it comes in contact with vaginal secretions. A vaginal ring, which would release spermicide for up to 30 days, also is under study.

— Barbara Barnett



FOOTNOTES

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"What we want is something that is not absorbed when it gets into the vagina," says Dr. David Phillips, who is conducting the research at the Population Council. "Since these compounds are very large in size, they're not easily absorbed by the body. They are generally found throughout nature, so they would be an inexpensive and stable source for microbicides."

The Population Council's studies have examined women's preferences about delivery systems, including film, gels, and suppositories. "One of the take-home messages is that any kind of vaginal product is going to have to be formulated in multiple ways," said Christa Coggins of the Population Council. "There is not going to be one product that will meet every woman's needs."

FHI, NIAID, National Institute of Child Health and Human Development, ReProtect Llc., and Johns Hopkins University are working to evaluate a buffer gel that would offer

protection against STDs, including HIV. This product, which would contain substances similar to some of the gel agents found in shampoos and soaps, would maintain the pH levels in the vagina even in the presence of semen, which normally neutralizes the vagina's acidity.

A buffer gel that maintains the acidity in the vagina could have numerous benefits, researchers say. Many types of enveloped viruses, including a strain of HIV, are inactivated by increases in acidity. Bacteria, including the type that causes gonorrhea, are killed when acid levels increase. "Trojan Horse" leukocytes — the HIV-infected cells in semen and cervical mucus that may enhance the transmission of HIV — appear to lose motility and viability and stop producing HIV when exposed to an acidic environment. And sperm are rapidly killed by mild acidity. The buffer gel is odorless, colorless and inexpensive, and it does not eliminate the lactobacilli, which help produce the acidity in the vagina.

Plant extracts, including gossypol (cottonseed oil) and neem, have been investigated for their microbicidal effects by the South to South Cooperation in Reproductive Health, based in Brazil. With gossypol, researchers are trying to develop a way to contain the substance in a gelatin capsule that could be inserted into the vagina. Creams and pessaries made from neem, which grows abundantly in the tropics, have been shown to be both spermicidal and microbicidal. However, initial safety studies among humans were discontinued because the odor was unacceptable to users and because it took too long for neem products to dissolve in the vagina. New formulations, with reduced odor, are being tested.

Other substances that are being studied as potential vaginal microbicides are synthetic protegrins, small proteins that occur in the white blood cells and have been shown *in vitro* to inactivate HIV, herpes, gonorrhea, chlamydia and other bacterial STDs; C31G, a substance in mouthwash that is both spermicidal and microbicidal; N-docosanol, an alcohol that blocks some enveloped viruses; and squalamine, a steroid-based compound that may be effective against bacterial and viral STDs.

Also, a modified version of beta-lactoglobulin, a protein found in the dairy product called whey, has blocked HIV transmission in human cells in test tube experiments at the New York Blood Center. The modified protein, called B69, does not seem to affect sperm.

The interest in microbicides has been fostered, in part, by the need for a female-controlled method that offers women protection against STDs. The best protection currently available is latex condoms, which men control. Yet, while microbicides have been discussed as a method that will benefit women, the development of these products may protect men from contracting STDs as well, Dr. Hitchcock suggests. And they may be more appealing than condoms to use.

— Barbara Barnett

BERYL GOLDBERG



IDEAL MICROBICIDES WOULD NOT HAVE CONTRACEPTIVE PROPERTIES, ALLOWING WOMEN TO PREVENT DISEASE BUT NOT PREGNANCY. WOMEN IN MONTEVIDEO, URUGUAY WAIT TO SEE A DOCTOR AT A MOBILE CLINIC.

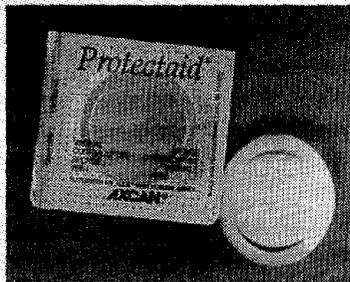
DEVELOPING NEW DIAPHRAGMS, CONDOMS AND SIMILAR DEVICES

Efforts are under way to improve condoms, diaphragms and similar devices that work by providing a physical barrier between sperm and egg.

Research organizations, including FHI and the World Health Organization, and private industry are exploring the use of new materials for male condoms, such as polyurethane (plastic) instead of latex, and new designs, such as loose-fitting condoms instead of the snug fit currently used. The first plastic condom was introduced last year in Europe and the United States. Plastic condoms have several advantages, including possibly a longer shelf-life than the latex condom, possibly improved sensation during sexual intercourse, and compatibility with oil-based lubricants, which destroy latex.

The polyurethane female condom, which can be used for contraception and STD prevention, is being studied to determine whether it can be used more than once. Being able to clean the device and reuse it safely and effectively could lower the cost to users. Additional FHI studies to evaluate the method's acceptability, including male partners' attitudes, are under way in Mexico. New types of female condoms are being studied, including the Bikini Condom, which is worn like a panty, and another product called Women's Choice, which is inserted with an applicator.

The contraceptive sponge, which is not widely available in many countries, is undergoing refinements. A new sponge, Protectaid, is available in Canada. Made of polyurethane, the device contains F-5 gel, a combination of three spermicides (nonoxynol-9, benzalkonium chloride and sodium cholate) in

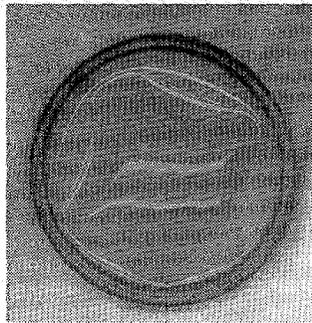


PROTECTAID SPONGE

low doses. Manufacturers believe these lower concentrations of spermicides will reduce irritation to the vaginal mucosa. A sponge containing benzalkonium chloride (BZK) is available in Europe. However, the Today sponge, which contains nonoxynol-9 (N-9) and was sold in the United States, is no longer manufactured.

The diaphragm has the advantage of being a female-controlled method that prevents pregnancy and appears to reduce the risks of some STDs, including gonorrhea and chlamydia, as well as pelvic inflammatory disease. Yet,

many women find the device inconvenient, since it must be inserted prior to intercourse, and messy, since it must be used with a spermicide gel or cream. Researchers are exploring ways to make this device easier and more appealing to use.



FHI

SILICONE DIAPHRAGM

In Brazil, women from three clinics participated in a study to compare contraceptive effectiveness of the diaphragm when used with spermicide during time of intercourse, and when not used with a spermicide but worn continuously. Spermicide use did not significantly improve effectiveness, researchers found, and the cost and messiness of spermicide may have discouraged

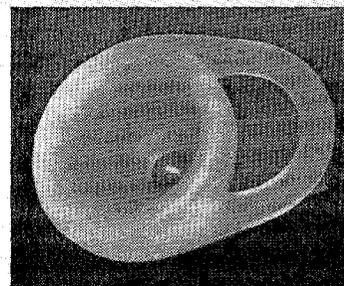
correct use.¹ Yet, because spermicides also act as microbicides, many researchers suggest that diaphragms without spermicide may offer little protection against STDs. A study in London found relatively high pregnancy rates, but promising continuation rates, among 110 women who continuously used a fit-free diaphragm (one that did not require fitting by a doctor) without spermicide. The 12-month accidental pregnancy rate was 24.1 pregnancies per 100 women.²

A new type of diaphragm — one made of silicone rather than latex — has been developed, and a study of this device's effectiveness and acceptability is now under way in Brazil. According to Dr. Carlos Petta of Centro de Pesquisas e Controle das Doencas Materno-Infantis de Campinas (CEMICAMP), the diaphragm, used without spermicide and worn continuously by women in the study, is re-

moved only for washing. This diaphragm comes in different colors, which researchers think may be more attractive to women.

Another new method, Lea's Shield, is a cup-shaped barrier that covers the cervix. This device has a valve that allows the draining of cervical secretions and menstrual flow, and has a U-shaped loop for easy removal. Made of silicone rubber, it can be worn up to 48 hours. The U.S.-based Contraceptive Development and Research program (CONRAD) has conducted safety and efficacy studies of this device, which eventually may be available without a visit to a health provider.

The Gynaeseal diaphragm tampon, available in Australia, has an inner chamber and an outer pouch. The inner chamber has a one-way valve that allows menstrual fluids to pass through, and cervical secretions are collected in the outer pouch.



YAMA INC.

LEA'S SHIELD

Cervical caps, available primarily in the United States and Europe, also are being refined. Shaped like a small dome, the cap is used with spermicide and can

be inserted 40 hours prior to intercourse, and must not be removed for at least eight hours following intercourse. Side effects include vaginal odor and discharge, vaginal tears and cervical irritation. Also, some cervical cap users report increased rates of urinary tract infections, as do diaphragm users.

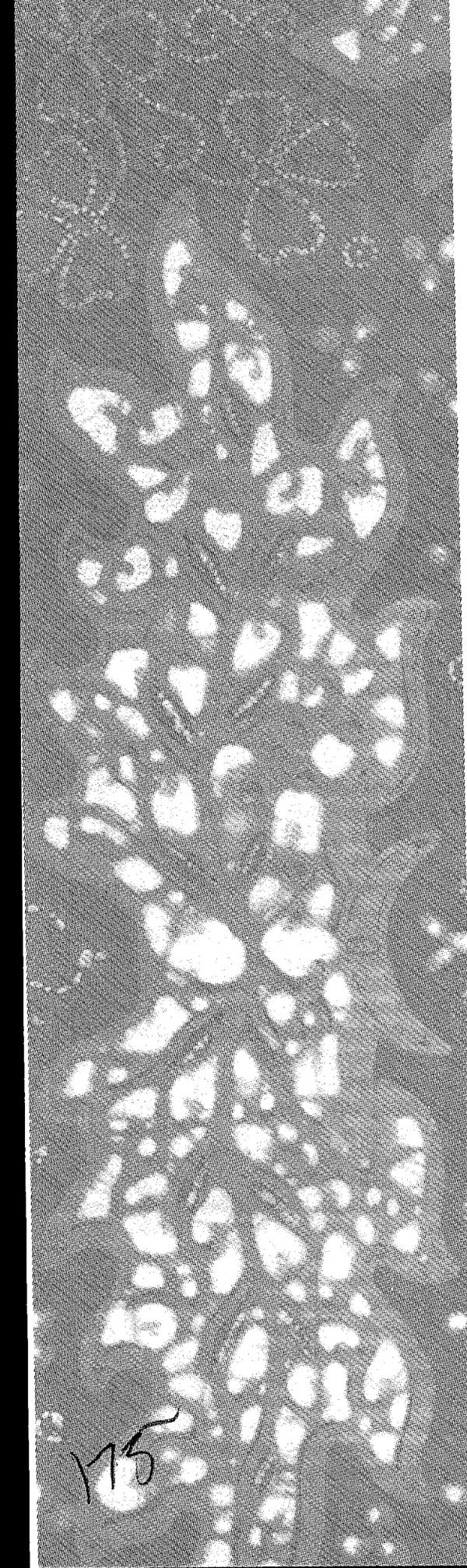
The safety and efficacy of a new type of cervical cap are being evaluated in the United States by FHI and CONRAD. Femcap, which is made of silicone rubber, is a device shaped like a hat with a wide, upturned brim. It fits over the cervix, is designed to be worn for up to 48 hours, and may be effective without spermicide.

— Barbara Barnett

FOOTNOTE

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STD Protection after Intercourse

Emergency protection after STD exposure has limitations and should be used for specific situations.

For couples to prevent unintended pregnancy after unprotected intercourse, emergency contraception offers a means. Yet unprotected intercourse also increases the risks of contracting a sexually transmitted disease (STD). Are there emergency measures that can be taken to reduce this risk after exposure?

Yes, experts say. However, these measures have limitations and are recommended only for certain groups of people, such as women who are victims of sexual assault. Emergency treatment of STDs is not recommended for routine use.

"The principal problem [with emergency treatment] is the multitude of STDs," says Dr. Robert Johnson, a medical epidemiologist with the Division of STD Prevention at the U.S. Centers for Disease Control and Prevention (CDC). "There isn't a single drug that can treat all STDs. The viral agents cannot be treated. Coming up with a regimen is problematic."

There are more than 20 types of sexually transmitted diseases. While latex condoms, used consistently and correctly, can reduce the risks of all of them, no single drug can successfully treat all of them.

Combinations of antibiotics may be used to reduce a woman's risks of infection from some bacterial STDs following sexual assault. Genital washing and medications have shown some effectiveness in preventing STDs among men serving in the military. Douches, used by many women to cleanse

the vagina, may not help prevent STDs and may actually promote infection in cases where contamination is introduced.

Worldwide, an estimated 250 million new cases of STDs occur annually.¹ Most scientists now agree that STD infection increases an individual's risk of contracting HIV, the virus that causes AIDS. There is evidence that STDs that cause genital sores, such as herpes, chancroid and syphilis, can enhance the risks of HIV transmission by creating a site of entry for the AIDS virus. Other STDs, which do not produce ulcers but do produce inflammation, may also increase susceptibility to HIV.²

Because latex condoms can prevent transmission of both bacterial and viral STDs, and because antibiotics can successfully treat bacterial STDs once a diagnosis has been made, research to find a method of emergency STD prevention — one that could be used after unprotected sexual intercourse but before symptoms develop — has been limited.

However, research is under way to develop microbicides, which would kill both bacterial and viral STD pathogens. Some researchers have speculated that these products, designed for use prior to sexual intercourse to prevent infection, might also be used for postcoital or emergency STD prevention. (See related article, page 15.)

"The need for such a product is evidenced by emerging data concerning the widespread prevalence of non-consensual and coercive sex in women's lives, even within married and consensual unions," write Christopher Elias of the Population

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Council and Lori Heise of the Health and Development Policy Project. "A postcoital method might also have some utility for women, especially adolescents, in communities where 'planning' to have sex is unacceptable."³

Postcoital STD treatment could also be helpful for couples who use condoms as a means of STD prevention but experience condom breakage or slippage, much as emergency contraception is used to prevent pregnancy when a couple experiences condom failure.

SEXUAL ASSAULT

For women who are the victims of sexual assault or non-consensual sex, the CDC has developed guidelines for emergency STD treatment. The guidelines recommend a combination of antibiotics, given within hours after sexual intercourse. This combination is designed to prevent the infections most commonly diagnosed after sexual assault — trichomoniasis, chlamydia, gonorrhea and vaginal bacteriosis.

The CDC recommends: 125 milligrams of ceftriaxone injected intramuscularly in a single dose; two grams of metronidazole orally in a single dose; and 100 milligrams of doxycycline taken orally twice a day for seven days.⁴

The CDC also recommends that health-care providers counsel the client about symptoms of STDs and the need for her to return to the clinic if these occur. Providers should counsel the client to use condoms until the antibiotic treatment is complete, to prevent the possibility of any STD transmission to her partner.

If available, clients should be given a vaccine to protect against Hepatitis B. If laboratory tests are available for STDs, the client should return for follow-up examinations at two weeks and 12 weeks after the sexual assault.

The likelihood of contracting an STD after sexual intercourse is less than the risk of becoming pregnant. Fewer than one in five people are infected with an STD at any given time, while nine out of 10 women under age 35 are fertile and could become pregnant.⁵ The use of antibiotics as a preventive measure is often done for psychological reasons as well as biological ones. The client, who has already undergone the physical and emotional trauma of assault, may have one less consequence to worry about if she takes antibiotics.



NASH HERNDON/FHI

WHILE LATEX CONDOMS CAN REDUCE THE RISKS OF ALL KNOWN STDs, NO SINGLE DRUG CAN SUCCESSFULLY TREAT ALL OF THEM.

There is some risk a woman will acquire HIV infection after sexual assault, but the CDC says the risks are very low. There are no emergency measures a health-care provider can take to reduce a woman's risk of HIV in this situation. Providers should offer HIV counseling and testing to clients, but some experts recommend that this be done during a return visit to the clinic, not during the initial visit when the client is frightened and upset.

Outside of use to prevent the development of STDs among sexual assault victims, the use of antibiotics for emergency STD prevention in the larger population is regarded by most experts as an unnecessary and an expensive use of scarce medical resources. "Emergency treatment will result in the overtreatment of people who are not infected," says Dr. Jonathan Zenilman, associate professor of medicine in the Infectious Disease Division of Johns Hopkins University in the United States. Given that some STDs have developed a resistance to certain antibiotics, treatment before diagnosis is not recommended.

MILITARY EXPERIENCE

The use of postcoital emergency treatment for STDs has had some success in the U.S. military. During World War I, military officials tried to reduce the incidence of STDs through educational campaigns that emphasized the need for servicemen to be "100 percent efficient to win the war." Mili-

tary personnel were encouraged to practice abstinence to prevent sexually transmitted diseases.

Servicemen who did engage in sexual activity with prostitutes were told to return to their military base and report for emergency treatment within three hours after sexual intercourse. The procedure involved several steps. First, the soldier urinated, then washed his genitals with soap and water, followed by bichloride of mercury. A medical attendant inspected the soldier's genital area, then injected Protargol, which contains silver protein, into the penis. The soldier would urinate five minutes later. Finally, calomel ointment was rubbed onto the penis, and the penis was wrapped in wax paper. The soldier was not to urinate for at least four to five hours after treatment.

To further reduce the incidence of sexually transmitted disease during World War I, U.S. soldiers were given an emergency treatment packet they could administer themselves. This was done on an experimental basis for soldiers who did not have access to a health clinic. The packet contained calomel ointment, carbolic acid and camphor.

Military health officials estimated this treatment could be 99.6 percent effective in preventing syphilis, gonorrhea and chancroid. Statistics on the success of military efforts to reduce STDs were not published.

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However, military officials estimate that several million men received emergency STD treatment.

During World War II, the U.S. military sought to reduce the incidence of STDs by offering educational programs, emergency STD treatment and condoms for STD prevention. With the discovery that antibiotics could effectively treat bacterial STDs, and the knowledge that condoms could prevent STD transmission, the use of emergency STD clinics diminished.⁶

In the 1970s, a study among some 500 U.S. male sailors who had sexual intercourse with women while on shore leave in the western Pacific concluded that STD infection rates did not decrease significantly if a man urinated within 30 minutes after intercourse or if he washed his genitals within an hour.⁷ Another study among 1,000 male sailors found that 200 mg of minocycline, taken orally a few hours after intercourse, offered some protection against the subsequent development of gonorrhea. However, researchers did not recommend widespread use of the antibiotic because drug-resistant strains of gonorrhea could develop.⁸

VAGINAL DOUCHING

Because many women practice routine vaginal douching for hygienic purposes, there has been speculation that postcoital douching might reduce the incidence of STDs. Studies have shown that douching may not offer any type of protection against STDs. In fact, it may promote some types of reproductive tract infections.

While vaginal douching may decrease the risks of gonorrhea, it may increase the risks of pelvic inflammatory disease and ectopic pregnancy.⁹ A study of more than 600 women in the United States found those who douched were more likely to have risk factors for STDs, including multiple sexual partners and first sexual intercourse at an early age. However, others say it is difficult to determine whether douching increases a woman's risk of infection or whether douching is simply a common practice among women at risk of STDs for other reasons.¹⁰

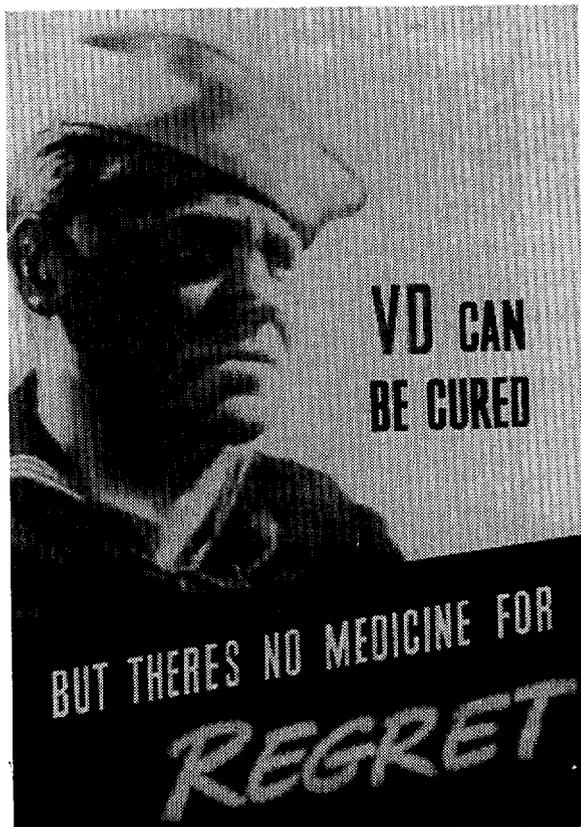
Normally, the pH in the vagina is low (acidic), but the pH levels change during intercourse with ejaculation, menses, estrogen deficiency, menopause and bacterial vaginosis. Researchers believe that pH levels in the vagina may play an important role in STD transmission.

Several small studies have examined the changes in normal vaginal microorganisms after douching. One study of 20 women in the United States found that small amounts of a douche preparation containing the antiseptic, chlorhexidine gluconate, did not significantly alter the vaginal flora after 30 days of use.¹¹ A small study at the Università di Sassari in Italy evaluated seven vaginal douche preparations to determine their *in vitro* effects on lactobacilli, a bacteria commonly found in the vagina. Lactobacilli produce hydrogen peroxide, which in-

hibits the growth of some pathogens, possibly STD pathogens.¹² Researchers concluded that frequent use of these douches could change the composition of the normal vaginal flora.¹³ A study of 10 women in the United States, which compared two types of douche preparations, found that those containing acetic acid (the acid in vinegar) caused short-term minor changes in the vaginal flora, while solutions containing povidone-iodine (Betadine) caused significant changes in the vaginal flora, which could increase the risks of infections and possibly the risks of pelvic inflammatory disease.¹⁴

The use of soft drinks as a postcoital douche is frequently suggested as a folk remedy to prevent pregnancy after unprotected sex, but is not effective since sperm enter the cervix within seconds after ejaculation. A study of seven men in Nigeria examined the effects of four different types of soft drinks on *in vitro* motility of sperm. The study found that one brand of drink, Krest bitter lemon, immobilized all sperm within one minute. The study did not, however, explore microbicidal effects.¹⁵ A study conducted in the United States investigated the spermicidal effects of Coca-Cola and found that different formulations of the soft drink did reduce sperm motility.¹⁶ A separate study of cola drinks found little effect on sperm motility. Researchers suggested the introduction of these liquids into the vagina might cause infection.¹⁷

Some researchers suggest that a microbicidal postcoital douche might be more culturally acceptable than condoms, which require negotiation between partners. A postcoital douche of tea or beer, which has a low pH, or sour milk, which contains lactobacilli that result in low pH levels, might offer protection against STDs, including AIDS, researchers suggest.



A U.S. NAVY POSTER FROM WORLD WAR II DISCOURAGES RISKY SEXUAL BEHAVIOR, USING THE TERM "VENEREAL DISEASE," OR VD, IN REFERRING TO SEXUALLY TRANSMITTED DISEASES.

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UNITED NATIONS/B. WOLFF

WOMEN GATHER AT A MARKET IN LOMÉ, TOGO.

SOAP AND WATER

Genital washing has been suggested as a means to prevent STD transmission to men. Studies of military personnel in World War I and World War II found that washing with soap and water soon after exposure to STDs helped prevent chancroid.

In sub-Saharan Africa, genital washing has been theoretically proposed as a way to reduce STD and HIV incidence. Lack of circumcision in men may be a risk factor for development of chancroid, a common cause of genital ulcer disease in Africa. Genital ulcer disease appears to be a risk factor for contracting HIV. Health advocates suggest that education about postcoital and precoital washing with instructions on how to clean the area beneath the foreskin of the penis might be one way to reduce the incidence of STDs in east, central and southern Africa, where male circumcision is less common and genital ulcer disease more common than in west Africa.¹⁸

But a study in Singapore, which questioned 100 prostitutes about methods they used to prevent sexually transmitted diseases, found that postcoital washing with antiseptic solutions had no STD prevention effect for this group of women.¹⁹

— Barbara Barnett

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Resources

FHI WORKING PAPER ON AIDS KNOWLEDGE IN HAITI

The discrepancy between women's knowledge about AIDS and the measures they take to protect themselves is the subject of a new FHI working paper, *Haitian Women's Role in Sexual Decision-Making:*



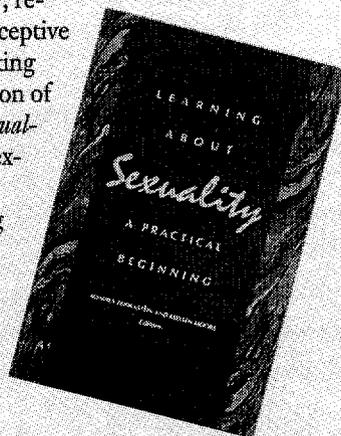
The Gap Between AIDS Knowledge and Behavior Change. The paper reports on qualitative research among poor Haitian women and men, in which focus groups were used to explore norms of sexual behavior and communication as a means to reduce behavioral risk (see related article, page 10). The 85-page report is available at no charge from: Publications Coordinator, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709 USA. Telephone (919) 544-7040, or fax (919) 544-7261.

NEWSLETTER ON REPRODUCTIVE HEALTH

Nexus, a bimonthly newsletter, covers reproductive health, sexually transmitted diseases, sexuality and women's and children's health. A digest of articles appearing in the Indian press, *Nexus* seeks to increase the quantity and quality of print media coverage of reproductive health. The newsletter is a resource for journalists, doctors, researchers and NGOs. Within India, subscriptions for single copies are free; additional subscriptions cost Rs. 32 per issue. Outside India, one year's subscription costs U.S. \$18. Subscription requests should be sent to Ms. Sadhna Mohan, Editor, *Nexus*, Population Services International, E-18A East of Kailash, New Delhi, 110065, India. E-mail address: nv.del@psi.sprintprg.sprint.com. Payments should be made via demand draft to Population Services International, payable at New Delhi.

POPULATION COUNCIL PUBLICATION

Health-care providers and social and biomedical scientists discuss sexuality, reproductive health, contraceptive practices, and health-seeking behavior in a new collection of essays. *Learning about Sexuality: A Practical Beginning* explores the experience of sexuality; the links among sexuality, contraception and reproductive health; and the prospect of challenging attitudes and



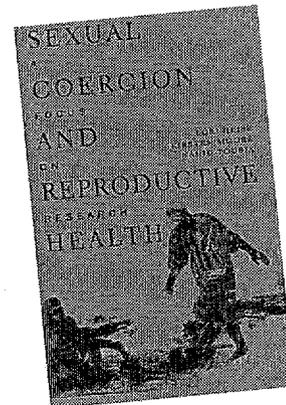
behavior related to sexuality. The 404-page book is free to readers in developing countries, and costs U.S. \$20 elsewhere. To request a copy, write to: The Population Council, One Dag Hammarskjold Plaza, New York, NY 10017 USA. Telephone (212) 339-0514, or fax (212) 755-6052.

BEIJING CONFERENCE COMMITMENTS

Commitments made at the 1995 Fourth World Conference on Women held in Beijing are summarized in a publication from Family Care International. *Commitments to Sexual and Reproductive Health and Rights for All: Framework for Action* outlines the actions recommended at the conference in the areas of policy, legislation, research, services, training and health education. Available in English, French and Spanish, the book costs U.S. \$1 in developing countries, and U.S. \$2 elsewhere. To order, write Family Care International, 588 Broadway, Suite 503, New York, NY 10012, USA. Telephone (212) 941-5300, or fax (212) 941-5563.

SEXUAL COERCION EXAMINED

The causes and consequences of sexual coercion in several cultures are examined in *Sexual Coercion and Reproductive Health*. The 59-page book emphasizes the importance of addressing sexual health when considering family planning, gender issues, AIDS and STDs, and young people. Family planning and reproductive health workers often see the effects of sexual coercion and sexual violence when they encounter un-



wanted pregnancy, STDs, unsafe abortion, and psychological trauma. The book is free of charge to readers in the developing world, and costs U.S. \$10 to others. Write: The Population Council, One Dag Hammarskjold Plaza, New York, NY 10017. Telephone (212) 339-0514, or fax (212) 755-6052.

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FAMILY HEALTH INTERNATIONAL
PRELIMINARY FINDINGS FROM THE WOMEN'S STUDIES PROJECT
June 13, 1996

Since its inception in October 1993, the Women's Studies Project (WSP) has initiated 24 primary research projects, 10 secondary analyses, and 3 case studies. In June 1996, mid-point in the USAID Cooperative Agreement that supports the WSP, some of these studies are at the development stage, while in others researchers are analyzing data and preparing preliminary findings. Most of the secondary analyses have been completed, and the results are in various stages of dissemination. The following highlights summarize key findings of several secondary analyses and some early results from primary data collection by WSP researchers in Jamaica. Primary data will soon be available also from Bolivia and The Philippines.

The Philippines

Secondary analysis of data from the Cebu Longitudinal Health and Nutrition Study (CLHNS) was conducted by researchers at the Carolina Population Center (CPC), the University of San Carlos in the Philippines, and FHI. The main focus of the analysis has been on changes in patterns of childbearing and labor force participation occurring in the interval between two data-collection periods: 1983 and 1991. Key findings are the following:

- * At baseline in 1983, nearly half (47%) of survey participants were working for pay. Workers were more likely than non-workers to be of higher parity, to be from a household with lower income, to have worked before marriage, and to have a higher education. Having a child under two decreased the probability of working.
- * Of women working for pay, 42 percent were self-employed in 1983, 31 percent were wage workers, 21 percent did piece work, and 7 percent worked in family businesses.
- * In 1991, 74 percent of the women were working for pay. Since 1983, the percentage of women doing piece work had declined to 15 percent, while the percentage of women who were self-employed rose slightly to 44 percent.
- * The likelihood of a woman working both in 1983 and in 1991 was higher if she had several children in 1983 and lower if she had a child under two years of age in 1991.
- * Among women who worked at both points in time, mean income increased by about 46 pesos per week from 1983 to 1991. Piece workers had the lowest gains, while wage workers had the highest (increases of 18.6 and 62.9 pesos per week respectively). Earnings per hour increased by a mean of 0.6 pesos, with the greatest advances in hourly earnings in the wage sector.

- * The average work week was 42 hours in 1983, increasing to 46 hours in 1991. Earnings per hour increased by a mean of 0.6 pesos, with the greatest advances in hourly earnings in the wage sector.
- * Children born during the eight-year interval translated into lower earnings. For each child born between 1983 and 1991, earnings decreased by approximately 10 pesos per week.

Income gains were not affected by the total number of children a woman had but rather by those additional children she gave birth to during the study interval. It appears, therefore, that the negative impact of children on earnings is temporary, since children up to eight affected their mothers' work hours and wages but older children did not, possibly because younger children require more intensive care. Also, women with decreased income gains due to additional children born during the study period may have fallen behind their counterparts by dropping out of the workforce when their children were infants, or may have moved to less profitable but perhaps more flexible occupations after giving birth to their children.

Presentation:

Adair, L., D. Guilkey, E. Bisgrove, and S. Gultiano, Effect of childbearing on Filipino women's labor force participation and earnings. Paper presented at PAA, New Orleans, May 1996.

Bangladesh

Dr. Sidney Schuler and her colleagues carried out two secondary analyses using material from in-depth interviews they had conducted with women and men in six rural Bangladesh villages between 1990 and 1993. They found that:

- * almost half of the 102 poor rural women in one sub-sample had experienced unwanted pregnancies; almost a third reported having taken action to interrupt pregnancy at least once.
- * most women view contraception as an effective, albeit risky, means of limiting fertility and maintaining or improving family well-being.
- * men tend to be non-committal or negative toward their wives' use of contraception.
- * concern about physical and economic costs of side-effects often leads to anxiety, family conflict, and discontinuation of methods.
- * Local female family planning workers play an important role in redefining reproductive norms for women. But, through door-to-door, woman-to-woman service delivery, the home-based family planning program may also be continuing women's isolation and

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reinforcing stereotypes that are counterproductive to women's empowerment.

Even in this strongly patriarchal culture, family planning has provided a context in which women are taking the initiative to improve their own and their families well-being. On the other hand, use of contraception does not appear to empower women to take action outside the household. The investigators speculate that reliance on home-based family planning services may reinforce women's subordination, while visits to a reproductive health clinic might encourage women to leave their homes and find new opportunities for greater independence in the public domain.

Publications:

Schuler, S.R., A.H. Jenkins, and S.Hashemi, Bangladesh's family planning success story: a gender perspective. International Family Planning Perspectives 21(4):132-137, 1995.

Schuler, S.R., S. Hashemi, A. Cullum, and M. Hassan, The advent of family planning as a social norm in Bangladesh: women's experiences. Forthcoming in Reproductive Health Matters (May/June 1996).

Malaysia

Dr. Mary Kritz and Dr. Douglas Gurak of Cornell have used event history analysis to re-examine 1978 and 1988 datasets from the Malaysia Family Life Survey. They found that:

- * contraceptive users were significantly less likely to experience marital disruption, with effectiveness of the method less important than simply whether or not a method was used.
- * users of contraception were not significantly different from non-users with respect to entering or leaving employment.

Unlike in the Philippines, these data revealed no association between fertility and labor force participation. In interpreting the relationship between contraceptive use and marital disruption, the investigators speculate that spousal communication may play a role in maintaining the marital relationship and fostering the use of family planning.

Publications:

Gurak, D. and M. Kritz, Family planning and women's lives: the Malaysian case. Journal of Population 1(2):131-156, 1995.

Kritz, M. and D. Gurak, The effects of family planning on marital disruption in Malaysia. Submitted to Demography.

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Jamaica

Researchers at the Fertility Management Unit at the University of the West Indies and FHI have reported the following findings from the first phase of a longitudinal study which explores knowledge, attitudes, and behaviors of Jamaican adolescents at high risk for early pregnancy and fatherhood:

- * Thirty-four percent of students ages 11 to 14 said they had had sexual intercourse. Sixty-three percent of boys said they were sexually experienced, in contrast to 6 percent of girls.
- * Among those reporting sexual activity, the mean age of first sexual intercourse was 11 for girls and nine for boys.
- * Both boys and girls said their first sexual partner was someone their own age or slightly older.
- * The two most common reasons given for having sex were curiosity and showing love.
- * Almost one-third of the girls and 57 percent of the boys believe a girl should have sex with a boy if he spends a lot of money on her.
- * Most teens said they did not use family planning the first time they had sex. Of those who did use contraception, the condom was the method most often used.
- * More than seventy percent said teens who are sexually active should use family planning. The majority do not believe people their age are ready for parenthood.
- * Teens had little correct knowledge about sex and family planning. While most teens believed condoms could protect against sexually transmitted diseases, the majority did not know pregnancy was possible at first intercourse.

The researchers speculate that sexual experience in this study may be over-reported by boys and under-reported by girls. However, although attitudes toward contraception are generally positive, knowledge of sex and reproduction is low, and a significant number of these high-risk adolescents are engaging in sexual activity with inadequate protection against pregnancy.