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Effects of Husband Involvement on Postabortion Patients' Recovery and Use of Contraception in Egypt

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Population-based studies on the incidence of abortion (spontaneous or induced) are lacking in Egypt, even though evidence suggests that abortion is a common medical procedure. A recent study of the postabortion caseload in Egyptian public-sector hospitals found that one out of every five admissions to the OB/GYN ward was to a postabortion patient (Huntington et al. 1998).

Although the proportion of postabortion patients admitted with serious complications is relatively small, their ability to recuperate after receiving emergency medical treatment is of concern, particularly because of evidence that postabortion patients in Egypt may not be receiving adequate care after hospital discharge.

A study examining psychosocial stress in the postabortion period found that postabortion patients (especially those in rural areas) resume their domestic labor shortly after the procedure (Huntington, Nawar, and Abdel-Hady 1997). Early resumption of hard work interferes with recovery and places a burden on postabortion patients' already compromised health. Moreover, many patients often have to deal with questions and doubts from their husbands or in-laws regarding their ability to conceive again or to carry a pregnancy to term. As a result, some patients may give in to family pressure for another pregnancy soon after their abortion in order to prove their fecundity.

Despite the documented role of husbands as decisionmakers in matters of reproductive health (Abdel-Aziz, El-Zanaty, and Cross 1992; Ali 1995), very little has been done to formally involve husbands in matters related to the health of their wives, particularly in relation to postabortion care. Current health services for postabortion patients seldom give any information to the patients themselves, let alone to their husbands. Studies that measure the effects of husbands' involvement have commonly been conducted in family planning settings. Moreover, most of the past research focused on a self-selected group of husbands who received counseling. Prior to the present study, it was not known in Egypt whether involving husbands would be feasible and acceptable, or whether it would have a positive impact on the health of their spouses.

The study examines the effects of counseling the husbands of postabortion patients on husbands' level of involvement in their spouses' recovery and on patients' recovery and subsequent use of contraception.

Study Hypotheses

The following hypotheses were tested in this study:

- Levels of positive husband involvement in spouses' postabortion recovery will be higher among husbands who receive counseling than among husbands who do not.
- Postabortion patients whose husbands receive counseling will report better physical and psychological recovery one month after discharge from the hospital than patients whose husbands do not receive counseling.
- Contraceptive use or intent to use in the near future, measured one month after discharge, will be higher among postabortion patients whose husbands receive counseling than among patients whose husbands do not.

Study Intervention

The study was conducted in six hospitals in Menia Governorate in southern Egypt. The component on husband counseling was added to an intervention that included improving postabortion clinical services through using

manual vacuum aspiration (MVA), improving case management procedures, and enhancing counseling for postabortion patients (Nawar et al. 1997a).

Content of Counseling for Husbands

The counseling of husbands emphasized the important role they can play in their wives' recovery and in the adoption of a family planning method during the postabortion period. Although the manner in which this information was transmitted varied, each husband received, at the minimum, a "health education" message (although physicians were encouraged to have more lengthy exchanges with husbands). These messages were on the following five topics: (1) patient's need for rest and adequate nutrition (emphasizing inexpensive nutritious food); (2) postabortion warning signs indicating need for follow-up care; (3) the possibility of a return to fertility within two weeks; (4) the need for family planning to avoid unwanted or poorly timed pregnancy; and (5) cause of the miscarriage (if appropriate) and source of referral care (if necessary). Because abortion is illegal in Egypt, no attempt was made to differentiate between cases of spontaneous or induced abortion.

Procedures for Counseling Husbands

All postabortion patients received improved medical care and complete counseling about their health condition and family planning. Counseling of patients and husbands was done separately. This decision was based on findings from previous studies that showed women felt less free to ask questions or express concerns in the presence of their husbands (Kim and Awasum 1996). Counseling of husbands was done by the attending physician when the patient was ready to leave the hospital. Because of the sensitive nature of abortion and the possibility that by involving the husband he might gain information about his wife's medical condition that could pose a risk to the woman (e.g., a husband might learn that his wife induced the abortion without his knowledge or that she concealed her pregnancy from him), considerable attention was devoted to establishing strict ethical guidelines and procedures (Abdel-Tawab, Huntington, and

Nawar 1997). Counseling was given only to husbands of consenting patients. The following enrollment procedure was developed through extensive pretesting to ensure protection of patient privacy while maximizing the number of husbands who would receive the intervention.

Procedures on patient admission. If the patient was brought to the hospital by her husband, the nurse in charge asked him to return at discharge to pick up and assist his wife. Husbands did not receive counseling at this point; they were counseled only after the patient's consent was obtained.

Obtaining patient's informed consent. The nurse in charge sought the patient's permission to have the doctor speak to her husband about her medical condition. The nurse read a standardized consent statement to the patient after she had received complete medical treatment (including counseling) and only after it was determined that she was in stable physical and emotional condition.

Contacting the husband. The pilot test of the informed consent procedures showed that family members often go back and forth to the patient's home while she is in the hospital. Thus it was relatively easy to contact those husbands who did not accompany the patient at admission. Patients who agreed to have their husbands counseled were asked to tell their relatives or companions, who were already at the hospital, to send for the husband to pick her up at discharge.

Procedures at discharge. The attending physician commonly signs the discharge forms and gives the patient any remaining instructions for postabortion care. If the patient had agreed to have her husband counseled and if the husband was present at discharge, the nurse would ensure that he met with the physician. In all cases husbands received counseling by the attending physician in private, away from their wives.

Training Providers on Procedures for Counseling Husbands

Thirty physicians (five from each hospital) received one day of orientation on the content and procedures for counseling the husbands of postabortion patients. The orientation was done in conjunction with train-

ing for the "scaling-up" intervention already in place, which included training on use of MVA and basic patient counseling (Nawar et al. 1997b). The orientation strategy focused on creating a cadre of supervisors who would then train their colleagues and provide daily on-site supervision and follow-up for a period of three months.

Research Methodology

Study Design

A true experimental, posttest-only control group design (Campbell and Stanley 1963) was used to measure the effects of counseling husbands on their level of involvement in matters related to their spouses' health and, by consequence, on their wives' recovery and use of contraceptive methods. Consenting postabortion patients were randomly assigned to either an intervention or a control group. Husbands in the intervention group received counseling about the medical condition of their wives. Husbands in the control group did not receive such counseling (although their wives did receive improved postabortion medical care and counseling). A follow-up interview was conducted with both groups of patients one month after hospital discharge to assess their physical and psychological recovery and to determine whether they were currently using or intended to use contraception in the near future. The 30-day period was deemed sufficient to measure the effects of counseling on recovery and immediate postabortion contraceptive use, although it was considered too short to investigate medium- and long-term morbidity or the attainment of other reproductive intentions.

Study Sample

The sample size was initially estimated at 220 couples from each group (intervention and control) to account for losses to follow-up, statistical significance tests, and budget considerations. All consenting postabortion patients who were admitted to the study hospitals during a two-month enrollment period were eligible for the study; this length of time was anticipated to be sufficient for the enrollment of the desired sample of patients.

Variables and Measurement

Independent variable. The principal independent variable is whether or not the husband received counseling regarding his wife's medical condition. This was determined by the physician's signature on the patient discharge form attesting that counseling was provided.

Intervening or mediating variables. The effects of counseling husbands on their wives' recovery is assumed to be mediated by the degree to which counseling translates into husbands' support. The study measures husband support as perceived by wives (i.e., based on patients' self-reports), which may or may not be the same as that perceived by the husbands or a third person.

A review of relevant literature, consultations with experts in the field, and exploratory studies revealed two broad dimensions of improved husband support: instrumental and emotional support. Preliminary analysis of the two indexes used to measure these two dimensions, however, revealed that they were moderately correlated (r=0.29). Confirmatory factor analysis was conducted in which items from the two indexes were pooled together to explore patterning of the data. Rotated factor analysis revealed a third factor, family planning support, that had been initially contained within the emotional support index. Separated out, these three indexes of husband support (instrumental, emotional, and family planning) were less correlated with one another (r=0.143) (i.e., more independent and with greater internal consistency reliability for each index).[3] Items included in each index are shown in Table 2.1.

The index for instrumental support measured the degree of tangible or material support provided by husbands. The index tapped indicators of help provided by husbands in buying and preparing food for the patient and assisting with various household activities. The index had five items and an internal consistency reliability of 0.77.

The emotional support index measured the husband's reaction to the lost pregnancy, as well as his understanding of his wife's physical and emotional needs as reported by the patient herself. The index had eight items and an internal consistency reliability of 0.86.

TABLE 2.1
Items on Instrumental, emotional, and family planning support indexes

Instrumental support index
- My husband buys nutritious food for me
- My husband helps prepare food for me
- My husband encourages me to stay in bed
- My husband prepares hot drinks for me
- My husband helps with cleaning the house

Emotional support index
- My husband was more concerned about my health than about the lost pregnancy
- My husband was willing to skip his work and stay with me
- My husband encouraged me to make a follow-up visit
- My husband reassured me about my health
- My husband was angry at me because I lost this pregnancy
- My husband was upset because we had to postpone sex
- My husband could not understand how exhausted I was
- I could not tell my husband how I was feeling

Family planning support index
- My husband would not let me use a family planning method
- I can talk freely with my husband about family planning
- My husband would let me choose any family planning method that I want
- My husband would agree to go with me to the family planning clinic
- My husband and I are in agreement with regard to family planning
- My husband encourages me to take a break from pregnancy and childbirth

The family planning support index measured aspects of family planning support by the husband, such as approval of his wife's use of family planning, openness to discussions about family planning with his wife, and willingness to accompany his wife to the family planning clinic. The index had six items and an internal consistency reliability of 0.85.

Dependent variables. The two principal dependent variables for the study are improved patient recovery and contraceptive use.

Three dimensions of the patient's health were measured to examine patient recovery: physical, emotional, and social health. Separate indexes were constructed for each dimension, using the same development process described above to identify the items on each index, followed by confirmatory factor analysis.

Physical health was measured through a "weakness index," which identified physical health problems that the patient might be having one month after her discharge from the hospital. Patients were asked whether they were having any of the following symptoms: fatigue, shortness of breath, or headache/dizziness. They were also asked whether they were having difficulty performing activities such as walking, standing, housework, and so forth. The index had eight items and an internal consistency reliability of 0.88. A high score on the weakness index was indicative of poor physical recovery.

Postabortion patients' emotional health status was assessed through the Psychological Distress Index (PDI), adapted from the Grief Scale developed by Peppers and Knapp (1980). Patients were presented with a list of emotional symptoms such as sleep difficulty, loss of appetite, anxiety, and so forth, and were asked to indicate whether they had experienced any of those symptoms in the past three days. The index had eight items and an internal consistency reliability of 0.88. A high PDI score indicated poor emotional recovery.

An index was constructed that included items on the patient's resumption of social activities such as talking with her husband about his work, visiting friends, resumption of sexual relations, and relations with her children. The index had a very low internal consistency reliability and was therefore dropped from subsequent analysis.

The second class of dependent variables that were measured in this study concerned contraceptive use. Respondents were asked whether they were currently using a family planning method. Those who said they were not were asked whether and when they intended to begin using a family planning method.

Control variables. Because of the potential effect of a great number of factors on husband involvement, patient recovery, or use of contraception, the study identified several control variables and utilized them in the analysis. The variables measured included patient's and husband's characteristics, husband–wife relationship characteristics, patient's medical characteristics, and characteristics of the index pregnancy. An autonomy index was used to measure husband–wife relations, composed of five items that measured the wife's ability to make a solitary decision on each of the following: visiting a neighbor, visiting her parents, going out with a friend, visiting the doctor, and choosing meals for the family. The patient's medical characteristics included presence of abortion complications as well as any preexisting medical conditions such as hypertension, kidney disease, parasitic disease, and so forth. With the exception of information on the

patient's medical characteristics, which was collected by the discharging physician, information about all other control variables was collected at the home interview with the patient.

Characteristics of the hospital where the patient was treated was another control variable measured in the study. The six study hospitals were divided into two groups: Group A and Group B hospitals (three in each group). Group A hospitals were generally smaller (i.e., they had fewer physicians) and therefore a larger proportion of physicians in those hospitals were exposed to the training and orientation. It was expected that even with the study's monitoring and supervision visits, performance of physicians from Group A hospitals would be somewhat better than that of those from Group B hospitals.

Data Collection Activities

Patient enrollment and randomization. A patient who agreed to participate in the study was asked her full name and address for the follow-up interview. Patients who preferred to have their follow-up interview outside their homes were asked to come back to the hospital on an assigned date and time. A special logbook was used for randomization purposes. Access to this logbook was strictly controlled. Patients with an even log number were assigned to the intervention group while those with an odd number were assigned to the control group (i.e., every second consenting patient was assigned to the intervention group). Three or four nurses in each of the participating hospitals were in charge of patient enrollment and randomization procedures.

At discharge, an attending physician gave the patient instructions regarding her health condition and information on family planning and also documented on the patient's discharge form any complications or preexisting medical conditions. If the patient was in the intervention group, a nurse arranged for the meeting to take place between the physician and the husband. The physician then indicated that the counseling had taken place and provided basic sociodemographic information about him/herself, including age, medical degrees, and position.

TABLE 2.2
Patients who participated in study: Enrollment, attrition, and completion

Patients	Intervention group	Control group	(n)	Percentage
Completed the study	136	157	293	80
Husband did not show up at discharge	45	—	45	12
Husband away for entire month	1	14	15	4
Lost to follow up	6	7	13	4
Total no. of patients agreeing to participate	188	178	366	100

Follow-up interviews. Follow-up interviews were conducted with patients in the intervention and control groups one month after discharge from the hospital. Unless the patient indicated a preference to have the interview at the hospital, follow-up interviews were conducted at patients' homes. To the extent that it was feasible, patients were visited 30 days after their discharge. If the patient was not available, revisits were made to her home, with a maximum of three callback visits within a four-day period. Five trained female interviewers conducted the follow-up interviews with patients. Interviewers were blinded as to the research group (i.e., intervention or control) to which the respondent belonged.

Results

Patients and Husbands Recruited for the Study

Of 381 postabortion patients who were admitted to the postabortion wards during the two months of data collection and who were approached for the study, 366 patients agreed to participate, yielding a refusal rate of 3.9 percent.

Table 2.2 shows the proportion of patients who completed the study and patients who were lost at different stages of the study; 12 percent of the patients who agreed to participate were excluded because their husbands did not show up at discharge and therefore did not receive counseling. Only patients in the intervention group were excluded from the study if the husband did not show up at discharge; 24 husbands of patients in the control group also did not show up at discharge (data not shown).

The following were reasons given for the husband's absence as explained by patients in the control group during the follow-up interview: husband out of town when the abortion happened (20 cases), husband arrived at hospital after patient's discharge (3 cases), husband was too busy at work (1 case). Unfortunately, similar information about husbands in the intervention group is lacking.

Very few patients were lost to follow-up (4 percent) and hence did not complete the follow-up interview. None of the patients who requested to have their follow-up interview at the hospital showed up on the assigned date and they were therefore lost to follow-up. Fifteen patients completed the follow-up interview but were later excluded from the analysis because their husbands were absent for the entire month of recovery. Thus the final sample was composed of 293 patients, 136 in the intervention group and 157 in the control group.

Patients' and Husbands' Characteristics

Table 2.3 shows that postabortion patients who participated in the study were more likely to be younger than 25 years or in their 30s, had little or no schooling, and had three or more living children. Forty-five percent of the patients reported previous use of contraception and 61 percent indicated a desire for more children in the future. According to 39 percent of the patients, the lost pregnancy was planned. Forty-three percent of patients said they lost their pregnancy at a gestational age of 12 weeks or higher. Seventy-seven percent of patients reported experiencing at least one complication such as excessive bleeding, fever, or offensive discharge during the 30-day recovery period. Sixty-five percent of patients were treated in a hospital that was classified in this study as Group B (i.e., a larger hospital with a smaller proportion of physicians who received direct training and orientation). On the patient autonomy index, the majority of patients scored a medium score (20–59 points out of 100).

Fifty-three percent of husbands of postabortion patients were 35 years or older and 63 percent had little or no schooling. Slightly more than half of the studied couples lived in a nuclear family setting (55 percent) while the remainder lived with parents or in-laws. The majority of couples who participated in the study lived in rural areas (76 percent).

TABLE 2.3
Percent distribution of selected sociodemographic and medical characteristics of postabortion patients and their husbands

Characteristic	Intervention (n=136)	Control (n=157)	Total (n=293)
Patient			
Age (years)			
<25	37	38	38
25–29	28	26	23
≥30	35	36	39
Education			
No school/less than primary	79	83	81
Primary or higher	21	17	19
No. of living children			
0	24	22	23
1–2	32	27	29
≥3	44	51	48
Preexisting medical conditions			
Yes	2	7	5
Gestational age of lost pregnancy*			
<8 weeks	14	20	17
8–11 weeks	48	30	39
≥12 weeks	38	48	43
Not known	0	2	1
Index pregnancy was planned			
Yes	37	40	39
Ever use of contraception			
Yes	46	45	45
Desire for more children			
Yes	62	60	61
Complications during recovery			
One or more	74	79	77
Hospital			
Group A	34	36	35
Group B	66	64	65
Autonomy level[a]			
Low	21	13	17
Medium	57	64	61
High	22	23	22

* $p<0.01$.

[a] The autonomy index range was 0–100. Scores were classified into <20, 20–59, ≥60 to denote low, medium, and high autonomy, respectively.

(continued)

Table 2.3 shows that patients in the intervention and control groups were comparable on most of the above characteristics. However, patients in the control group were more likely to have lost the index pregnancy at

TABLE 2.3 *(continued)*

Characteristic	Intervention (n=136)	Control (n=157)	Total (n=293)
Husband			
Age			
<30	28	27	28
30–34	20	19	19
≥35	52	54	53
Education			
No school/less than primary	62	64	63
Primary/preparatory	13	16	15
Secondary/college	25	20	22
Household composition			
Nuclear	50	59	55
Extended	50	41	45
Residence			
Urban	21	27	24
Rural	79	73	76

12 or more weeks than patients in the intervention group, who were more likely to have lost it between 8 and 11 weeks. This difference is statistically significant.

Support Given by Husbands During Recovery

The study posits that counseling will lead to greater involvement by husbands, which, in turn, will positively affect their spouses' recovery. The intervening variable, husband involvement, is operationalized through an expression of greater instrumental, emotional, and family planning support by the husband. This section presents the results of the intervening variable—the indicator of how the study's intervention was translated into action by the husbands. It also examines the effects of the control variables on these demonstrable actions as a prelude to investigating the impact of the intervention on the two dependent variables.

Figure 2.1 shows mean levels of the different types of support provided by husbands of postabortion patients. On average, husbands in the two groups provided a higher level of emotional and family planning support than instrumental support to their wives (mean 83, 65, and 17, respectively). Bivariate analysis showed no differences between the intervention and the control with regard to the degree of support provided by husbands.

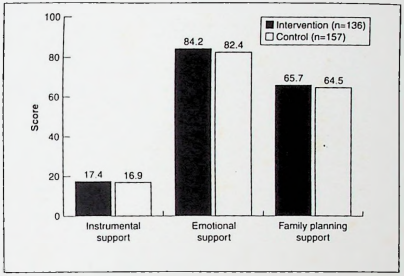

FIGURE 2.1 Mean score on three indexes of support provided by husbands of postabortion patients

Because of the relatively small sample size and skewness of observations, respondents were classified into two groups depending on the level of support provided by husbands (i.e., below mean corresponds to low support; above mean corresponds to high support). Logistic regression analysis was conducted to measure the association between counseling of husbands and each type of support provided, after controlling for potential confounders. A hierarchical modeling technique was used to enter variables into the model. Counseling of husbands was entered first and then other variables were entered for forward selection with alpha set at 1.0.

Table 2.4 shows that after adjusting for other patient characteristics, counseling of husbands was associated with an increase in the likelihood that the husband will provide high instrumental, emotional, or family planning support to his wife during recovery. Counseling was associated with a greater increase in family planning and instrumental support than emotional support. Other factors associated with increased instrumental support by the husband were: living in a nuclear family arrangement, patient's experience of complications during recovery, and higher education of the husband (i.e., secondary or above). Interestingly, receiving coun-

TABLE 2.4
Logistic regression analysis of variables associated with high level of instrumental, emotional, and family planning support provided by husbands[a] (n=293)

Variable	Adjusted odds ratio	90% confidence interval
Instrumental support[b]		
Household composition (nuclear)	2.6	1.7, 4.0
Complications during recovery (yes)	1.8	1.1, 3.2
Husband's education (secondary or above)	1.7	1.0, 2.5
Husband counseled (yes)	1.5	0.9, 2.4
Group A hospital and husband counseled (yes)	0.5	0.2, 0.9
Emotional support[c]		
Index pregnancy planned (yes)	2.8	1.8, 5.0
No. of living children (≥3)	2.0	1.2, 3.3
Husband and wife blood relatives (yes)	1.9	1.2, 2.9
Husband counseled (yes)	1.3	0.8, 1.9
Family planning support[d]		
Desire for more children (no)	5.0	2.5, 10.0
Husband's education (secondary or above)	2.5	1.4, 5.0
No. of living children (≥3)	2.5	1.4, 5.0
Group A hospital	1.7	1.1, 2.7
Husband counseled (yes)	1.6	1.1, 2.6

a Logistic regression analysis was used to measure association between counseling of husbands and each type of support after controlling for other patient characteristics. Dependent variable in each model was high level of that dimension of husband support.

b Reference categories are: couple lives with in-laws/parents, patient did not experience complications during recovery, husband completed less than secondary education, husband did not receive counseling, patient was admitted to Group B hospital and husband did not receive counseling.

c Reference categories are: index pregnancy was not planned, patient has fewer than 3 living children, husband and wife are not blood relatives, husband did not receive counseling.

d Reference categories are: patient wants more children in the future, husband completed less than secondary education, patient has fewer than 3 living children, patient was admitted to Group B hospital, husband did not receive counseling.

seling in a Group A hospital (i.e., a smaller hospital with more trained physicians) was associated with decreased instrumental support by husbands.

Emotional support by husbands was less likely to be affected by counseling than by patient and husband characteristics. Husbands were more likely to provide emotional support to their wives if the index pregnancy was planned. Patients who had three or more living children were more likely to receive emotional support from their husbands than patients with fewer children. Also, when patients and their husbands were blood relatives husbands were more likely to provide emotional support to their wives.

Husbands' support of family planning was mostly determined by the couple's demographic characteristics. When a couple did not want more children in the future, the husband was five times more likely to provide family planning support to his wife than if the couple wanted more children. Also, if the couple had three or more living children, the husband was 2.5 times more likely to provide family planning support to his wife. Husbands with secondary or higher education were more likely to provide family planning support than husbands with fewer years of schooling. Patients who were treated in smaller Group A hospitals were 1.7 times more likely to receive family planning support from their husbands than patients who were treated in larger Group B hospitals.

TABLE 2.5
Logistic regression analysis of variables associated with good physical recovery of postabortion patients[a] (n=293)

Variable	Adjusted odds ratio	90% confidence interval
Emotional support by husband (high)	1.7	1.1, 2.6
Husband counseled (yes)	1.3	0.8, 2.0
Instrumental support by husband (high)	1.1	0.7, 1.7
Complications during recovery (yes)	0.2	0.1, 0.3

a Reference categories are: low level of emotional support by husband, husband did not receive counseling, low level of instrumental support by husband, patient did not experience complications during recovery.

Outcomes of Counseling

This section reviews the results of the two outcome indicators: patient's recovery and use of contraception.

Physical recovery. The aforementioned weakness index measured patients' physical recovery one month after discharge. Patients scoring less than 7 out of 14 on the weakness index were considered as having experienced good physical recovery while those with a score of 7 or above were considered to have poor physical recovery.

Table 2.5 shows results of logistic regression analysis of variables associated with good physical recovery. The variables husband counseled, instrumental support, and emotional support were entered first, then the following variables were entered for forward selection: gestational age, hospital group, experience of complications during recovery, number of

TABLE 2.6
Logistic regression analysis of variables associated with good emotional recovery of postabortion patients[a] (n=293)

Variable	Adjusted odds ratio	90% confidence interval
Patient's education (no school/less than primary)	2.5	1.4, 4.3
Emotional support by husband (high)	2.0	1.3, 3.0
Index pregnancy planned (yes)	1.7	1.1, 2.6
Husband counseled (yes)	1.0	0.6, 1.4
Complications during recovery (yes)	0.4	0.2, 0.7
Patient's autonomy index score		
Low	0.4	0.2, 0.8
Medium	1.0	0.6, 1.7

a. Reference categories are: patient completed primary or higher education, low level of emotional support by husband, index pregnancy was not planned, husband did not receive counseling, patient did not experience complications during recovery, patient scored high (≥60) on autonomy index.

living children, and interaction between counseling of husband and hospital group. Interestingly, a high level of emotional support by the husband was significantly associated with improved physical recovery by the patient, whereas instrumental support by the husband was not. The strongest predictor of physical recovery, however, was absence of any complications during convalescence. Patients who experienced complications were five times less likely to report physical recovery than patients who did not experience complications.

Emotional recovery. The aforementioned Psychological Distress Index showed that slightly more than half of the study patients (53 percent) did not report any emotional symptoms, hence were considered as having experienced good emotional recovery. Table 2.6 shows results of logistic regression analysis of variables associated with good emotional recovery. The variables husband counseled and emotional support were entered first. The following variables were entered for forward selection (alpha=0.1): number of living children, desire for more children, whether index pregnancy was planned, patient's educational level, patient's autonomy level, experience of complications during recovery, hospital group, and interaction between hospital group and husband counseled.

As shown in the table, a positive association exists between emotional support by the husband and good emotional recovery. Patients who reported receiving a high level of emotional support from their husbands were twice as likely to experience good emotional recovery. Two additional variables were associated with improved emotional recovery: patients with little or no education and patients reporting that the index pregnancy was planned. Two variables were negatively associated with good emotional recovery: low level of patient autonomy and patient's experience of complications during recovery.

Family planning use. The second outcome indicator examined in this study was family planning practice. By the end of the one-month follow-up period, 14.7 percent of women reported having started using contraception. An additional 34.5 percent of patients said they were planning to use contraception within one month. Because of the small number of observations of patients in the first category, subsequent analysis combined the two groups into one, for a total of 49.2 percent of postabortion patients.

Logistic regression analysis was conducted to determine association between patient's use of family planning and counseling of husbands and degree of family planning support, while controlling for potential confounders. The following variables were entered into the model for forward selection: number of living children, desire for more children, patient's age, previous use of contraception, whether index pregnancy was planned, patient's experience of complications during recovery, hospital group, and interaction between hospital group and counseling of husband.

Table 2.7 shows that after controlling for other variables, husband support of family planning is highly predictive of contraceptive use or intention to use. Other variables that were predictive of use of contraception were previous use of family planning, husband receiving counseling at a Group A hospital, and couples with three or more children. On the other hand, if the index pregnancy was planned, the patient was less likely to use or to intend to use a family planning method in the near future.

Discussion

The study was the first to test an intervention for counseling the husbands of postabortion patients in Egypt. Its primary aim was to examine

TABLE 2.7
Logistic regression analysis of variables associated with use of or intention to use family planning by postabortion patients[a] (n=293)

Variable	Adjusted odds ratio	90% confidence interval
Family planning support by husband (high)	5.9	3.5, 10.0
Group A hospital and husband counseled (yes)	3.8	1.5, 9.4
Previous use of family planning (yes)	3.5	1.7, 5.6
No. of living children (≥3)	2.5	1.4, 5.0
Husband counseled (yes)	0.6	0.3, 1.2
Index pregnancy planned (yes)	0.4	0.2, 0.7

a. Reference categories are: low level of family planning support by husband, patient was admitted to Group B hospital and husband did not receive counseling, patient has not used family planning before, patient has fewer than 3 living children, husband did not receive counseling, index pregnancy was not planned.

the effects of counseling on husbands' behavior and on postabortion patients' recovery and use of contraception. Other issues addressed included the feasibility of counseling husbands and of conducting follow-up assessments of postabortion patients while protecting their rights to privacy.

Overall the study findings show a positive association between counseling husbands and their involvement in their spouses' recovery. On average, patients in the two study groups received more emotional and family planning support than instrumental support from their husbands. Because the study was conducted in a traditional society, where men are often discouraged from participating in what are perceived as women's activities, this result is expected. It is interesting to note, however, that husbands were more likely to provide instrumental support to their wives when the couple lived within a nuclear family, implying that husbands are willing to help if no other women are available to provide such support.

The results show that support by husbands is crucial for patients' recovery and use of contraception. Emotional support by husbands is particularly important for women's physical and emotional recovery. Family planning support by husbands is the strongest predictor of family planning use by the patient. These findings are in agreement with those documented in the literature on the health effects of social support (Cohen and Syme 1985). The family planning literature also documents an association between husbands' support of family planning and adoption and continuation of contraception (Joesoef, Baughman, and Utomo 1988; Terefe and Larson 1993).

Also supported is the primary hypothesis of the study that counseling of husbands will result in positive changes in their behavior, which in turn will lead to better patient outcomes. Counseling of husbands is most likely to influence patient outcomes through changes in husbands' level of involvement.

Program managers in Egypt should consider including counseling of husbands as part of the medical services provided to postabortion patients. The content of counseling should highlight the importance of emotional and family planning support, because these two dimensions of support were associated with better patient outcomes. Counseling should be more vigorous with husbands of patients who are otherwise less likely to receive support from their husbands. According to the findings of this study these include patients with fewer living children and those with husbands who have less education. It is important that providers establish two-way communication during counseling in order to identify husband groups who are less likely to provide support to their wives.

The study also shows that counseling of husbands is associated with better outcomes in some hospitals than in others. This clearly suggests that having senior and better-trained staff provide the counseling leads to a stronger impact on husbands' behavior. It also suggests that the two-tiered system (training of trainers) may not be as effective as direct training of all service providers, although, obviously, the former is less expensive. It would have been helpful if counseling sessions were observed directly so that variations in quality of counseling given in different hospital groups could be ascertained.

Some administrative and logistic changes may be needed in each hospital in order to make counseling of husbands more feasible and effective. The current set-up in OB/GYN wards may need to be changed to make the hospital environment more husband-friendly and to encourage husbands to accompany their wives to the hospital. Providing family plan-

Improving the Quality of Services and Contraceptive Acceptance in the Postabortion Period in Three Public-Sector Hospitals in Bolivia

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Maternal mortality is one of the most important public health problems in Bolivia; although the Ministry of Health (MOH) has declared that maternal mortality is one of its first priorities and several campaigns aimed at reducing it have been implemented, the rate is 390 maternal deaths per 100,000 live births, one of the highest in the region. Based on the latest available data it is estimated that 27–35 percent of maternal deaths are due to complications from abortion (Encuesta Nacional de Demografía y Salud 1994; UNICEF 1992). In 1994 the Ministry of Health (MOH) declared that maternal mortality was one of the most important women's health problems and instituted a plan for its accelerated reduction. This included the goal of reducing induced abortions and their complications.

Analysis of abortion in Bolivia is difficult because, as in other countries of Latin America and the Caribbean (LAC), statistical information is scant and estimates of its incidence are not reliable. There is evidence, however, that due to very restrictive legislation, most women try to solve problems resulting from unwanted pregnancy and induced abortion without consulting public-sector medical services. This explains why 95 percent of deaths due to induced abortion occur at the woman's home

(Ministerio de Relaciones Exteriores y Culto 1994). Women usually present for services only after they have suffered long periods of pain and bleeding; frequently complications are severe and lead to serious sequelae or even to death (Rance 1993). In addition, women do not admit to inducing their abortions because of the risk of being mistreated, denounced, or sued.

Between 1966 and 1976, abortion complications represented 46 percent of all obstetric hospitalizations; in the next decade they made up 51 percent of all such hospitalizations (Rance 1990; UNFPA 1990). A report published by USAID in 1990 stated that, in the Bolivian social security system, by far the most important cause of hospitalization of women of reproductive age was complications of illegal abortions (USAID 1990).

The Caja Nacional de Salud (Social Security Institute) found that the unit cost of treating induced abortion is several times higher than that for deliveries because most women present with complications at more than one time after the induction of their abortion, which, in most cases, has been done by a person without formal training in gynecology or even in medicine. The most frequently used methods to induce abortion are introducing objects, curettage, oral abortifacients, and injections.

Women presenting to hospitals with postabortion complications are intensively interrogated to discover whether the abortion was illegally induced. It is a common practice to charge a higher fee to women presenting clear evidence of induced abortion. In some cases the fee charged is so high that it prevents hospitalization or leads to a significant negative impact on the family budget.

The rationale given by providers for this excessive fee is that it might discourage repeated abortions. Sometimes women are mistreated or simply not accepted in the hospital. On the other hand, women who supposedly have spontaneous abortions and are unable to pay the entire fee are interviewed by a social worker who is then authorized to lower or even waive the fee.

It is worth noting that a small proportion of women (17 percent) who resort to abortion had at one time used a modern contraceptive method (Bailey et al. 1988). The same study showed that most women

declared that either they did not believe in the efficacy of contraceptive methods or they were not informed about them.

Data from an unpublished survey of women with abortion complications, conducted by the Bolivian Society of Obstetrics and Gynecology (Taborga, Pooley, and Rada 1988), showed that lack of information was the main reason women did not use contraception (48 percent). Eighteen percent said that they thought they would not get pregnant or that they were not able to get pregnant. Almost 10 percent gave religious reasons for not using contraception. Only 2 percent mentioned lack of access as the reason for not using contraceptive methods. The remaining 22 percent did not use contraception because they wanted to get pregnant, were already pregnant, or were lactating. The study also showed that most women did not receive contraceptive counseling after resolution of the abortion, confirming that postabortion contraceptive services have not received priority.

A qualitative assessment conducted by the MOH in collaboration with the World Health Organization showed that access to abortion services is limited. Some hospitals, mainly Catholic ones, do not accept women if they are suspected of having induced their abortions. In addition, counseling during the postabortion period is not given, and contraceptive methods are not offered. As a consequence, many women get pregnant soon after their abortions and resort to another induced abortion, again placing their lives at risk (Camacho et al. 1996).

Based on that assessment, the MOH decided to implement a strategy to improve women's access to and the quality of postabortion services, including postabortion contraception as a means of decreasing mortality due to repeated abortions. Moreover, postabortion contraception is considered the best means to break the vicious cycle of unwanted pregnancy followed by induced abortion, lack of counseling, and new unwanted pregnancy (Benson 1996).

The MOH requested technical assistance from the Population Council in order to implement a pilot project aimed at assessing the feasibility of carrying out a program to improve the quality of services for postabor-

tion complications, including contraceptive counseling and services, and the impact on client satisfaction and contraceptive acceptance. This chapter presents the results of the pilot project undertaken in three public-sector hospitals from October 1995 through December 1997.

Materials and Methods

Study Sites

The study was undertaken in three maternity hospitals in three cities: Hospital de la Mujer, La Paz; Instituto de Maternidad Percy Boland Rodríguez, Santa Cruz de la Sierra; and the Hospital Gineco-Obstétrico, Jaime Sánchez Porcel, Sucre. The three hospitals are the most important of their respective departments and are women's health referral centers. They attend primarily people from middle and low socioeconomic levels.

The largest, with 165 beds for obstetrics and gynecology, is in Santa Cruz, the largest of the three cities in our study, with approximately 870,000 inhabitants. Before the initiation of the project, the hospital had already implemented some family planning activities. In addition, some physicians were implementing selected activities in the postabortion period, including providing contraceptive services. More than 1,400 cases of complicated abortions were attended in the hospital during the year before the initiation of the project. Two or three months after project initiation, the hospital opened an outpatient clinic specifically devoted to adolescents.

The hospital in La Paz has fewer beds devoted to gynecology (58), although the population of the city (830,000) is comparable to that of Santa Cruz. The social and economic status of the population attended is similar to that attended in the Santa Cruz hospital, but the proportion of indigens is higher. Indigens have a cultural resistance to seeking hospital-based care, which may explain why the number of abortions attended in the La Paz hospital the year before the project (253) was far lower than the number attended in Santa Cruz. During the first months of the project after the training course, hospital personnel, especially physicians, were

reluctant to initiate project activities. They were apprehensive about possible negative reaction of the church, which exerts strong influence on the health authorities. This fact explains, at least in part, the lower contraceptive acceptance in La Paz, compared with Santa Cruz.

The third hospital is in Sucre, a smaller city with only 176,000 inhabitants. Sucre is the official capital of the country and the base of the Judiciary. It is home to a well-known university, with one of the best law schools in the country and several other highly regarded faculties. Because the university receives students from all over the country, Sucre has a greater percentage of adolescents, most of whom are living away from their families. Their abortion rate is high, and it is for this reason the abortion rate in the city is far higher than that in La Paz and Santa Cruz. During the year before the project, the hospital attended 414 abortions (2.4 per 1,000 inhabitants) compared to 1.6 per 1,000 in Santa Cruz and 0.3 per 1,000 in La Paz. Implementation of the project was difficult because the Judiciary insisted that all women who have induced abortions be denounced and prosecuted. In 1994 and 1995, judges had sued and condemned at least 10 women for having induced abortions. For this reason, physicians were reluctant to participate in a program designed to give greater attention to all women having abortions, induced or spontaneous. It was not easy to convince physicians to stop denouncing women, but agreement was obtained during the second year. In turn, judges began simply ignoring the fact that induced abortions were no longer denounced.

At the beginning of the project, the three hospitals improved their postabortion facilities and equipment significantly, making the hospitals appropriate for attending the demand for services. The technical level of the persor.nel was similar in the three hospitals. La Paz had more problems implementing good counseling, mainly because of the initial reluctance of physicians to authorize postabortion counseling and family planning services.

None of the three hospitals previously had a specific program for postabortion care. Women with postabortion complications were attended as emergencies and discharged from the hospital as soon as possible with-

out receiving postabortion counseling. In addition, before the initiation of the project, women were frequently mistreated because physicians and most other health providers considered them to be criminals whom they should punish for having initiated abortion. The situation was worse in Sucre where, due to the legal situation, physicians acted more as prosecutors than as physicians.

For all these reasons, women with postabortion complications tried to avoid attending these hospitals. When they finally consulted, it was usually with severe complications, after long periods of suffering at home. The situation was somewhat better in the hospital in Santa Cruz, where some physicians had been trained in the technique of manual vacuum aspiration (MVA) and some actions aimed at improving the quality of care had been implemented previously.

Training and Monitoring

Physicians and counselors at the three participating hospitals attended a training course on elements of postabortion care, including contraceptive technology. The course emphasized the importance of appropriate counseling during the postabortion period, related both to contraception and to other health issues, such as resumption of sexual activity and infection prevention. The main objective of the training was to change the attitude of health providers, emphasizing the need to treat women as human beings in need of health care rather than as criminals. Training also emphasized that the staff should use all opportunities available during the women's stay at the hospital to provide information and counseling on postabortion care. Particular emphasis was given to avoiding another abortion.

The initial assessment of conditions at the three hospitals showed that physicians and other personnel involved in the treatment of abortion complications were technically well prepared and did not need training on technical issues.

At each of the hospitals one of the trainees acted as coordinator of the activities, trained the rest of the personnel, and supervised them in order to maintain high-quality services. In addition, the general coordinator of the project maintained continuous contact with the hospitals and visited them at several times after training. Monitoring and supervision visits showed that the quality of care, specifically counseling, improved significantly after training. These visits were useful in reinforcing the training and providing opportunities to retrain some health workers who still were not providing considerate treatment to women.

Improvement of Facilities and Equipment

Two rooms, one to perform curettage and another for individual counseling, were equipped and placed in service in each of the three hospitals. This allowed the hospitals to give priority and privacy to women presenting with postabortion complications. It also served to define a patient flow for these cases that was independent of and not interrupted by the other activities of the hospitals.

Clinical Activities and Data Processing

After the training course, the participating hospitals implemented a counseling program that included activities at admission, in the surgical room, and after curettage. At each point, women were offered the opportunity to decide to use contraception and to choose a method. Those who did not reach a decision had an additional opportunity during the postabortion follow-up visit scheduled one month after discharge from the hospital. All data were registered in a logbook and also in the clinical records of the hospitals.

After discharge, the women received a card with instructions and an appointment for the postabortion follow-up visit. After this visit, women were then scheduled for a six-month visit.

The project evaluation consisted of a pre- and postintervention assessment of the quality of postabortion services and the level of contraceptive acceptance over the duration of the study. Qualitative analysis was performed through structured questionnaires and in-depth interviews with women and health providers. Quantitative analysis was based on service statistics.

Results

Evaluation of Training and Quality of Services

Evaluation of the pre- and posttraining questionnaires showed an important improvement in the level of providers' knowledge of postabortion care, including contraception. In addition, monitoring visits showed that providers changed the way they treated women with postabortion complications. They became more considerate and compassionate, treating women as patients in need of assistance rather than as criminals who should be punished for their actions. Counseling was implemented and offered over the course of women's hospital stays.

Interviews with women in the three hospitals showed that a great majority mentioned that they had been well treated and emphasized the supportive attitudes of the nurses and auxiliaries. Most women stated that the counseling they had received had been very appropriate and useful. Several women mentioned spontaneously that the quality of the counseling was perhaps the most important reason they had evaluated the attention they received as good.

The changes in provider attitudes and improvement of quality of services became apparent in Santa Cruz soon after training. In Sucre, it took longer but changes were also very positive. In La Paz, however, improvements in quality, especially in counseling, were very slow and did not reach the same level as at the other hospitals.

Quantitative Results

Table 4.1 shows that the monthly average number of women coming to the three hospitals for postabortion complications remained fairly stable during the study period, maintaining levels comparable with the prestudy period. With the exception of the hospital in Sucre, a slight increase was observed in 1997. During the study period, all three participating hospitals attended a population very similar to the one attended during the five years before project initiation. Therefore the changes in the number or characteristics of women coming to the hospitals for treatment of abortion complications may be due to the intervention.

TABLE 4.1
Monthly average number of women with postabortion complications

Hospital	Before training	After training		
	Jul–Dec 1995	Jan–Jun 1996	Jul–Dec 1996	Jan–Jun 1997
La Paz	35	36	38	47
Santa Cruz	136	138	135	146
Sucre	38	32	33	33

TABLE 4.2
Percent distribution of women with postabortion complications, by age

Age (years)	La Paz		Santa Cruz		Sucre	
	1996	1997	1996	1997	1996	1997
≤19	15.9	15.6	15.5	30.1	11.9	29.6
20–34	65.8	63.9	73.5	57.0	72.4	63.6
≥35	18.4	20.6	11.1	12.9	15.8	6.8
N	441	379	1,635	1,300	387	294

The rate of moderate to severe complications (e.g., severe anemia, infection, and uterine perforation) in women admitted to the hospitals varied from 3.4 percent to 8.4 percent in different periods (data not shown). The rate of complications was somewhat higher in La Paz, due to higher rates of infection. Four women, two in Santa Cruz and one in each of the other hospitals, died as a consequence of their abortions. The four cases arrived at the hospital in very bad condition, after a long period of illness at home or in another health facility.

Table 4.2 shows the age distribution of women over the two years of the project. In Santa Cruz and Sucre, the percentage of adolescents with postabortion complications sharply increased in the second year. In 1997 roughly 30 percent of all women in both hospitals were less than 20 years old. In La Paz, the proportion of women less than 20 years old remained fairly stable during the study period.

Other characteristics of women coming to the three hospitals remained the same during the study period and were very similar to the ones observed in the prestudy period. Most women were poor, and between 60 and 70 percent were married or in a consensual union (data not shown).

The history of previous abortions among women in the three hospitals is shown in Table 4.3. The percentage of women who had no previ-

TABLE 4.3
Percent distribution of women with postabortion complications, by number of previous abortions

Previous abortions	La Paz		Santa Cruz		Sucre	
	1996	1997	1996	1997	1996	1997
None	51.3	52.3	65.9	54.3	73.7	73.8
One	30.6	31.9	22.2	26.2	17.8	18.0
Two or more	18.1	15.8	11.9	19.5	8.5	8.2
N	441	379	1,635	1,300	387	294

TABLE 4.4
Percentage of women receiving contraceptive counseling

Hospital	Before training	After training		
	Jul–Dec 1995	Jan–Jun 1996	Jul–Dec 1996	Jan–Jun 1997
La Paz	2.8	77.3	74.7	84.6
Santa Cruz	12.2	90.1	100.0	100.0
Sucre	3.6	73.2	92.4	97.0

ous abortions was higher in Sucre, while the percentage of women who had two or more abortions was lower. The proportion of women with a history of previous abortions remained fairly stable during the study period in La Paz and Sucre. In Santa Cruz, the proportion of women with two or more abortions was higher in 1997.

Contraceptive counseling was almost nonexistent in two of the three hospitals before the study. Nevertheless, interviews with women during the six months before the study showed that some counseling activities had been developed, mainly in Santa Cruz. Table 4.4 shows that counseling sharply increased after training of personnel. The increase was very rapid in Santa Cruz, where all women received counseling on contraception starting with the second half of 1996. Sucre saw a substantial increase in counseling as well, reaching almost 100 percent.

In La Paz the percentage was somewhat lower because some physicians refused to participate and influenced personnel during the periods they were in charge of the emergency room. Although the general coordinator of the study made several monitoring visits to this hospital, by July 1997 some physicians still remained reluctant to participate.

TABLE 4.5
Percentage of women accepting contraception following treatment for postabortion complications, by method

Hospital and method	Before training	After training		
	Jul–Dec 1995	Jan–Jun 1996	Jul–Dec 1996	Jan–Jun 1997
La Paz				
IUD	2.9	25.0	13.2	25.5
Hormonal	5.7	5.6	10.5	10.6
Other	5.7	30.6	28.9	27.7
None	85.7	38.9	47.4	36.2
Santa Cruz				
IUD	2.9	31.2	41.5	36.3
Hormonal	4.4	37.7	39.3	39.0
Other	2.9	4.3	7.4	12.3
None	89.7	26.8	11.9	12.3
Sucre				
IUD	0.0	12.5	27.3	27.3
Hormonal	2.6	6.3	9.1	18.2
Other	10.5	28.1	27.3	36.4
None	86.8	53.1	36.4	18.2

All women who received counseling declared that counselors were very friendly, gave complete information about methods, and left the decision on method choice up to the woman. In addition, counselors also gave good and complete information on when and where to return for postabortion follow-up.

Table 4.5 shows total contraceptive acceptance. As expected, contraceptive acceptance in the first period (before training of personnel) was low, between 10 and 15 percent. Women who accepted contraception in this period were mostly those who initiated a follow-up visit and requested a contraceptive method.

Contraceptive acceptance in the three hospitals increased soon after training and the implementation of the counseling program. In La Paz, contraceptive acceptance in the first six-month period after training was 61.2 percent. Acceptance decreased to 52.6 percent in the next period and then increased to 63.8 percent in the last period. The acceptance of IUDs followed the same pattern, with a sharp initial increase, a decrease in the next period, and a recovery in the third period.

In Sucre the process was slower; however, a steady increase was observed during the period evaluated. At the end of the study period total acceptance reached a higher level than it did in La Paz.

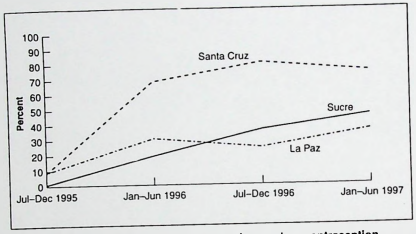

FIGURE 4.1 Percentage of women accepting modern contraception

Contraceptive acceptance in Santa Cruz was the highest, 73.2 percent in the first six-month period after training and 87.6 percent in the last period evaluated. In the last period observed, acceptance of hormonal methods stood at 39.0 percent and IUDs at 36.3 percent. It is also worth highlighting that in La Paz and Sucre a substantial increase was observed in the acceptance of other methods such as condoms (condom data included as part of other methods).

Figure 4.1 illustrates the rise in acceptance of modern contraception (IUDs and hormonal methods) in the three hospitals during the periods evaluated. Santa Cruz exhibited the highest rates and the steepest increase after training.

Sucre had a slower takeoff but showed a steady increase, attaining moderately high rates of acceptance. In third place, La Paz had a fairly quick response, but the acceptance rate presented great variability over time due to several changes in the composition of the staff during the project. Surprisingly, hormonal methods had high acceptance, mainly in Santa Cruz. The services at all three hospitals had a reputation of being IUD clinics, and it was expected that this method would be favored by providers. However, the increase in acceptance of pills and injectables clearly demonstrates that the concept of free informed choice truly was incorporated by counselors and physicians.

TABLE 4.6
Percentage of women attending postabortion follow-up visit

	Before training	After training		
	Jul–Dec 1995	Jan–Jun 1996	Jul–Dec 1996	Jan–Jun 1997
La Paz	2.0	25.1	29.5	48.8
Santa Cruz	3.6	17.1	29.8	20.8
Sucre	2.3	14.0	22.2	28.4

All women, whether or not they accepted a contraceptive method, were scheduled for a follow-up visit approximately one month after discharge. Before the initiation of the project this was not standard procedure, which explains why the percentage of women attending a follow-up visit in the pretraining period was very low in the three hospitals (Table 4.6).

After training, the percentage increased in the three hospitals, with La Paz showing the highest return rates, reaching 48.8 percent during the first half of 1997. Sucre presented a lower but steady increase, reaching 28.4 percent in the same period. In Santa Cruz the rate also increased but was variable. During the first half of 1997 the percentage was lower than it was in the second half of 1996.

Discussion

It is widely accepted that successful family planning programs that increase contraceptive prevalence are effective in preventing unwanted pregnancies and, consequently, induced abortions. The impressive increase of contraceptive prevalence observed worldwide in the last three decades has had an important effect on maternal mortality, but there is still room for improvement. This was clearly demonstrated in Chile where the introduction of family planning led to a significant drop in hospitalizations due to abortions and in maternal mortality attributed to abortion (Barzelatto 1986; Viel 1986). Conversely, in countries where access to contraception is difficult and antiabortion policies are actively implemented, maternal mortality due to abortion increased (Hord et al. 1991).

It has also been demonstrated that targeting family planning to groups at high risk for unwanted pregnancy can decrease maternal mortality (Ickis 1987; Ross, Rich, and Molzan 1989). Unfortunately, although

it is widely recognized that women in the postabortion period constitute a high-risk group, only a few programs have focused on them.

There are many reasons for the lack of focus on postabortion counseling and contraception acceptance. Hospitals and health providers spend minimal time on counseling, and women often do not return for follow-up. In addition, postabortion care is usually given in wards where family planning is not routinely offered, and the approach to care is usually strictly curative. From the clinical point of view, sometimes a woman's health is precarious after an abortion, and she is not in a situation conducive to receiving counseling about contraception; usually her only concern is recovering and going back home. From the psychosocial and cultural perspective, the main difficulties are lack of adequate support in the postabortion period and little knowledge about contraceptive use after abortion. Clinics are also not prepared to talk about sexuality, and there is commonly a lack of knowledge about the return of fertility after an abortion.

For these and other reasons, postabortion family planning is a service almost nonexistent in the LAC region, although in the 1970s some authors showed that it was feasible to provide postabortion family planning and that this service was widely accepted by women (Goldsmith et al. 1972; Hardy and Hend 1975). In 1990 Profamilia and the Instituto Peruano del Seguro Social published the results of a program of postabortion contraception, coordinated by the Population Council, that showed training and motivation of personnel was critical for the success of the program (Profamilia and Instituto Peruano del Seguro Social 1990).

These successful experiences with postabortion contraception, showing that modern contraceptive methods are perfectly suitable for use during this period, suggest that the lack of effective implementation of these programs derives mostly from social and political rather than technical reasons. The main problems stem from three overarching factors that have contributed to isolating abortion from family planning and other reproductive health services.

First, the legal and administrative constraints to abortion force many women to seek care in clandestine environments, where family planning is usually not available. In addition, women's low socioeconomic status

and the taboos regarding abortion combine to make the health needs of women who have abortions a very low priority. Finally, the United States government's Mexico City Policy (promulgated at the 1984 International Conference on Population and rescinded in 1993) prohibited foreign nongovernmental organizations that receive US funds from engaging in most abortion-related activities.

Improving access to services for women with postabortion complications is the first step to improving the quality of services. Services offering compassionate, humanized, and technically adequate care will attract women who will seek care before serious complications arise. It is also clear that quality of services, including better interpersonal communication, is the main factor that will create a favorable environment for effective counseling and acceptance of contraceptive methods.

The results of this study show that it is feasible to increase quality of services with very modest material input and an emphasis on training, oriented mainly to obtaining a change in providers' attitudes. The results also show that hospitals where staff were highly motivated and remained in their positions after training showed more improvement than those where personnel left the hospital soon after they were trained. In addition, the commitment and support of authorities, program monitoring, and active supervision are crucial in order to obtain and maintain improvements in quality.

In Santa Cruz, where almost all the personnel trained remained in their jobs through the entire study period, eventually 100 percent of women were discharged from the hospital having received counseling on contraception. Conversely in La Paz, where most of the trained professionals were replaced at various times after training, the percentage of women receiving counseling increased less than in Santa Cruz and varied over time.

The importance of motivating personnel was also clearly illustrated in Santa Cruz. At the initiation of the study, counseling activities were performed by the registered nurse trained for that activity. She was a highly qualified professional, but she was not motivated to implement the project because she had several other responsibilities and counseling was an addi-

tional burden. As a consequence, counseling rates were very low in the first two months. The supervisor detected the situation and replaced her with a nurse auxiliary, who was trained by the nurse and was highly motivated. The results were impressive and immediate: Counseling rates increased to 100 percent in a short period. This person was such a good counselor and so popular in the hospital that women in the postpartum period also began to attend postabortion counseling sessions.

From the point of view of users, counseling is the key issue in quality of services. Users' evaluation of quality showed a clear positive relationship with the quality of counseling and with providers' attitudes. Warm and compassionate providers were almost always evaluated as excellent providers.

Contraceptive acceptance increased dramatically in the three hospitals soon after initiation of the project. In the first six-month period after training, contraceptive acceptance reached 73.2 percent in Santa Cruz, 61.2 percent in La Paz, and 46.9 percent in Sucre. With the exception of La Paz, where various trained professionals were replaced, contraceptive acceptance continued increasing, reaching 87.6 percent in Santa Cruz and 81.9 percent in Sucre. It is clear that contraceptive acceptance depends more on the quality of services, particularly counseling, than on the characteristics of the population, as demonstrated by the negative impact on acceptance of the replacement of trained personnel observed in La Paz.

The differences between the three hospitals were due more to the influence of external factors. In La Paz, the turnover of hospital authorities, in addition to high staff turnover, led to changes in the policy of service delivery. One of the directors of the hospital, who was in charge for only a short period of time, attempted to suspend the program and removed the trained staff.

In Sucre, the difficulties were mainly with members of the Judiciary, who insisted that physicians denounce women inducing abortion. It was not an easy process, but physicians gradually stopped denouncing women and adopted a caring attitude, which was stimulated by training and continuous supervision. This translated to a slow but steady increase in contraceptive acceptance.

Those who oppose the promotion of postabortion contraception argue that in this period women are extremely vulnerable and will accept whatever is offered, without making an informed choice. Coercion to accept a method may occur, as has been demonstrated in selected case studies. However, our data show that, when training is adequate and counseling is properly given, women can indeed freely choose the method that best fits their current needs, or choose not to use contraception at all.

This is evident in Santa Cruz, where IUDs are traditionally the most prevalent method, in part because it is the method strongly promoted by the hospital. We expected that IUDs would be by far the method most widely accepted. To our surprise, in the last period evaluated, hormonal methods had a higher acceptance than IUDs. Condoms also had a significant acceptance (condom data included as part of other methods).

It has also been argued that there is no need to offer contraception immediately after abortion. Rather, women can come to a follow-up visit one month later, at which point they can arrive at a decision on method choice and initiate its use. This can be risky for women for two reasons, however. First, it has been demonstrated that ovulation frequently occurs during the first four weeks after an abortion, and most women resume sexual activities before the first menses. This places them at risk of becoming pregnant. Offering contraception one month after abortion is effective only if women do not resume sexual activities for 30 days. Also, despite improvement in the quality of counseling, the percentage of women who returned for a scheduled follow-up visit was not very high in our study. In the hospital in La Paz, which had the highest return rate, it was only in the third period evaluated that the return rate came close to 30 percent. In the other two hospitals the return rate remained under 30 percent throughout the study period, confirming the fact that it is very difficult to reach high levels of return. It is still more difficult to maintain high levels of return in routine work, when the stimulus of the research project has ended. Moreover, a great proportion of women live far from the hospital

and do not have access to services designed to deliver IUDs and other clinic-based methods to them. While women are provided information on what they should do and where they should go if they experience complications, the health facilities located closer to their homes often are not able to provide contraceptive methods; therefore, it is important to provide contraceptive services while these women are in the hospital.

In summary, our findings indicate that it is feasible to implement a postabortion program that significantly improves the quality of care, including contraception acceptance, in the postabortion period with scarce material inputs, even in resource-constrained facilities.

The key elements for obtaining these results are:

- training providers on technical issues but, more importantly, on how to give considerate and compassionate care;
- improving providers' communications skills;
- encouraging continuous support from the administrative and technical authorities; and
- providing refresher training and continuous active supervision.

The best indicator of the success of this project has been the request from the MOH and the directors of the women's health division, who are not those who authorized and initiated the project, to maintain the activities in the hospitals already involved and to replicate the project in other regions of the country.

The current challenge for the three hospitals is to maintain and improve the quality of services they now provide after the resources of the project have been exhausted and the service activities become part of the normal routine.

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Insertional pain and other IUD insertion-related rare events for breastfeeding and non-breastfeeding women – a decade's experience in developing countries

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Abstract

The possible effect of breastfeeding on intrauterine device (IUD) insertion events was investigated. Analysis included a total of 6493 women who enrolled in multicenter IUD clinical trials over a ten-year period. Findings indicate that breastfeeding exerts a protective effect on the incidence of moderate to severe insertional pain and reduces the need for cervical dilatation to facilitate insertion. The pain protection effect was most evident in breastfeeding women who were still in lactational amenorrhea. Subjects with amenorrhea, both breastfeeding and non-breastfeeding, had a significantly lower incidence of pain at IUD insertion than the corresponding menstruating subjects. This effect may be related to a higher secretion of beta-endorphin in the breastfeeding and lactational amenorrheic subjects.

Introduction

Breastfeeding provides health benefits to infants. It is a natural, convenient and cost-effective contraceptive method; and by lengthening the birth interval, it also provides health benefits to mothers [1]. The health benefits of breastfeeding are especially important in developing countries.

The duration of the contraceptive effect of breastfeeding is, however, variable. Accordingly, women who want an extended birth interval or no more children need to switch to another contraceptive method before ovulation resumes. The intrauterine device (IUD) is a good contraceptive choice for these women, particularly those who are not yet ready for a permanent and generally irreversible sterilization. The efficacy of IUDs is far superior to that of barrier methods and, unlike combination oral contraceptives (OCs), IUDs do not exert a systemic effect that adversely affects

lactation [2–4]. Equally important, studies have shown that breastfeeding during IUD use does not adversely affect the IUD's performance [5,6]. For women in developing countries, the fact that one insertion of an IUD can provide a considerably long-lasting contraceptive effect makes it a much more desirable contraceptive method than barriers or orals, which demand regular supply and compliance, and are generally more costly. In the most recent World Health Organization (WHO) report, the IUD was recommended as the best contraceptive method for lactating women [7].

Attention has recently been directed to the relationship between breastfeeding and IUD insertion-related problems. A frequently cited case–control study conducted on US data revealed a 10-times higher risk of IUD-associated uterine perforation for lactating women as opposed to non-lactating women [8]. Two recent case–control studies using an international data set, on the other hand, suggested a rather unexpected protective effect of breastfeeding on severe pain occurring at IUD insertion [9] and a reduction in the need for cervical dilatation to facilitate insertion [10]. Similar case–control analyses on this international data set did not delineate breastfeeding at IUD insertion as either a deleterious or beneficial factor for other IUD insertion-related events such as failed insertion [11], syncope and other vasovagal reactions [12], uterine perforation [13] and cervical laceration (Chi *et al.*, in preparation).

The relationship between breastfeeding and IUD insertion is programmatically important and needs clarification. Both breastfeeding and IUD use are prevalent in developing countries, and many breastfeeding women in these countries use IUDs. Women having characteristics leading to a smooth IUD insertion are an ideal group to encourage others to use this method, and, conversely, any distressing events experienced during insertion can directly affect the acceptability of a family planning program offering IUDs. The fall of the Singapore IUD Action Program following a rumor of a high incidence of uterine perforation is one unfortunate example [14]. With more than 80 million women worldwide using IUDs (60 million of them residing in China) [15], even rare IUD insertion-related events can be translated into a significant public health problem*.

Although the case–control analysis approach is generally the most useful method, and sometimes the only feasible one, for the delineation of risk factors for rare events, an important limitation is that complete elimination of bias cannot be assured [17]. Findings from this study approach usually need to be replicated by other case–control or prospective studies before they can be accepted. We believe the international IUD database developed by Family Health International (FHI) during the last ten years is sufficiently large to examine these rare events 'prospectively' and to determine if the results thereof generally agree with the findings of case–control studies.

*According to Irving Sivin, if the risk of pregnancy (also a rare event) can be reduced from five to two per 100 at two years of IUD use in the People's Republic of China, it could mean a reduction of about 600 000 unwanted pregnancies each year [16].

Methods and materials

The IUD data used in this analysis were collected from international multi-center clinical trials coordinated by FHI between 1977 and 1986. All participating centers used identical case record forms and similar protocols.

Our study population was defined as women who were:

1. Parous and whose last pregnancy was a vaginally delivered term live birth,
2. Users of a common IUD type (i.e., Loops and variants, Copper T, Cu-7 and Multiload devices) during the interval period (> 42 days since last delivery), and
3. From centers where one of the above IUD types was inserted in at least 100 women during the study period, breastfeeding status at insertion was known for at least 75% of the acceptors, and at least 10% of these subjects were breastfeeding at IUD insertion.

Altogether 6493 women were included for study, 3450 of whom were not breastfeeding (NBF) and 3043 of whom were breastfeeding (BF, including partially breastfeeding, defined as breastfeeding with supplementary food) at the time of IUD insertion. Eighteen international centers were included, seven located in Asia, seven in Latin America and four in the Middle East.

In this analysis, the IUD types were pooled into three categories according to configuration, namely: Loops, T-shaped devices (including the Cu-7) and Multiloads, which are horseshoe-shaped devices. Our study population comprised the following number of women, grouped by type of IUD inserted:

IUD type	*Number of users*	
Loops		
LLD	904	
Photo-reduced*	316	
Tapered*	237	
LLC	134	
LLD with copper*	130	
Subtotal		1721
T-shaped devices		
TCu200	1616	
TCu380A	1362	
TCu380Ag	363	
Cu-7	106	
Subtotal		3447
Multiloads		
250	945	
375	380	
Subtotal		1325

* These experimental IUD types were developed by FHI and used for a short time only. They were of the same shape as the Lippes Loop and were included for study to increase the sample size.

IUD insertion-related events (the outcome variables) examined in this analysis included: moderate/severe insertional pain, cervical dilatation required to facilitate insertion, cervical laceration, syncope, insertion failure and uterine perforation. Analysis focuses upon insertional pain because of its relatively high incidence, its close relationship with other insertion events [18], as well as its strong negative association with breastfeeding as revealed from our previous case–control study [9].

Patient characteristics and characteristics of the situation surrounding IUD insertion were first examined between the NBF and BF groups. Incidences of IUD insertion-related events were then compared between groups by univariate analysis, stratification and logistic regression [19]. Degree of association was computed using relative risks (RRs) or odds ratios (ORs) derived from logistic regression. A relative risk or odds ratio with 95% confidence limits (CLs, two-tailed) excluding unity was considered statistically significant. The NBF women were used as the reference group.

Results

1. Characteristics of BF and NBF women (Table 1)

Compared to the NBF women, the BF women were, in general, two years younger; less likely to have used contraceptives, especially oral contraceptives, in the month prior to this IUD insertion; and more likely to be in the postpartum/lactational amenorrhea period. The BF women, as would be expected, had a much shorter open interval (months between ending of last pregnancy and IUD insertion). Also, the BF women were somewhat more likely to have a retroverted uterus. Other variables such as number of live births, educational level, proportion living in urban areas, proportion wanting more children, type of IUD inserted and type of inserting personnel (obstetrician/gynecologist *vs* other types of insertors) were generally similarly distributed between the two groups. Among women who had resumed menses, the timing of IUD insertion in relation to menstrual cycle was also similar.

2. Incidences of insertion-related events, univariate analysis (Table 2)

The BF women were about two times less likely to suffer any degree of insertional pain, and three times less likely to suffer severe pain as compared to the NBF women. Per 100 women, 3.5 in the BF group and 7.5 in the NBF group experienced moderate to severe insertional pain. The incidence of severe pain was 0.6 and 2.0 per 100 women in the respective groups. Similarly, cervical dilatation was also less likely to have been necessary for BF women than for NBF women. The respective incidences per 100 women were 0.4 and 1.9. Using NBF as the reference group, the relative risk (RR) for moderate/severe pain for BF women was 0.47 (for severe pain only, RR = 0.30) and that for cervical dilatation was 0.21. All of the 95% CLs for these relative risks excluded unity.

Table 1 Selected characteristics of the non-breastfeeding and breastfeeding groups

	Non-breastfeeding women (n = 3450)	*Breastfeeding women (n = 3043)*
A. *Patient characteristics*		
Mean age in years (SD)	27.9 (5.7)	25.5 (5.0)
Mean live births (SD)	2.5 (1.6)	2.4 (1.6)
Mean education in years (SD)	6.8 (7.3)	6.6 (7.0)
% Living in urban area	71.9	70.9
Contraceptive method used in last month (%)		
IUD*	13.1	8.2
Orals	42.5	17.2
Injectables	5.3	1.7
Others	10.2	7.8
None	29.0	64.9
Uterine position (%)		
Anteverted	61.0	56.8
Retroverted	11.7	27.3
Midpositioned	14.7	10.4
Not determined	2.5	5.5
B. *IUD insertion-related characteristics*		
% Timing of insertion in relation to menstrual cycle (in days)		
1–5	65.8 (71.3**)	42.8 (68.3)
6–17	21.8 (23.6)	17.0 (27.1)
18+	4.8 (5.2)	2.9 (4.6)
Lactational/postpartum amenorrhea	6.3	36.2
Unspecified	1.3	1.1
Open interval (%)		
<6 months	20.3	61.3
6–11.9 months	15.9	22.7
12–23.9 months	19.1	12.8
24+ months	44.7	3.2
Type of insertor		
Obstetrician/Gynecologist	67.9	73.3
Other physician	13.2	11.0
Nurse/midwife	17.2	13.0
Others	1.7	2.6
Type of IUD inserted*** (%)		
Loops	28.5	24.3
T-shaped devices	52.6	53.6
Multiloads	18.9	22.1

* The current insertion was thus a reinsertion for these subjects. The exact length of the interval between termination of last IUD use and the current insertion is unknown except that the interval should not be longer than one month

** Percentage distribution in parentheses is limited to women who resumed menses at insertion

*** Loops include Loops C and D, Loop D with copper, the Tapered Loop and the Photo-reduced Loop. Copper devices include Cu-7, TCu200, TCu 380A and TCu380Ag. Multiloads include Multiload Cu250 and 375

Table 2 Crude incidences* of various IUD insertion-related rare events by breastfeeding status at insertion

Events	Non-breastfeeding women** (n = 3450) No.	%	Breastfeeding women (n = 3043) No.	%	Relative risk*** (95% CLs)
Pelvic pain					
Moderate or severe	259	7.51	107	3.52	0.47 (0.37–0.59)
Severe only	69	2.00	18	0.59	0.30 (0.17–0.51)
Dilatation required	65	1.93	12	0.40	0.21 (0.11–0.39)
Cervical laceration	22	0.64	14	0.46	0.72 (0.35–1.47)
Syncope	12	0.35	13	0.43	1.23 (0.53–2.86)
Insertion failure	3	0.09	3	0.10	1.13 (0.18–6.99)
Immediate uterine perforation	2	0.06	5	0.16	2.83 (0.49–21.04)
Any events except immediate uterine perforation***	339	9.83	139	4.57	0.46 (0.38–0.56)

* Incidences were based on the number of women for whom the event status was known
** Non-breastfeeding women were used as the reference group
*** Multiple events may be reported for the same woman

Incidences of insertion failure, syncope and cervical laceration were generally similar between the two groups of women. The incidence of immediate uterine perforations was very low in both groups, but was slightly higher in the BF women than in the NBF women. The difference, however, was not statistically significant.

Considering all women with one or more IUD insertion-related events except uterine perforation, the BF women were half as likely as the NBF women to have an insertion event (RR = 0.46, 95% CLs = 0.38–0.56).

3. *Stratification*

The observed greater risk for NBF women of incurring insertional pain and cervical dilatation could have been biased because of differences between BF and NBF women in patient characteristics, in the situational factors surrounding IUD insertion, or in the type of IUD used. We therefore conducted an analysis of the study events stratified by these factors.

Table 3 Incidence of moderate/severe insertional pain by patient characteristics, IUD insertion situational factors and breastfeeding status at insertion

	Non-breastfeeding women* (n = 3450) Total women	No. with pain	%**	Breastfeeding women (n = 3043) Total women	No. with pain	%**	Relative risks* (95% CLs)
Age							
<25	1139	97	8.5	1547	70	4.5	0.53 (0.39–0.72)
25–29	1149	88	7.7	911	18	2.0	0.26 (0.15–0.43)
30+	1158	74	6.4	585	19	3.2	0.51 (0.30–0.85)
Parity							
1–2	2097	156	7.4	1978	69	3.5	0.47 (0.35–0.62)
3+	1351	103	7.6	1065	38	3.6	0.47 (0.32–0.68)
Education							
0–3 years	1185	73	6.2	1112	46	4.1	0.67 (0.46–0.98)
4–9 years	1386	141	10.2	1220	54	4.4	0.44 (0.32–0.60)
10+ years	875	45	5.1	701	7	1.0	0.19 (0.08–0.44)
Wanting additional children							
No	1859	137	7.4	1526	57	3.7	0.51 (0.37–0.69)
Yes	1587	122	7.7	1515	50	3.3	0.43 (0.31–0.60)
Contraception used in month prior to insertion							
IUD	450	19	4.2	249	7	2.8	0.66 (0.26–1.64)
OC	1466	139	9.5	530	19	3.6	0.38 (0.23–0.61)
Others (including none)	1531	101	6.6	2263	81	3.6	0.54 (0.40–0.73)
Uterine position							
Anteverted	2105	179	8.5	1729	78	4.5	0.53 (0.40–0.69)
Retroverted	748	36	4.8	832	14	1.7	0.35 (0.18–0.66)
Midpositioned	509	41	8.1	316	14	4.4	0.55 (0.29–1.02)
Timing of insertion in relation to menstrual cycle							
<5 days	2269	218	9.6	1303	68	5.2	0.54 (0.41–0.71)
6–17 days	751	24	3.2	518	11	2.1	0.66 (0.31–1.40)
18+ days	164	10	6.1	87	7	8.0	1.32 (0.46–3.64)
Amenorrheic	219	3	1.4	1103	19	1.7	1.26 (0.36–5.32)
Open interval							
<6 months	700	43	6.1	1865	48	2.6	0.42 (0.27–0.64)
6–12 months	550	38	6.9	690	30	4.3	0.63 (0.38–1.03)
13–24 months	659	50	7.6	388	24	6.2	0.82 (0.49–1.33)
25+ months	1539	128	8.3	98	5	5.1	0.61 (0.22–1.48)
IUD type at this insertion							
Loops	981	190	19.4	739	86	11.6	0.60 (0.47–0.78)
T-shaped	1814	66	3.6	1632	18	1.1	0.30 (0.17–0.52)
Multiloads	653	3	0.5	672	3	0.4	0.97 (0.16–5.99)
Insertor type							
OB/GYN	2341	54	2.3	2231	23	1.0	0.45 (0.27–0.74)
Others	1106	204	18.4	811	84	10.4	0.56 (0.44–0.72)

* Non-breastfeeding women were used as the reference group
** The percentages are based on the number of subjects with valid values. Due to some subjects with unknown values, the totals may not add up to 3450 for non-breastfeeding women and 3043 for breastfeeding women

a. Moderate/severe insertional pain (Table 3)

In most cases, no matter how the data were divided, the BF women were consistently associated with a lower incidence of moderate/severe pain than the NBF women. It is especially important that this was the case when stratification was performed by age, contraceptive method used in month prior to this IUD insertion, length of open interval, and uterine position, because these variables were (1) differently distributed between the two groups of women and (2) known to be simultaneously related to both the study variable (breastfeeding) and the outcome variable (the incidence of insertional pain). Most impressive is the finding illustrated by Figure 1, that in 12 of the 18* study centers, BF women consistently had a lower incidence of pain than NBF women. When the incidence of moderate/severe pain is stratified by breastfeeding status and menstrual status at insertion, however, the consistent pattern was noticeable only in those women who had resumed menses. For women resuming menses, the incidences of moderate/severe pain were respectively 4.51 for the BF and 7.91 for the NBF women (RR = 0.57, and 95% CLs = 0.44–0.73). Among those women who were still amenorrheic, there was no significant difference in insertional pain between those who were and those who were not breastfeeding. Amenorrheic women, both in the BF and in the NBF groups, had a lower incidence of insertional pain than the corresponding menstruating women. Most of the non-menstruating and non-breastfeeding women were still in the period of lactational amenorrhea.

b. Need for cervical dilatation (Table 4)

Consistent with our findings on insertional pain, IUD insertions requiring cervical dilatation were, in general, also found to be less frequent in BF than NBF women. This finding was unaffected by age, parity, educational level, whether the IUD was inserted for family-spacing or limiting purposes, previous contraceptive method used, type of inserting personnel, IUD type used, or length of open interval. Also, the incidence of cervical dilatation was lower in the BF than the NBF group, irrespective of whether the woman was still amenorrheic or had resumed menses at the time of insertion. Seven of the 18 centers** had a lower proportion of cervical dilatation for the BF women than for the NBF women (Figure 2).

*Among the six centers not exhibiting the consistent patterns (Figure 1), three did not report any cases of moderate/severe insertional pain in either group. One center reported identical incidences between the two groups. In another center, there were only 35 NBF women, none of whom reported pain. One of the 122 BF women in this center complained of pain. Only the last center had adequate numbers of NBF (n = 396) and BF (n = 369) women; one of the NBF women and three of the BF women reported pain.

**In another eight centers, there were no dilatations in either group. One center reported identical incidences in the two groups of women. Only in the remaining two centers was the incidence of cervical dilatation higher for BF than for NBF women (one center had <80 women in each group).

Table 4 Incidences of cervical dilatation performed to facilitate IUD insertion by patient characteristics, IUD insertion situational factors and breastfeeding status at insertion

	*Non-breastfeeding women** (n = 3450)			*Breastfeeding women* (n = 3043)			
	Total women	*No. with dilatation*	*%***	*Total women*	*No. with dilatation*	*%***	*Relative risk** (95% CLs)*
Age							
<25	1095	26	2.4	1518	3	0.2	0.08 (0.02–0.29)
25–29	1131	25	2.2	904	6	0.7	0.30 (0.11–0.76)
30+	1145	14	1.2	577	3	0.5	0.42 (0.10–1.56)
Parity							
1–2	2043	46	2.2	1944	6	0.3	0.14 (0.05–0.33)
3+	1330	19	1.4	1055	6	0.6	0.40 (0.14–1.05)
Education							
0–3 years	1122	7	0.6	1074	4	0.4	0.60 (0.15–2.35)
4–9 years	1377	22	1.6	1214	3	0.2	0.15 (0.04–0.54)
10+ years	872	36	4.1	701	5	0.7	0.17 (0.06–0.46)
Wanting additional children							
No	1833	31	1.7	1510	6	0.4	0.23 (0.09–0.59)
Yes	1538	34	2.2	1487	6	0.4	0.18 (0.07–0.45)
Contraception used in month prior to insertion							
IUD	447	12	2.7	246	1	0.4	0.15 (0.01–1.10)
OC	1428	28	2.0	515	1	0.2	0.10 (0.01–0.67)
Others (including none)	1497	25	1.7	2237	10	0.4	0.27 (0.12–0.58)
Uterine position							
Anteverted	2071	42	2.0	1708	8	0.5	0.23 (0.10–0.51)
Retroverted	733	12	1.6	828	3	0.4	0.22 (0.05–0.83)
Midposition	487	9	1.8	300	1	0.3	0.18 (0.01–1.36)
Timing of insertion in relation to menstrual cycle							
<5 days	2198	39	1.8	1263	8	0.6	0.36 (0.15–0.79)
6–17 days	747	17	2.3	515	3	0.6	0.26 (0.06–0.91)
18+ days	165	8	4.8	87	0	0.0	***
Amenorrheic	218	1	0.5	1102	1	0.1	0.20 (0.01–7.22)
Open interval							
<6 mos.	671	9	1.3	1847	6	0.3	0.24 (0.08–0.74)
6–12 mos.	534	8	1.5	674	5	0.7	0.50 (0.14–1.65)
12–23 mos.	646	14	2.2	380	1	0.3	0.12 (0.01–0.87)
24+	1522	34	2.2	96	0	0.0	***
IUD type at this insertion							
Loops	966	10	1.0	727	7	1.0	0.93 (0.32–2.63)
T-shaped	1755	33	1.9	1600	5	0.3	0.17 (0.06–0.41)
Multiloads	652	22	3.4	672	0	0.0	***
Insertor type							
OB/GYN	2274	51	2.2	2192	8	0.4	0.16 (0.07–0.35)
Others	1098	14	1.3	806	4	0.5	0.39 (0.11–1.26)

* Non-breastfeeding women were used as the reference group

** The percentages are based on the number of subjects with valid values. Due to some subjects with unknown values, the totals may not add up to 3450 for non-breastfeeding women and 3043 for breastfeeding women

*** The relative risk cannot be calculated

c. Other IUD insertion-related events (Table 5)

Incidences of other events were too low for stratified analysis. Stratification by IUD type showed a somewhat higher risk of immediate uterine perforation and a lower risk of syncope for BF as compared to NBF women, both for Loop users only. Neither of these differences was statistically significant.

4. Multivariate analysis, logistic regression (Table 6)

Stepwise logistic regression analysis was used to examine the independent effect of breastfeeding on the two events, moderate/severe insertional pain and need for cervical dilatation. Breastfeeding status (yes *vs* no) was forced into each model, and then other covariates were allowed to enter. The variables with the opportunity to enter the model were: age (< 25 *vs* ⩾ 25 years), IUD use, OC use, menstrual status (amenorrhea *vs* resumed menses), open interval (< 12 months *vs* ⩾ 12 months), and Center (Center O *vs* other centers for pain, Center A *vs* other centers for dilatation). For models of insertional pain and need for dilatation, center was the first covariate to enter the model. Two other covariates were important in modelling pain: open interval and OC use; two other covariates also entered the dilatation model: menstrual status and age.

When center was the only additional covariate in the insertional pain model, the adjusted odds ratio for breastfeeding was 0.55 (95% CLs = 0.43–0.71). After all three of the additional important covariates had entered this model, the effect of breastfeeding was reduced (odds ratio = 0.76, 95% CLs = 0.57–1.02). For the dilatation model, the adjusted odds ratio for breastfeeding was 0.18 (95% CLs = 0.09–0.34) when center was the only additional covariate, and was 0.51 (95% CLs = 0.25–1.01) when all three of the additional important covariates were in the model.

5. The effect of degree of breastfeeding (Table 7)

We further divided the BF women into full and partial breastfeeding to see if there was a 'dose-response' in the breastfeeding effect on pain and dilatation. Table 7 shows that both breastfeeding groups had lower incidences for both events than the non-breastfeeding group, but full breastfeeding offered no extra protective effect as compared to partial breastfeeding. This is a crude breakdown of breastfeeding since we have no duration or frequency information.

Table 5 Incidences of syncope and immediate uterine perforation at IUD insertion by breastfeeding status and IUD type

Device type	*Non-breastfeeding women* (n = 3450)* Total women	No. with event	%	*Breastfeeding women* (n = 3043)* Total women	No. with event	%	*p-value by Fisher's Exact Test*
A. *Event of syncope*							
Loops	981	12	1.22	738	7	0.95	0.618
T-shaped devices	1815	0	0.00	1632	2	0.12	0.224
Multiloads	653	0	0.00	672	4	0.59	0.124
B. *Event of immediate uterine perforation*							
Loops	962	0	0.00	739	3	0.40	0.079
T-shaped devices	1815	1	0.06	1632	1	0.06	1.000
Multiloads	653	1	0.15	672	1	0.15	1.000

*Due to some unknown values, the totals may not add up to 3450 for non-breastfeeding women and 3043 for breastfeeding women

Table 6 Adjusted odds ratio and 95% confidence limits (CLs) for the effect of breastfeeding at IUD insertion on (A) moderate/severe insertional pain and (B) need for cervical dilatation

	Odds ratio for breastfeeding women*	*95% CLs*	*p value*
A. *Moderate/severe insertional pain*			
Controlling for			
a. Center (O *vs* others)	0.55	0.43–0.71	< 0.001
b. Center and two other confounding variables: Open interval (< 12 months *vs* ⩾ 12 months) and OC use in month prior to insertion	0.76	0.57–1.02	0.059
B. *Cervical dilatation*			
Controlling for			
a. Center (A *vs* others)	0.18	0.09–0.34	< 0.001
b. Center and two other confounding variables: Menstrual status (amenorrhea *vs* resumed menses) and age (< 25 *vs* ⩾ 25)	0.51	0.25–1.01	0.043

*Non-breastfeeding women were used as the reference group. The odds ratios were derived from a stepwise logistic regression model with the insertion event (pain or dilatation) as the dependent variable and with breastfeeding status forced to enter the model

Table 7 Incidence of (A) moderate/severe insertional pain and (B) cervical dilatation performed to facilitate IUD insertion by extent of breastfeeding at insertion

	*Total women**	*No. with event*	*%*	*Relative risk (95% CLs)*
A. *Event of moderate/severe insertional pain*				
Non-breastfeeding	3448	259	7.51	1.00
Partial breastfeeding	1362	29	2.13	0.30(0.20–0.44)
Full breastfeeding	1681	78	4.64	0.63(0.49–0.82)
B. *Event of cervical dilatation*				
Non-breastfeeding	3373	65	1.93	1.00
Partial breastfeeding	1328	4	0.30	0.16(0.05–0.45)
Full breastfeeding	1671	8	0.48	0.25(0.11–0.54)

*Due to some unknown values, the totals may not add up to 3450 for non-breastfeeding women and 3043 for breastfeeding women

Discussion

Our findings from this 'prospective' study generally agree with findings from previous case–control studies. Breastfeeding exerts a protective effect on the incidence of moderate/severe insertional pain, and also a beneficial effect of reducing the need for cervical dilatation to facilitate IUD insertion. An association between breastfeeding and other IUD insertion-related rare events, namely insertion failure, syncope and cervical laceration, was, however, not detected. Our analysis does suggest that uterine perforation at IUD insertion may be more likely to occur in a BF woman receiving a Loop device.

The study designs of the case–control approach and the prospective approach have individual strengths and weaknesses. They are, however, methodologically complementary and when they produce similar findings, the validity of the findings is greatly enhanced. Two additional aspects strengthen the validity of our findings: (1) the outcome variables under study are those that occurred during and were recorded immediately after IUD insertion, so the reporting of these events is likely to be complete and not subject to recall bias (for the case–control approach) or subject to bias due to loss of follow-up (for the prospective approach) and (2) the potential beneficial effect of breastfeeding on reduction of insertional pain and the need for cervical dilatation had not been suspected previously. Therefore, bias due to selective reporting by the women or prejudice of the insertors is not likely. That similar results were derived when controlling for potentially confounding variables, either one at a time through stratification or simultaneously through multivariate analysis, further strengthened the validity of our findings.

These findings are also supported by results from an experimental study which actually measured the IUD insertion force in 103 parous women [20]. The study found

that significantly less insertion force is needed to insert an IUD in breastfeeding, recently delivered women (1.75 newtons) compared to non-breastfeeding, long delivery interval women (2.8 newtons). In that study, breastfeeding and non-breastfeeding women were matched by IUD type and parity. Due to few non-breastfeeding women with recently delivered infants, the independent effect of breastfeeding controlling for the length of delivery interval (i.e., open interval) could not be evaluated.

One limitation of our data set is the lack of information regarding the length of time women had breastfed in the past (for NBF women) or had been breastfeeding (for BF women) at the time the IUD was inserted. It is possible that, in our study, an NBF woman might have breastfed for quite some time but stopped immediately before this IUD insertion. While it is also possible that some women might have just started breastfeeding before this IUD insertion and were duly categorized as breastfeeding cases, it is thought highly unlikely. If the effect of breastfeeding on IUD insertion takes some time to appear (and to disappear), this 'misclassification' effect could produce bias; this bias would, however, underestimate rather than overestimate the differences between the BF and NBF groups. Frequency and intensity of breastfeeding could only be crudely measured by whether the breastfeeding was full or partial.

We are also cognizant of the intercenter variation and center clustering pattern in the reporting of insertional pain and cervical dilatation. The results from our analyses were probably heavily influenced by one center's data (Center O for pain and Center A for dilatation) and may lack representativeness. However, the most powerful evidence supporting the asserted breastfeeding and insertional pain association was the lower incidence of insertional pain for BF women across virtually all 18 study centers (Figure 1). To some extent, this was also true for the finding on cervical dilatation (Figure 2). No bias could produce such a consistent finding since most service providers and IUD receivers would not have expected this effect. The beneficial effect of breastfeeding on both events remained when the center effect was adjusted in the multivariate analysis. Further adjusting for other confounders, namely previous OC use and open interval for insertional pain, and menstrual status and age for dilatation, somewhat mediated the breastfeeding effect, probably due to the close correlation of the variables with breastfeeding.

Insertional pain appears to be associated with all other insertion-related events, whether as an effect (pain may be caused by cervical laceration or cervical dilatation) or as a cause (pain probably is an immediate cause for syncope and insertion failure) (Table 8). One possible reason that we did not detect a similar protective relationship between breastfeeding and these other events is that their incidences in both the BF and NBF groups were too low and the differences too minimal for a study of this size to detect.

Among the rare events under study, uterine perforation is the one with the most potentially serious medical consequences. Our suggestive finding that its risk is higher in breastfeeding women inserted with a Loop device, although in agreement with Heartwell and Schlesselman's study results [8], was based on a very small number of occurrences. An experimental *in vitro* study reported by Goldstuck, however, gives

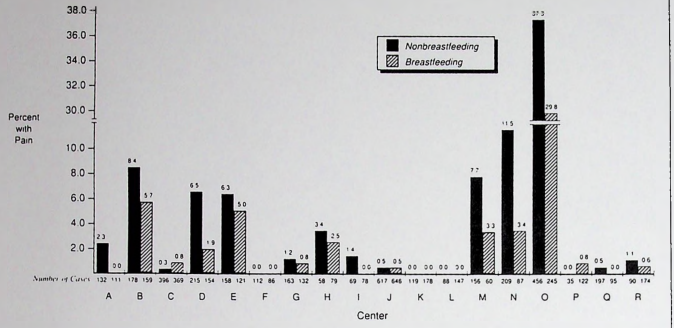

Figure 1 Incidences of moderate/severe insertional pain by breastfeeding status at insertion and by center

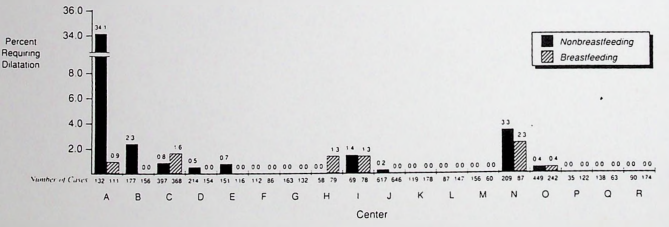

Figure 2 Incidences of cervical dilatation required to facilitate IUD insertion by breastfeeding status at insertion and by center

Table 8 Interrelationship between insertional pain and other insertion-related events by breastfeeding status at IUD insertion

A. *Events leading to insertional pain*					
			Women with moderate/severe insertional pain		
			*Total**	*No.*	*%*
Cervical dilatation	(+)		77	14	18.2
	(−)		6295	345	5.5
Cervical laceration	(+)		36	5	13.9
	(−)		6456	361	5.6
B. *Insertional pain leading to other events*					
			Women with syncope		
			*Total**	*No.*	*%*
Moderate/severe pain	(+)		366	12	3.3
	(−)		6125	13	0.2
			Women with insertion failure		
			*Total**	*No.*	*%*
Moderate/severe pain	(+)		366	1	0.3
	(−)		6125	5	0.1

*Due to some unknown values, the total may not add up to 6493 study subjects

support and provides an explanation for why the Lippes Loop*, as compared to other devices, is more likely to be associated with uterine perforation [21]. If this association is true, it is possible that the lack of insertional pain in breastfeeding women makes inserters less careful during insertion. Less careful attention during insertion, coupled with the possible biological changes of the uterine wall due to lactation, could contribute to a greater risk of immediate uterine perforation at IUD insertion for breastfeeding women.

While not directly relevant, other risk factors delineated in this study were also delineated in our previous case–control studies [18]. For example, from both types of study approaches, we found that women who were younger than 25 (*vs* older women), had used OCs prior to this insertion (*vs* those using no or other methods), had an open interval of one or more years (*vs* those with a shorter interval) and/or were inserted with a Loop (*vs* another IUD type) were more likely to suffer moderate/severe insertional pain. More relevant, however, is the general finding that the relative effect of these other risk factors seems to be somewhat diminished in BF women.

*According to Goldstuck, the inserter tube of the Lippes Loop is much more rigid than that of other devices, and the forces produced by the Lippes Loop are close to the lower range from uterine perforation experiments *in vitro* (about 12 newtons). The push mechanism of the insertion may also contribute to its higher risk of uterine perforation [21].

The finding of a protective effect on the incidence of pain at the time of IUD insertion associated with breastfeeding, in particular with breastfeeding and lactational amenorrhea, and with amenorrhea in breastfeeding and non-breastfeeding women, is of particular clinical importance. It has been shown that suckling episodes during lactation stimulate the release of β-endorphin in the hypothalamus of the ewe [22], and that the peripheral levels of β-endorphin rise after suckling in the rat [23]. This suckling-induced secretion of β-endorphin plays an important role in the suppression of ovarian activity during lactation. Endorphins affect several behavioral and physiological measures, and β-endorphin is clearly the most potent of these substances. It has an analgesic effect when applied centrally that is markedly more potent than morphine [24]. It is possible that a rise in β-endorphin secretion resulting from suckling in the breastfeeding women accounts for the decrease in insertion-related pain observed in these subjects. It is also reasonable to assume that breastfeeding women who are still amenorrheic maintained higher levels of endorphins as a result of more frequent suckling episodes and as a consequence this group had a higher degree of pain protection.

Estrogens promote uterine contractile activity and prostaglandin formation in the myometrium. In the vast majority of women, both breastfeeding and non-breastfeeding, who were already menstruating at the time of IUD insertion, the IUD insertion took place on days 1–17 of the menstrual cycle (Table 1). The estrogen levels present at this time of the cycle would promote uterine contractibility and prostaglandin formation in the myometrium. Conversely, amenorrheic women, breastfeeding or non-breastfeeding, would be free of this estrogenic effect. It is possible that this factor also played a role in the reduced incidence of pain at the time of insertion observed in the amenorrheic women.

With the growing cognizance of the health benefits of breastfeeding and of the superior use- and cost-effectiveness of IUDs, the number of IUD insertions in breastfeeding women will probably increase. Our study results indicate that, except for uterine perforation, interval insertions in breastfeeding women do not seem to be associated with increased incidences of insertion-related rare events. In fact, breastfeeding seems to have the beneficial effect of reducing the occurrence of insertional pain and the need for cervical dilatation. Programmatically, it appears that IUD insertion during breastfeeding should be encouraged and that compared to breastfeeding women, non-breastfeeding women may need more intensive counseling. Further epidemiological studies are definitely needed to clarify whether there is a causal association between breastfeeding and IUD-associated uterine perforation, although intuitively, uterine perforation as well as cervical laceration would seem to be more related to inserter factors than to patient characteristics. Accordingly, the cardinal rule, as asserted by Hatcher *et al.* [25], that 'everything done at the time of IUD insertion should be done slowly and gently' should be conscientiously observed for all women. Also, more basic research on the physiological and anatomical changes of the cervix and uterine wall in breastfeeding women is needed.

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Resumé

Cette étude présente les effets possibles de l'allaitement au sein sur des phénomènes liés à l'insertion de dispositifs intra-utérins (DIU). La recherche portait 6493 femmes inscrites dans plusieurs centres pour participer à des essais cliniques pendant une période de dix ans. On a constaté que l'allaitement au sein a un effet protecteur contre l'apparition de douleurs modérées à fortes au moment de l'insertion et qu'il réduit la nécessité de dilater le col utérin en vue de faciliter l'insertion. Cet effet de protection contre les douleurs prédominait chez les femmes qui allaitaient et se trouvaient encore en aménorrhée de lactation. Les douleurs au moment de l'insertion étaient significativement moins fréquentes au moment de la pose du DIU chez celles qui, allaitant ou non, étaient encore en période d'aménorrhée, que chez celles dont le cycle menstruel avait repris. Cet effet peut être lié à une sécrétion plus abondante de β-endorphine chez les femmes en période d'allaitement ou d'aménorrhée de lactation.

Resumen

Se investigaron en este estudio los posibles efectos del amamantamiento sobre la inserción de dispositivos intrauterinos (DIU). El estudio comprendió 6493 mujeres que participaron en ensayos clínicos en diversos centros durante un período de diez años. Los resultados indican que el amamantamiento ejerce un efecto protector contra la aparición de dolores moderados a fuertes en el momento de la inserción y reduce la necesidad de dilatar el cuello del útero para facilitar la inserción. Este efecto de protección contra el dolor predominó entre las mujeres que amamantaban y se hallaban aún en amenorrea de lactación. Las mujeres con amenorrea, tanto las que amamantaban como las que no lo hacían, señalaron un nivel de dolor significativamente menor en el momento de inserción del DIU que aquellas cuyo ciclo menstrual se había reanudado. Este efecto puede estar relacionado con una mayor secreción de β-endorfina en las mujeres en período de amamantamiento o de amenorrea de lactación.

Recommendations for Updating Selected Practices in Contraceptive Use

Volume II

Produced by the Technical Guidance/Competence Working Group (TG/CWG)
Results of a Technical Meeting and Other Technical Review

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1.8 Progestin-Only Pills During Breastfeeding*

This section outlines recommendations on the following selected procedural questions for Progestin-Only Pills (POPs) during breastfeeding:

1. **When** can POPs be started for **breastfeeding** women?
2. Are there special **considerations when a breastfeeding woman is switching** from POPs to other hormonal methods?
3. If a woman is using POPs during breastfeeding, when **should she be advised to switch** to another method?
4. Can POPs be **used when not breastfeeding**?
5. **How many POP cycles** should be given at the first visit for a new user? At subsequent visits?
6. When breastfeeding, is there a **best time of day** to take POPs?
7. Are **back-up methods** advisable in the following situations:
   a) If a breastfeeding client is taking antibiotics, including anti-tuberculosis medications?
   b) If a breastfeeding client is taking anticonvulsants?
   c) If a breastfeeding client is taking anti-malarial medication?
   d) If it is a breastfeeding client's first cycle of POPs?
   e) If a breastfeeding client has missed pills?
   f) If a breastfeeding client has severe diarrhea and/or vomiting?

* Because the vast majority of POP users are breastfeeding women, this chapter focuses on POPs during breastfeeding. However, POPs are an acceptable contraceptive method for use by women who are not breastfeeding (See Question 4).

Q.1. When can POPs be started for breastfeeding women?

Recommendations	Rationales
a) If breastfeeding, POPs may be started after six weeks postpartum. POPs are not usually recommended in the first six weeks postpartum in breastfeeding women. The timing of postpartum initiation of POPs should consider a woman's breastfeeding intentions.	a) For breastfeeding women, delaying POP initiation for six weeks after delivery avoids exposing the newborn to exogenous steroids during the time of greatest neuroendocrine development. In breastfeeding women, the risk of ovulating in the first six weeks postpartum is very low. The timing of postpartum initiation of POPs should be dependent on the woman's preference, her previous experience with breastfeeding and her intentions regarding the duration of breastfeeding. 1) Howie PW, McNeilly AS, Houston MJ, Cook A, Boyle H. Fertility after childbirth: postpartum ovulation and menstruation in bottle and breast feeding mothers. Clinical Endocrinology 1982;17:323-32. 2) Diaz S, Rodriguez G, Peralta O, Miranda P, Casado ME, Salvatierra AM, et al. Lactational amenorrhea and the recovery of ovulation and fertility in fully nursing Chilean women. Contraception 1988;38(1):53-67. 3) Visness C, Rivera R. Progestin-only pill use and pill switching during breastfeeding. Contraception 1995;51:279-81.
b) A woman who initially chooses to rely on the Lactational Amenorrhea Method (LAM) is advised to begin POPs, or whichever method she chooses to switch to when one of the following takes place: • her menses return, or • she is no longer fully or nearly fully breastfeeding, or • six months postpartum. Preferably, POP packets are given to the woman before her intended start date to ensure that she is able to begin the method when she needs to. However, if she prefers, POPs can also be started when a woman is still relying on LAM (providing her with dual protection).	b) While relying on LAM, a postpartum woman has at least 98% protection from pregnancy for six months if she remains amenorrheic and fully or nearly fully breastfeeds (perfect use effectiveness rate). Programs sometimes encourage waiting to initiate POPs until reliance on LAM ends, because it may be more programmatically affordable and because using POPs while breastfeeding may potentially prolong lactational subfertility. 1) Kennedy K, Rivera R, McNeilly A. Consensus statement on the use of breastfeeding as a family planning method. Contraception 1989;39(5):477-96. 2) Chaudhury RR, Chompootaweep S, Dunitsin N, Friesen H, Tankeyoon M. The release of prolactin by medroxyprogesterone acetate in human subjects. British Journal of Pharmacology 1977;59:433-4.

(continued on next page)

Q.1. When breastfeeding? (continued)

Recommendations	Rationale
c) After the first six weeks postpartum, POPs can be initiated any time you can be reasonably sure a woman is not pregnant (see Appendix A and POP Question 7d).	c) Based on current literature, including studies with other progestin-only methods, it is unlikely that there is a significant effect on the growth of breastfeeding infants whose mothers initiate POPs after the sixth postpartum week. 1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. Contraception 1984;30(6):505-21. 2) Shaaban M, Salem H, Abdullah K. Influence of levonorgestrel contraceptive implants, Norplant, initiated early postpartum upon lactation and infant growth. Contraception 1985;32(6):623-35. 3) Pardthaisong T, Yenchit C, Gray R. The long-term growth and development of children exposed to Depo-Provera during pregnancy or lactation. Contraception 1992;45:313-24. 4) McCann MF, Moggia AV, Higgins JE, Potts M, Beeker C. The effects of a progestin-only oral contraceptive (levonorgestrel 0.03 mg) on breastfeeding. Contraception 1989;40(6):635-48.
d) Even if POPs are inadvertently initiated during pregnancy, there is no known risk to the fetus.	d) Epidemiologic studies have found no significant effect on fetal development or malformations due to taking hormonal methods in early pregnancy. 1) Bracken MB. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. Obstetrics and Gynecology 1990;76:552-7. 2) Wiseman RA, Doddi-Smith IC. Cardiovascular birth defects and antenatal exposure to female sex hormones: a re-evaluation of some base data. Teratology 1984;30(3):359-70. 3) Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. Advances in Contraception 1990;6:141-67.
e) Non-hormonal methods are preferable to hormonal methods during breastfeeding because they have no effect on breastfeeding and the infant is not exposed to exogenous steroids. However, WHO lists POPs as Category 1 after six weeks postpartum, and women should be given a choice of contraceptive methods.	e) Although the amount of exogenous progestins in breastmilk is extremely low, it is prudent to try to minimize infant exposures to any drug. 1) Institute of Reproductive Health. Guidelines for breastfeeding in family planning and child survival programs. Washington, DC: IRH, 1992. 2) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

Q.2. Are there special considerations when a breastfeeding woman is switching from POPs to other hormonal methods?

Recommendations	Rationale
No. A breastfeeding woman can switch from POPs to another hormonal method any time the new method is appropriate. No back-up method is necessary when the new method is initiated if the woman has been breastfeeding, and has been taking the POPs fairly consistently. Estrogen-containing methods should generally not be used by breastfeeding women prior to six months postpartum or preferably any time during long-term breastfeeding.	As long as the woman is breastfeeding and taking the POPs fairly consistently, she is fully protected through the transition to the new hormonal method. 1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6). Clinical trial data indicate that the pregnancy protection conferred by POP use during breastfeeding is high, indicating a synergistic pregnancy prevention effect for breastfeeding while using POPs. In addition, women in lactational amenorrhea have additional protection due to their lowered fecundity. 1) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. Contraception 1993;47:23-35. 2) Kennedy KI, Visness C. Contraceptive efficacy of lactational amenorrhea. Lancet 1992;339:227-30.

Q.3. If a woman is using POPs during breastfeeding, when should she be advised to switch to another method?

Recommendations	Rationale
a) Women can rely on POPs after the first six weeks postpartum, and safely use them during the entire duration of breastfeeding.	a) In general, POPs are highly effective, and safe, during breastfeeding. 1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6). 2) Dunson TR, McLaurin VL, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. Contraception 1993;47:23-35.
b) Women can continue using POPs after they stop breastfeeding, provided that they have been informed of the advantages and disadvantages of the method and are willing to use the POPs correctly and consistently. It is not mandatory for a woman to switch from POPs to another family planning (FP) method after she stops breastfeeding or at six months postpartum.	b) POPs are an effective contraceptive method, even when not breastfeeding, if used correctly and consistently. However, all women should be informed of the advantages and disadvantages of POPs in the absence of breastfeeding, especially that POPs need to be used consistently and correctly to provide effective pregnancy protection (e.g., the pill should be taken at the same time each day), and that they often cause irregular menstrual bleeding. 1) Visness C, Rivera R. Progestin-only pill use and pill switching during breastfeeding. Contraception 1995;51:279-81. 2) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6). 3) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
c) Breastfeeding women using POPs should be advised not to switch to combined oral contraceptives (COCs), or other methods containing estrogen, until at least six months postpartum.	c) Even low-dose (30 mcg) COCs decrease breastmilk production and alter its composition. 1) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. Contraception 1984;30:505-21. 2) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6).
d) Breastfeeding women can switch to non-hormonal methods at any time, as appropriate.	d) If not inserted with 48 hours of delivery, postpartum IUDs are usually not inserted until uterine involution is complete. Progestin-releasing IUDs are not inserted until six weeks postpartum, even if involution is complete before six weeks, to avoid the theoretical risks of infant steroid exposure. Diaphragms are not fitted until involution is complete. 1) O'Hanley K, Huber D. Postpartum IUDs: keys for success. Contraception 1992;45:351-61. 2) Wiley A. The Diaphragm. In: Corson S, Derman R, Tyrer L, editors. Fertility Control. Boston: Little, Brown & Company, 1985:223-32. 3) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.

Q.4. Can POPs be used when not breastfeeding?

Recommendations	Rationale
Yes, if taken consistently and correctly. Many women gain experience with and confidence in POPs during breastfeeding and should be allowed to continue POPs after breastfeeding if POPs are the woman's method of choice.	POPs are an effective contraceptive method even when the woman is not breastfeeding if taken consistently and correctly. POPs are a useful alternative for many women who want to use oral contraceptives (OCs) but for whom COCs are not appropriate. Women should be informed of the advantages and disadvantages of POPs, especially that POPs need to be used consistently and correctly to provide effective pregnancy protection (e.g., the pill should be taken at the same time each day) and that POPs often cause irregular menstrual bleeding. Unless a woman is breastfeeding, a back-up method of contraception should be used if a POP is taken more than three hours after her regularly scheduled time (See Question 7e). 1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6).

Q.5. How many POP cycles should be given at the first visit for a new user? At subsequent visits?

Recommendations	Rationale
a) **New user?** Postpartum women who plan to use LAM can be given their pill cycles immediately postpartum, with instructions to begin taking them (see Question 1) when any of the LAM criteria no longer apply. Women who plan to rely on LAM for six months can be given at least a six month supply (to begin when the LAM criteria no longer apply), so they will have contraceptive protection for at least one year. Up to 13 cycles (a full year's supply) can be given, although only three or four may be programmatically feasible. The greatest need is to guarantee continuous, ready access.	a) The woman's convenience is important. To avoid running out of pills, the woman should have ready access to more POP cycles. Ideally, she should be able to obtain plenty of POP cycles at her visit. While some providers suspect that clients who receive multiple pill cycles may "share" these with friends, such "sharing" is likely to be as safe and effective as over-the-counter distribution systems.
b) **Subsequent visits?** There is no compelling medical reason for a routine return visit concerning POP use, but clients should be encouraged to return at any time with concerns, problems or questions. For first-time users of POPs, programs may encourage a three-month follow-up visit for counseling to assess whether the client is satisfied with the method and is correctly using the method, to reinforce instructions, and to help clients with the management of side effects.	b) The extremely low dose of progestins in POPs make them a very safe method of contraception. The greatest health risk from POPs is pregnancy due to method failure, which is preventable by assuring adequate POP supply and correct, consistent method use.

1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6).
2) Harlap S, Kost K, Forrest JD. Preventing pregnancy, protecting health: a new look at birth control choices in the United States. Washington, D.C.: The Alan Guttmacher Institute, 1991.

Q.6. When breastfeeding, is there a best time of day to take POPs?

Recommendations	Rationale
a) POPs may be taken at any time of the day for effective use during breastfeeding. The client may wish to select a certain time to help her remember to take a pill every day; it may help to link this time to a daily event.	a) Breastfeeding women have additional protection due to their lower fecundity. Clinical trial data indicate that the pregnancy protection conferred by POP use during breastfeeding is extremely high. The synergistic pregnancy protection by POP use in combination with breastfeeding should sufficiently eliminate a client's risk of conception, even if she takes POPs at different times of the day. 1) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. Contraception 1993;47:23-35. 2) Wright SW, Fotherby K, Fairweather F. Effect of daily small doses of norgestrel on ovarian function. Journal of Obstetrics and Gynaecology of the British Commonwealth 1970; 77:65-8.
b) However, if a woman continues taking POPs after breastfeeding cessation, then it is important to take the POP at the same time every day, preferably late afternoon or four to five hours before the usual time of sexual activity, so that the pill's effect on the cervical mucus is at its maximum by the time sexual activity occurs.	b) The most immediate contraceptive effect of POPs is the alteration of cervical mucus. The POP's effect on cervical mucus peaks approximately four to five hours after ingestion of the pill, and is essentially gone by 24 hours after taking one POP. 1) McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6). 2) Chretien FC, Sureau C, Neau C. Experimental study of cervical blockage induced by continuous low-dose oral progestogens. Contraception 1980;22:445-56.

Q.7. Are back-up methods advisable in the following situations?

Recommendations	Rationale
a) **If a breastfeeding client is taking antibiotics, including anti-tuberculosis medications?** Back-up methods are not usually required, unless the woman is taking **rifampin/rifampicin**. With the exception of rifampin/rifampicin, antibiotics are unlikely to significantly reduce the effectiveness of POPs in breastfeeding women. If the breastfeeding woman is taking rifampin/rifampicin, she should know that rifampin/rifampicin: • passes through breastmilk (with potential infant side effects), • may increase breakthrough bleeding, and • lowers progestin levels, possibly significantly reducing the effectiveness of POPs.	a) Broad-spectrum antibiotics such as ampicillin, erythromycin and tetracycline have **not** been shown to decrease effectiveness of POPs in careful clinical studies. Rifampin/rifampicin, which is used primarily for treating tuberculosis, induces hepatic enzymes and increases the liver metabolism of progestins, thus decreasing the effectiveness of POPs. The enzyme-inducing effects of rifampin/rifampicin last about four weeks after short-term use and eight weeks after long-term use. Griseofulvin, an anti-fungal antibiotic and another hepatic enzyme inducer, has not been proven to reduce POP effectiveness in humans, but may increase menstrual irregularities. Rifampin/rifampicin is passed in breastmilk (milk:plasma ratio of 0.2 to 0.6). Griseofulvin may also be passed in breastmilk. Infant exposure to rifampin/rifampicin or griseofulvin is appropriate only when the maternal benefits outweigh the potential risks to the infant. 1) Back DJ, Orme ML. Drug interactions. In: Goldzieher JW, Fotherby K (editors.) Pharmacology of the Contraceptive Steroids. New York: Raven Press, 1994:407-25. 2) Fotherby K. Interactions with oral contraceptives. American Journal of Obstetrics and Gynecology 1990;163:2153-9 3) Drug Facts and Comparisons. St. Louis: Facts and Comparisons, June 1996, p. 358 and October 1990, p.387a 4) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996. 5) Baciewicz AM, Self TH, Bekemeier WB. Update on rifampin drug interactions. Archives of Internal Medicine 1987;147(3):565-8.

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Q.7. Back-up methods (continued)

Recommendations	Rationale
b) **If a breastfeeding client is taking anticonvulsants?** Yes, usually. The common anticonvulsants, hydantoins (e.g., phenytoin), barbiturates (e.g., phenobarbital, primidone), and probably carbamazepine significantly decrease the effectiveness of oral contraceptives. POPs are not recommended if using these enzyme-inducing anticonvulsants. Additionally, because anticonvulsants are excreted in breastmilk, and because there is a potential for serious adverse reactions in nursing infants, women taking hydantoins, barbiturates, or carbamazepine for **chronic** seizure control may be advised to explore safe alternatives to breastfeeding. Injectable contraceptives, such as Depo Provera®, will be effective despite anticonvulsant use, but infant exposure to the anticonvulsants will continue. Non-hormonal methods will continue to be effective despite anticonvulsant use.	b) The hepatic enzyme-inducing effects of most anticonvulsants probably decrease pregnancy protection and increase rates of irregular bleeding among some POP users. It should be noted however that POPs may decrease the probability of seizures among users of anticonvulsants. Because of the dangers of fetal exposure to most anticonvulsants, full protection against pregnancy is essential. Although increased doses of POPs might be effective, they might also further increase bleeding irregularities. 1) Mattson RH, Rebar RW. Contraceptive methods for women with neurologic disorders. American Journal of Obstetrics and Gynecology 1993;168:2027-32 If a woman ingests hydantoins, barbiturates, or carbamazepine, her breastmilk will contain significant quantities of these substances. In areas where safe alternatives to breastfeeding exist, and where maternal seizures cannot otherwise be controlled, women on long-term anti-seizure medications may be advised to consider safe alternatives to breastfeeding, to avoid chronic infant drug exposure. 1) Drug Facts and Comparisons. St. Louis: Facts and Comparisons, July 1996, pp. 282-4 2) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996. 3) Anderson GD, Graves NM. Drug interactions with antiepileptic agents. CNS Drugs 1994;2(4):268-79.
c) **If a breastfeeding client is taking anti-malarial medication?** No back-up is needed. There is no evidence that anti-malarial medications reduce the effectiveness of OCs. Chloroquine and related anti-malarials are excreted in breastmilk.	c) Chloroquine, primaquine and tetracycline have not shown any effect on OC hormonal levels, and are not known to reduce the effectiveness of POPs. A nursing infant may consume about half of a mother's 300 mg chloroquine dose over 24 hours; the maternal milk: blood ratio may be about 0.36. Children are especially sensitive to chloroquine and primaquine.

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Q.7. Back-up methods (continued)

Recommendations	Rationale
	c) Weighing the nutritional value of the milk to the child against the effects of the chloroquine, clients are usually not advised to stop breastfeeding while on anti-malarial treatment, unless safe alternatives to breastmilk are available. 1) Drug Facts and Comparisons. St. Louis: Facts and Comparisons June 1996, pp. 358 and 387a.
d) **If it is a breastfeeding client's first cycle of POPs?** No back-up is needed. However, if a breastfeeding woman has resumed menstruating and is beginning the pills later than the first seven days of her cycle, some programs recommend that she use a back-up method for seven days after beginning POPs.	d) The cervical mucus thickens enough to prevent sperm penetration within 24 hours. Also, the synergistic protection against pregnancy conferred by concurrent POP use and breastfeeding should sufficiently eliminate a client's risk of conception. Thus, a back-up method for a full seven days may not be necessary. 1) Cirteuen FC, Sureau C, Neau C. Experimental study of cervical blockage induced by continuous low-dose oral progestogens. Contraception 1980;22:445-56. 2) Kesseru-Kows E. Influence of various hormonal contraceptives on sperm ingration in vivo. Fertility and Sterility 1971;22:584-603. 3) Moghissi KS, Syner FN, McBride LC. Contraceptive mechanism of lauroloste noredinindrate. Obstetrics and Gynecology 1973;41:585-94.
e) **If a breastfeeding client has missed pills?** If the breastfeeding woman is still amenorrheic, missed pills are of minimal consequence. For a breastfeeding woman who has already returned to menses, if two or more pills are missed, the woman should: • resume taking a pill as soon as she remembers, • take the next pill at the regular time that day (for added protection), and • use a back-up method or abstinence for 48 hours (some programs recommend use of a back-up method for up to seven days).	e) After missing one pill, breastfeeding women previously taking POPs are estimated to be sufficiently subfertile that the probability of the woman becoming pregnant is extremely low. The most immediate effect of POPs is on cervical mucus, each tablet offering protection for approximately 24 hours. Clinical trial data indicate that the pregnancy protection conferred by POP use during breastfeeding is high, indicating a synergistic pregnancy prevention effect for breastfeeding while using POPs. In addition, women in lactational amenorrhea have additional protection due to their lowered fecundity. 1) Kesseru-Kows E. Influence of various hormonal contraceptives on sperm ingration in vivo. Fertility and Sterility 1971;22:584-603. 2) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. Contraception 1993;47:23-35. 3) Kennedy KI, Visness C. Contraceptive efficacy of lactational amenorrhoea. Lancet 1992;339:227-30.

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Q.7. Back-up methods (continued)

Recommendations	Rationale
f) **If a breastfeeding client has severe diarrhea and/or vomiting?** If a woman is breastfeeding and amenorrheic, no back-up method is needed since the synergistic effect of both breastfeeding and POP use should provide sufficient pregnancy protection. If a breastfeeding woman has resumed menstruating, some programs recommend use of a back-up method for 48 hours or for 7 days after the severe vomiting or diarrhea stops.	f) The synergistic protection conferred by POP use and breastfeeding should sufficiently eliminate a client's risk of conception, because women in lactational amenorrhea have additional protection due to their lowered fecundity. 1) Dunson T, McLaurin V, Grubb G, Rosman A. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. Contraception 1993;47:23-35 2) Orme M, Back DJ, Breckenridge AM. Clinical pharmacokinetics of oral contraceptive steroids. Clinical Pharmacokinetics 1983; 8:95-136 3) Kennedy KI, Visness C. Contraceptive efficacy of lactational amenorrhea. Lancet 1992;339:227-30

Classification of Selected Procedures for Progestin-only Pills (POPs) during Breastfeeding

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	• A pelvic exam is not necessary to ensure safe use of POPs as a contraceptive method[1]. • In some cases, a pelvic exam may help evaluate the question of pregnancy if a menstrual history suggests the possibility beyond six weeks duration. In this case it is Class A. • Conditions which would restrict use of POPs should be identified by the client's history before method initiation.
Blood pressure	C	Current evidence does not demonstrate any notable effect of POPs on blood pressure[2,3].
Breast examination	C	POPs do not cause breast cancer[4,5]. Lumps that are suspicious as cancer should be evaluated. While any hormonal treatment may in theory cause such lumps to grow, pregnancy causes much higher hormonal levels; therefore, potential malignancies of the breast should not be a reason to delay a woman's access to the use of this contraceptive method.
STD screening by lab tests (for asymptomatic persons)	C	The presence of an STD will not affect the safe use of POPs. Clients at risk of STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible.
Cervical cancer screening	C	POPs have no known relation to risk of cervical cancer[6].
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	The effect of POPs on cholesterol, blood glucose and normal liver function are slight, and of no demonstrated clinical significance[6-8].
Proper infection prevention procedures	C	Proper infection prevention procedures are not applicable to POP use.

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KEY:

Class A = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method

Class B = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings

Class C = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method

Class D = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

Classification of Selected Procedures for Progestin-only Pills (POPs) during Breastfeeding
(continued)

Procedure	Class	Rationale
Specific counseling points for POP use: • efficacy • common side effects, including alterations in bleeding patterns (e.g. frequent or irregular bleeding, extended amenorrhea) • correct use of method (including instructions for missed pills) • signs and symptoms for which to see a health provider • STD protection (when/as appropriate)	A	• Accurate client education is essential for maximum quality of FP services. • Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation. • Irregular or absent menstrual bleeding is the single most common side effect of POPs, and the chief complaint leading to discontinuation[9]. • POPs are highly effective if taken correctly and consistently. However, POPs are less effective than COCs after weaning. • The woman should be encouraged to return if she has any problems or at any time she has questions or concerns.

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KEY:

Class A = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method

Class B = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings

Class C = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method

Class D = not materially related to either good routine preventive health care or to the safe and effective use of the contraceptive method

Classification of Selected Procedures for Progestin-only Pills (POPs) during Breastfeeding
(continued)

Citations for Procedures Table:

1) Huber DH, Huber SC. Screening oral contraceptive candidates and inconsequential pelvic examinations. Studies in Family Planning 1975;6(2):49-51.
2 Ball MJ, Ashwell E, Gillmer MDG. Progestagen-only oral contraceptives: comparison of the metabolic effects of levonorgestrel and norethisterone. Contraception 1991;44(3):223-35.
3) Wilson ESB, Cruickshank J, McMaster M, Weir RJ. A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen. British Journal of Obstetrics and Gynaecology 1984;91:1254-60.
4) Stanford JL, Thomas DB. Exogenous progestins and breast cancer. Epidemiologic Reviews 1993;15(1):98-107.
5) UK National Case-Control Study Group. Oral contraceptive use and breast cancer risk in young women. Lancet 1989;1:973-82.
6) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
7) Miale JB, Kent JW. The effects of oral contraceptives on the results of laboratory tests. American Journal of Obstetrics and Gynecology 1974;120(2):264-72.
8) Korba VD, Paulson SR. Five years of fertility control with microdose norgestrel: an updated clinical review. Journal of Reproductive Medicine 1974;13(2):71-5
9) Belsey EM, WHO Task Force on Long-acting Systemic Agents for Fertility Regulation. The association between vaginal bleeding patterns and reasons for discontinuation of contraceptive use. Contraception 1988;38(2):207-25.

For further information see McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6).

Effect of breastfeeding on infant and child mortality due to infectious diseases in less developed countries: a pooled analysis

*WHO Collaborative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality**

Summary

Background The debate on breastfeeding in areas of high HIV prevalence has led to the development of simulation models that attempt to assess the risks and benefits associated with breastfeeding. An essential element of these simulations is the extent to which breastfeeding protects against infant and child mortality; however, few studies are available on this topic. We did a pooled analysis of studies that assessed the effect of not breastfeeding on the risk of death due to infectious diseases.

Methods Studies were identified through consultations with experts in international health, and from a MEDLINE search for 1980–98. Using meta-analytical techniques, we assessed the protective effect of breastfeeding according to the age and sex of the infant, the cause of death, and the educational status of the mother.

Findings We identified eight studies, data from six of which were available (from Brazil, The Gambia, Ghana, Pakistan, the Philippines, and Senegal). These studies provided information on 1223 deaths of children under two years of age. In the African studies, virtually all babies were breastfed well into the second year of life, making it impossible to include them in the analyses of infant mortality. On the basis of the other three studies, protection provided by breastmilk declined steadily with age during infancy (pooled odds ratios: 5·8 [95% CI 3·4–9·8] for infants <2 months of age, 4·1 [2·7–6·4] for 2–3-month-olds, 2·6 [1·6–3·9] for 4–5-month-olds, 1·8 [1·2–2·8] for 6–8-month-olds, and 1·4 [0·8–2·6] for 9–11-month-olds). In the first 6 months of life, protection against diarrhoea was substantially greater (odds ratio 6·1 [4·1–9·0]) than against deaths due to acute respiratory infections (2·4 [1·6–3·5]). However, for infants aged 6–11 months, similar levels of protection were observed (1·9 [1·2–3·1] and 2·5 [1·4–4·6], respectively). For second-year deaths, the pooled odds ratios from five studies ranged between 1·6 and 2·1. Protection was highest when maternal education was low.

Interpretation These results may help shape policy decisions about feeding choices in the face of the HIV epidemic. Of particular relevance is the need to account for declining levels of protection with age in infancy, the continued protection afforded during the second year of life, and the question of the safety of breastmilk substitutes in families of low socioeconomic status.

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Introduction

The recognition that HIV is transmitted through breastmilk raised the important question of whether strategies that promote breastfeeding in areas of high HIV prevalence should be changed.[1] This policy decision is particularly difficult, given that breastfeeding provides important protection against infectious diseases,[2–6] which account for over two-thirds of the 12 million annual deaths in children younger than 5 years in less developed countries.[7]

Theoretical models have been developed to assess the advantages and disadvantages of breastfeeding for HIV-positive women, as well as for women of unknown HIV status who live in areas of high HIV prevalence.[8–11] These models have taken into account the risk of transmission through breastfeeding with regard to the age of the infant, the protection afforded by breastmilk against infectious disease mortality, the underlying HIV prevalence, and the rate of infant and child mortality. However, according to a recent WHO/UNAIDS review,[12] an important limitation of these models was the poor quantification of the relative risks for mortality associated with lack of breastfeeding. Such models used relative risk estimates ranging from 1·3 to 7·9, and no model allowed for variable levels of protection within the first year of life. We did a comprehensive pooled analysis of existing studies of the effect of not breastfeeding on risk of infant and child mortality due to infectious diseases.

Methods

Through consultations with experts in international health, the Division of Child and Adolescent Health (WHO, Geneva, Switzerland) obtained a list of published and unpublished datasets that might provide information on the risk of infant and childhood mortality according to feeding practices. The search was limited to studies carried out in the 1980s and 1990s, to those that provided data on deaths in the first year of life (and if possible on second-year deaths as well), and to those in which the cause of death was ascertained. This list was complemented by a MEDLINE search from 1980 to December, 1998, with the keywords "breastfeeding" and "mortality". These sources revealed a total of 13 research groups who might have had datasets containing the information required.

The datasets were revised to make them compatible in terms of the names of variables, and of coding. All deaths that occurred in the first week of life were excluded, since breastfeeding is unlikely to have had a marked impact on these deaths (which were mainly due to perinatal causes and congenital malformations). Also, deaths not attributed to infectious diseases and deaths for which the cause was not known, were excluded from most analyses. For the Ghana study, two independent raters defined the cause of death, and there was no attempt to reach a consensus. The κ statistic for inter-rater agreement was 0·65 ($p<0·001$). We arbitrarily chose to use the opinion of the first rater, but since the study contributed only 33 deaths to the analysis, we assumed that the pooled estimate would not be markedly affected. For the Philippines study, deaths classified as due to "diarrhoea and acute respiratory infections" were included in both categories. Information on AIDS-related deaths was not specifically collected in the studies—all but one were carried out in the

	Brazil[a]	The Gambia[b]	Ghana[c]	Pakistan[d]	Philippines[e]	Senegal[f]
Number of children	1070	431	1099	2166	9682	3534
Site	Pelotas	Upper River Division	Upper East Region	Lahore	Cebu	Niakhar
Design	Case-control	Case-control	Cohort	Cohort	Cohort	Cohort
Setting	Urban	Mostly rural	Rural	Rural and urban slums	Urban	Rural
Year	1988–90	1990–91	1990–91	1983–87	1988–91	1983–86

Table 1: **Characteristics of studies included in pooled analysis**

	Brazil	The Gambia	Ghana	Pakistan	Philippines	Senegal
Total deaths	357	202	33	41	165	425
Deaths by age (months)*						
0–1	51 (14·3%)	61 (30·1%)	1 (3·0%)	17 (41·5%)	19 (11·5%)	30 (9·3%)
2–3	113 (31·7%)	16 (7·9%)	5 (15·2%)	8 (19·5%)	16 (9·7%)	29 (8·9%)
4–5	84 (23·5%)	29 (14·3%)	10 (30·3%)	8 (19·5%)	22 (13·3%)	34 (10·5%)
6–8	80 (22·4%)	26 (12·8%)	7 (21·2%)	3 (7·3%)	48 (29·1%)	41 (12·6%)
9–11	29 (8·1%)	26 (13·8)	3 (9·1%)	0	27 (19·4%)	43 (13·2%)
12–23	–	42 (20·7%)	7 (21·2%)	5 (12·2%)	33 (20·0%)	148 (45·5%)
Deaths by cause						
Acute respiratory infections	127 (35·6%)	131 (49·3%)	10 (30·3%)	30 (69·8%)	39 (15·1%)	140 (13·5%)
Diarrhoea	170 (47·6%)	27 (10·2%)	5 (15·2%)	9 (10·9%)	62 (24·0%)	288 (27·8%)
Diarrhoea and acute respiratory infections	–	–	–	–	44 (17·1%)	–
Other infections	60 (16·8%)	45 (16·9%)	13 (39·4%)	2 (4·7%)	20 (7·8%)	–
Other causes	–	63 (23·7%)	5 (15·2%)	2 (4·7%)	93 (36·1%)	607 (58·7%)†
Breastfeeding prevalence by age (months) among controls						
0–1	84%	100%	100%	98%	80%	100%
2–3	60%	100%	100%	95%	77%	100%
4–5	39%	100%	100%	92%	72%	100%
6–8	28%	100%	100%	88%	64%	100%
9–11	26%	98%	100%	80%	57%	99%
12–23	–	75%	99%	46%	26%	91%

*Excluding deaths occurring in the first week of life, and deaths from non-infectious causes. †Including deaths due to infections other than acute respiratory infections or diarrhoea.

Table 2: **Distribution of deaths by age and cause, and breastfeeding prevalence among controls**

1980s—but HIV is unlikely to have caused more than a few deaths at any of the sites.

Since maternal education varied markedly across countries, this variable was classified separately for each study, according to approximate terciles. In Brazil, the classifications used were 0–2 years, 3–5 years, and 6–17 years of education; in Pakistan, women were classed as either illiterate, able to read, or able to read and write; and in the Philippines, women were grouped into those having 0–5 years, 6–10 years, or 11–16 years of education. For the African studies, stratification by maternal education was not possible.

To allow pooling of the data from case-control studies and cohort studies, results from the latter were stratified by age groups (0–1, 2–3, 4–5, 6–8, 9–11, 12–15, 16–19, and 20–23 months); the numbers of deaths and of survivors (ie, those who remained in the study until the end of each age stratum) were used in the analyses. An 11-month-old child from a cohort study, therefore, provided information on breastfeeding frequency for the first four age strata. Stratification was not required for the preparation of the data files for case-control studies, since each control child only provided information on breastfeeding at a single age. This pooling of case-control and cohort data, which has been used in other collaborative reanalyses,[11] is analogous to treating cohort studies as nested case-control studies.

In the analysis of cases, we assessed breastfeeding status before the onset of the fatal disease to avoid reverse causality—ie, feeding changes as a result of illness. When this information was not available, we used breastfeeding status 7 days before death. For controls, we assessed breastfeeding in the middle of each of the age intervals described. In the Brazilian study, most deaths took place in a hospital, and although hospital-acquired infections may have contributed to mortality,[12] the underlying cause of death was diarrhoea severe enough to warrant hospital admission. In Brazilian children who had one or more admissions due to diarrhoea in the 2 months before their death, breastfeeding status was classified before the first of these admissions. For the analyses of infant mortality stratified by sex, maternal education, and cause, the same strategy was used, but due to smaller sample sizes, only two age groups were used (0–5 and 6–11 months).

After preparing the data, we did the analyses using standard meta-analytic procedures—ie, Mantel-Haenszel pooled estimates and Cornfield confidence intervals.[13] We added 0·5 to all table cells containing a value of zero, so that calculation of the odds ratio was possible. The analyses were done with Stata 5.0 (Stata Corporation, College Station, TX, USA) and the "metan" procedure.

Results

We identified eight studies that met our criteria; data were obtainable from six of them.[9–14] Of those we could not obtain, one dataset had been destroyed, and the author of the other failed to respond to repeated attempts to contact him. The studies were all done between 1983 and 1991, and covered both urban and rural areas (table 1). Table 2

Age-group (months)	Brazil			Pakistan			Philippines			Pooled			Pooled‡		
	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)		Cases	Odds ratio (95% CI)	
0–1	51	7·2 (3·3–15·9)	43·7	17	21·3 (7·9–57·7)	6·2	18	2·5 (1·0–6·3)	50·1	86	5·6‖ (3·4–9·8)		125	4·2 (2·8–6·3)	
2–3	113	3·8 (2·3–6·1)	83·3	8	11·8 (3·1–45·4)	2·5	15	5·1 (1·9–13·7)	14·2	136	4·1 (2·7–6·4)		144	3·6 (2·4–5·5)	
4–5	84	2·5 (1·4–4·5)	67·2	8	1·6 (0·0–10·3)	5·0	22	2·8 (1·1–5·8)	27·8	114	2·5 (1·6–3·9)		119	2·5 (1·6–4·0)	
6–8	80	2·4 (1·2–4·7)	37·0	3	3·5 (0·0–27·1)	1·7	47	1·5 (0·8–2·6)	61·4	130	1·8 (1·2–2·8)		149	1·7 (1·1–2·5)	
9–11	29	1·9 (0·7–5·3)	31·9	0	..	0	27	1·2 (0·6–2·5)	68·1	56	1·4 (0·8–2·6)		68	1·4 (0·8–2·4)	
All	357	3·2 (2·3–4·2)	..	36	7·9 (3·8–16·3)	..	129	1·9 (1·3–2·7)	..	522	..		605		

Deaths due to non-infectious causes, and deaths in the first week of life were excluded.
*Weight of data in pooled estimate. †Including deaths due to non-infectious causes. ‡Heterogeneity test, p=0·009.

Table 3: **Infant mortality associated with not breastfeeding, by country and age-group**

Age (months) and sex	Brazil			Pakistan			Philippines			Pooled	
	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)
0–5											
Boys	140	3·5 (2·3–5·4)	70·2	16	10·7 (3·9–29·4)	3·6	32	2·4 (1·2–4·9)	26·4	188	3·5 (2·4–5·0)
Girls	108	3·6 (2·4–6·2)	73·8	17	6·8 (2·2–20·7)	4·9	25	4·5 (2·1–9·7)	21·3	150	4·1 (2·8–6·1)
6–11											
Boys	63	1·5 (0·8–3·1)	58·7	2	5·7† —	1·3	26	2·0 (0·9–4·3)	40·0	91	1·8 (1·1–3·0)
Girls	46	3·9 (1·5–10·3)	36·0	3	11·6* —	2·2	24	2·0 (0·9–4·3)	61·9	73	2·9 (1·6–5·2)

Deaths due to non-infectious causes, and deaths in the first week of life were excluded.
*Weight of data in pooled estimate. †Confidence interval undefined owing to small sample size.

Table 4: **Infant mortality associated with not breastfeeding, by country, age-group, and sex**

Age-group (months)	Gambia			Ghana			Pakistan			Philippines			Senegal			Pooled‡	
	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	Odds ratio (95% CI)	Weight (%)*	Cases	OR (95% CI)
1–15	15	0·7 (0·1–4·0)	20·1	4	23·8 (5·5–103·3)	0·3	3	1·1 (0·0–8·0)	10·3	18	1·5 (0·6–4·0)	54·0	51	3·0 (1·0–9·3)	15·4	91	1·6 (0·8–3·2)
16–19	16	1·3 (0·3–6·7)	18·0	2	11·0 (0·1–138·7)	0·7	2	4·5 (0·3–63·5)	4·4	11	1·0 (0·3–3·5)	36·2	35	2·9 (1·3–6·4)	40·6	66	2·1 (1·1–4·0)
20–23	7	0·8 (0·1–4·5)	9·8	1	3·9 (0·0–88·3)	0·9	0	—	0	4	1·7 (0·5–5·3)	3·3	62	1·8 (1·1–2·9)	86·0	74	1·7 (1·0–2·7)
All	38	0·9 (0·3–2·6)		7	7·9 (3·2–53·2)		5	2·0 (0·4–11·5)		33	1·4 (0·6–2·9)		148	2·0 (1·4–3·1)		231	

*Weight of data in pooled estimate. †All cases were breastfed. ‡Contains one or more zero cells. Odds ratios and 95% CI calculated by adding 0·5 to all table cells. §95% CI undefined owing to small sample size.

Table 5: **Mortality at 12–23 months of age associated with not breastfeeding, by country and age-group**

shows the number of deaths by age, excluding deaths in the first week of life and non-infectious deaths. All studies except those from Ghana and Pakistan included more than 160 deaths. Taking into account the different widths of the age strata, the highest mortality rates were observed in infants younger than 2 months of age in The Gambia and Pakistan, in those 2·0–3·9 months old in Brazil, in those 4·0–5·9 months old in Ghana and Senegal, and in those 6·0–8·9 months old in the Philippines.

Acute respiratory infections or diarrhoea were the leading cause of death from infectious diseases in three studies. However, some differences in design and the classification of the cause of death affected the comparability of the studies. The Brazilian study was restricted to deaths due to infections. The study from the Philippines had a category of "diarrhoea and acute respiratory infections" for deaths of children with symptoms of both disorders, whereas in the other studies the referees assigned such deaths to the single cause that initiated the chain of events leading to death. Deaths due to infections other than acute respiratory infections or diarrhoea in Senegal were grouped with non-infectious deaths.

Breastfeeding patterns varied markedly between studies (table 2). In the three African sites, virtually every child was breastfed during the whole of their first year of life. Therefore, these studies could not be included in the analyses of lack of breastfeeding and infant mortality. In the Gambian study, breastfeeding status was ignored because mothers were unable to provide information on breastfeeding duration in 14 cases (6·9%) and 19 controls (8·3%); in the study in the Philippines, it was ignored in three cases (1·8%) and 113 controls (1·2%). Table 3 shows the odds ratios for infant mortality associated with lack of breastfeeding in each group in each study. Pooled data are also shown. The protection against mortality provided by breastmilk tended to decline with age in all three studies. When deaths due to non-infectious causes were included in the pooled estimate, odds ratios for the youngest age ranges were affected the most (table 3).

The protection provided by breastfeeding against all infant deaths (ie, in any age group) was greatest in Pakistan, intermediate in Brazil, and lowest in the Philippines (table 3). Protection provided by breastfeeding was slightly greater for girls than for boys, but the fact that the confidence intervals overlap should be noted (table 4). In the first 6 months of life, protection against diarrhoea was substantially greater (odds ratio 6·1 [95% CI 4·1–9·0]) than against acute respiratory infections (2·4 [1·6–3·5]), but all 6–11 months of age, similar levels of protection were observed against both causes of death (1·9 [1·2–3·1] *vs* 2·5 [1·4–4·6], respectively). Whereas protection against diarrhoea declined markedly with age, protection against acute respiratory infections was constant.

Lack of breastfeeding was associated with a substantially larger risk in 0–5-month-old children of poorly educated mothers (1st tercile; odds ratio 7·6 [4·7–12·3]) than in those with more educated mothers (2·7 [1·8–4·1] and 3·5 [2·0–6·1] for 2nd and 3rd terciles, respectively). This effect was also seen in 6–11-month-old children (5·1 [2·8–9·3], 2·0 [1·1–3·8], and 1·1 [0·5–2·6] for 1st, 2nd, and 3rd terciles, respectively).

All studies except the Brazilian one provided data on deaths in the second year of life. Except for two studies (Ghana and Senegal), there was no clear pattern of decreasing risk with age. There was no significant heterogeneity. The overall odds ratio for the second year was greatest in Ghana (7·9, based on only seven deaths). The Senegal and Pakistan studies showed odds ratios of 2·0, but the latter was not significant. No significant effect was observed in the Gambian and Filipino studies (table 5).

Discussion

This paper presents the findings from a comprehensive attempt to obtain available data on all studies on cause-specific mortality according to breastfeeding. A large number of investigators were contacted by WHO, and datasets from those willing and able to participate were

included. Nevertheless, only three datasets provided information on deaths in the first year of life, and six provided data on deaths in the second year. Also, we have not been able to rule out publication bias, which is likely to result in the exclusion of small studies with negative findings. Of the two datasets that were identified but could not be included, one showed a protective effect of breastfeeding, and the other was not published.

Observational studies of breastfeeding and infant health may be affected by a number of methodological problems, including self-selection, reverse causality, and confounding, which have been reviewed in detail elsewhere.[24-27] In this analysis, an attempt was made to avoid reverse causality by recording breastfeeding before the fatal illness episode. Also, stratification by maternal education—a potential confounder and effect modifier—showed a consistent increase in risk for weaned infants in most education categories.

An extensive review of the literature on breastfeeding and all-cause mortality revealed one meta-analysis published in 1984[28] (which covered eight pre-1950 studies and one 1979 study), and 13 other studies.[29-41] Most of these consisted of reanalyses of existing datasets, which were mainly retrospective demographic surveys. These studies were not included in the present analysis because they did not provide information on cause of death. The studies vary substantially in terms of definitions of breastfeeding variables, in the types of analyses used, and on how the results were presented. Most investigators did not attempt to rule out reverse causality. Owing to these limitations, most of the results could not be compared with our findings. However, all studies showed significant protective effects of breastfeeding, at least for some age groups. The review confirmed that our reanalysis included most of the well-designed, published studies of breastfeeding and mortality.

Even studies that made specific attempts to control for bias have shown a protective effect of breastfeeding,[18-22,24] and several reviews agree that the overall evidence is compelling.[2-5] Randomised trials of breastfeeding promotion and infant mortality would be prohibitively difficult and ethically questionable, but one trial in India compared the effects of different types of milk given by bottle to high-risk newborns.[42] Raw human milk provided substantial protection against the incidence of septicaemia, conjunctivitis, diarrhoea, and umbilical sepsis. Our decision to exclude first-week deaths from this analysis—in order to avoid reverse causality—will underestimate the protection provided by breastmilk against neonatal infections. Another issue to bear in mind in this reanalysis is that studies did not employ a uniform protocol for defining causes of death. Most studies used verbal autopsy methods which are substantially more accurate for some causes (such as measles and diarrhoea) than for others (such as acute respiratory infections or malaria).[43,44] Nevertheless, a higher level of protection was provided against diarrhoea than against acute respiratory infections in the first six months of life within each study. Unfortunately, most studies did not provide sufficient information on breastfeeding pattern (exclusive, predominant, or partial) to allow a pooled analysis of this variable. Breakdown by sex suggested a slightly larger protection for girls, but, as noted, the confidence intervals overlap.

Our reanalysis showed that infants who are not breastfed have a six-fold greater risk of dying from infectious diseases in the first 2 months of life than those who are breastfed, but that protection decreases steadily with age, and is probably due to lower intakes by older children who also receive complementary feeding. There was significant heterogeneity within the pooled estimate for the first age group, so this estimate should be regarded with caution. The heterogeneity was mainly due to the very high odds ratio observed in Pakistan (21·3, based on 17 deaths); when Pakistan was excluded, there was no significant heterogeneity. Since 98% of infants under 2 months of age in Pakistan were reportedly breastfed, those who were not breastfed may have had underlying morbidity. In the first year of life, protection was observed in three studies from three different continents. For the second year, results were less consistent, but still suggested a protective effect.

We suggest that our data should be used in future simulations of the impact of withholding breastfeeding in HIV-positive mothers. Since our estimates refer to mortality due to infectious diseases, the relative weight of infections in overall infant and child mortality should be taken into account in the simulations. Our results will also help assess the risks and benefits associated with breastfeeding for children of different ages, since the risk of HIV transmission also depends on duration of breastfeeding.[45,46] Of direct relevance to the debate on HIV and breastfeeding are the higher levels of protection seen among less educated women, particularly for deaths at ages 6–11 months. Such results are consistent with the finding that infant-mortality differentials according to breastfeeding status are virtually non-existent in more developed countries where maternal education is high.[46] The main policy issue is whether or not HIV-positive mothers with low levels of schooling and income will be able to feed their infants with safe breastmilk substitutes. Earlier research from Malaysia showed that the association between breastfeeding and mortality is twice as strong in households without piped water or a toilet than in those with such facilities.[29] This question exceeds the scope of our analysis, but our results suggest that it will be difficult, if not impossible, to provide safe breastmilk substitutes to children from underpriviledged populations.

There is a wide agreement that the final decision on whether or not to breastfeed if a woman is HIV-positive should reside with the mother and the family.[1] We hope that our results will provide a firmer basis for policy decisions on how to help families in this difficult situation.

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How to be Reasonably Sure a Client is Not Pregnant

If the client answers YES to any question, proceed to the box at the bottom of the YES column

NO		YES
	1. Are you less than 6 months postpartum *and* fully breastfeeding *and* free from menstrual bleeding since you had your child?	
	2. Have you abstained from sexual intercourse since your last menses?	
	3. Have you given birth in the last 4 weeks?	
	4. Did your last menstrual period start within the past 7 days?	
	5. Have you had a miscarriage or abortion in the past 7 days?	
	6. Have you been using a reliable contraceptive method consistently and correctly?	

Client answered NO to <u>all</u> of the questions

↓

Pregnancy cannot be ruled out

↓

Client should await menses or use pregnancy test

Client answered YES to <u>at least 1</u> question

↓

Client is free of signs or symptoms of pregnancy

↓

Provide client with desired method

FHI

WHO/FRH/FPP/96.9
Original: English
Distr.: General

Improving Access to Quality Care in Family Planning

Medical Eligibility Criteria for Initiating and Continuing Use of Contraceptive Methods

Low-dose combined oral contraceptives (COCs)
Emergency contraceptive pills (ECPs)
Combined injectable contraceptives (CICs)

Progestogen-only pills (POPs)
Depot Medroxyprogesterone acetate (DMPA)
Norethisterone enanthate (NET-EN)
Norplant implants (NOR)

Copper IUDs (Cu-IUDs)
Levonorgestrel-releasing IUD (LNG-IUD)
IUD for emergency contraception

Male sterilization
Female sterilization

Natural family planning (NFP)
Barrier methods
Lactational amenorrhea

SUMMARY TABLES							
CONDITION	**COC**	**CIC**	**POP**	**NET-EN DMPA**	**NOR**	**Cu-IUD**	**LNG-IUD**
	I = Initiation, C = Continuation						
PREGNANCY	4	4	4	4	4	4	4
BREAST-FEEDING							
a) < 6 weeks postpartum	4	4	3	3	3		
b) 6 weeks to 6 months: (primarily breast-feeding)	3	3	1	1	1		
c) ≥ 6 months postpartum	2	2	1	1	1		
POSTPARTUM (in non-breast-feeding women)							
< 21 days	3	3	1	1	1		
≥ 21 days	1	1	1	1	1		
POSTPARTUM (breast-feeding or non-breast-feeding) including post-caesarian section							
a) < 48 hours						2	3
b) 48 hours to 4 weeks						3	3
c) ≥ 4 weeks						1	1[a]
d) Puerperal sepsis						4	4

[a] If the woman is breast-feeding, LNG-IUD becomes a category 3 until 6 weeks postpartum.

SUMMARY TABLES								
CONDITION	**COC**		**CIC**	**POP**	**NET-EN DMPA**	**NOR**	**Cu-IUD**	**LNG-IUD**
	I = Initiation, C = Continuation							
POST-ABORTION								
a) First trimester	1		1	1	1	1	1	1
b) Second trimester	1		1	1	1	1	2	2
c) Immediate post-septic abortion	1		1	1	1	1	4	4
AGE	< 40 = 1 ≥ 40 = 2		< 40 = 1 ≥ 40 = 2	< 16 = 2 ≥ 16 = 1	< 16 = 2 ≥ 16 = 1	< 16 = 2 ≥ 16 = 1	< 20 = 2 ≥ 20 = 1	< 20 = 2 ≥ 20 = 1
SMOKING								
a) Age < 35	2		2	1	1	1	1	1
b) Age ≥ 35								
light	3		2	1	1	1	1	1
heavy (> 20 cigarettes/day)	4		3	1	1	1	1	1
ESSENTIAL HYPERTENSION	**I**	**C**						
a) **History of hypertension** where blood pressure cannot be evaluated (excluding hypertension in pregnancy)	3	3	3	2	2	2	1	2

ARTICLES

Contraceptive Use Among Postpartum Women: Recent Patterns and Programmatic Implications

By Shyam Thapa, Sushil Kumar, Jeanne Cushing and Kathy Kennedy

This study of postpartum women, based on Demographic and Health Surveys in 25 developing countries, reveals that the proportion of women who are exposed to the risk of pregnancy within two years after childbirth ranges from one-third in Sub-Saharan Africa to nearly two-thirds in Latin America and the Caribbean. More than half of postpartum women are current contraceptive users. Women exposed to the risk of pregnancy are more likely than unexposed women to be using reversible methods, usually the pill. Among women who are unexposed to the risk of pregnancy as a result of abstinence or amenorrhea associated with breastfeeding, 19% are using a contraceptive method, usually sterilization. The proportion of contraceptive users who initiate use of a modern method before menses returns ranges from 27–57% among countries in Latin America and the Caribbean and Asia, and from 24–46% among African countries. Smaller proportions of hormonal contraceptive users initiate use before the return of menses. About one-fifth of exposed women are not using any contraceptive method. Of this group, more than one-third want no more children and another one-third want to space their next pregnancy.

(International Family Planning Perspectives, 18:83, 1992)

The concept of implementing special family planning programs for postpartum women is not new. As early as 1966, The Population Council introduced the International Postpartum Program in a few countries to evaluate the feasibility of providing family planning services for women immediately after childbirth or abortion.[1] The program was gradually expanded to 21 countries, with services offered in 135 urban areas and four large rural areas (in the Philippines, Indonesia, Nigeria and Turkey).[2]

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International policymakers, program managers and health care providers have recently expressed renewed interest in postpartum family planning programs. The following factors may have contributed to the recent attention: modest improvements in contraceptive technology or its application;[3] increased appreciation of the role of breastfeeding in regulating fertility;[4] expansion of the service delivery infrastructure; increased support from donor agencies; and, perhaps most important, the realization that service delivery during the postpartum period, which is thought to be a desirable and effective time to introduce contraceptives, has not been promoted in family planning programs.

Strategies for the delivery of postpartum family planning services have been based partly on the demographic rationale that the sooner contraceptives are adopted after childbirth, the greater the impact on fertility, through longer birth intervals. These strategies have also been based on the behavioral assumptions that women tend to be more motivated to accept contraceptives immediately after childbirth than at other times, and that their contact with medical facilities at the time of delivery is an ideal opportunity for health care providers to offer family planning counseling and services.

In a recent article, Beverly Winikoff and Barbara Mensch critically examined these issues and questioned both the demographic rationale and the behavioral assumptions. They concluded that there is "little conceptualization of the postpartum period and the needs of the [postpartum] women." They also pointed out that, from the women's perspective, "it is necessary to understand more about women's needs, their preferences for an array of health services and their desires as to the timing and type of contraceptives available to them."[5]

This study examines contraceptive behavior and needs among postpartum women in developing countries, and addresses three interrelated issues. First, what is the prevalence of contraceptive use among postpartum women and when do they begin using contraceptives after childbirth? Second, what are their preferences for future childbearing? Third, to what extent do women have contact with health care personnel before, during and after the delivery, who might help them initiate contraceptive use?

Data and Definitions

Data on postpartum women in 25 developing countries were obtained from the first phase of the Demographic and Health Surveys (DHS), completed between 1986 and 1989. The countries included 10 in Sub-Saharan Africa, three in North Africa, nine in Latin America and the Caribbean, and three in Asia. They represented approximately 35% of the total population of developing countries, excluding China and India.

The term "postpartum period" is conventionally defined in medical circles as the time from parturition until six weeks after childbirth. This definition reflects clinical considerations, mainly, the usual

time for involution of the uterus to have been completed. Although this definition is generally accepted in clinical contraceptive research, family planning programs have not established a consistent definition of the postpartum period. Winikoff and Mensch have suggested that in family planning programs, postpartum is commonly considered an "approach" to the delivery of contraceptives immediately after childbirth or abortion.[6] The lack of a time-bound definition for family planning providers probably reflects the need to consider programmatic aspects of contraceptive service delivery as well as physiologic circumstances.

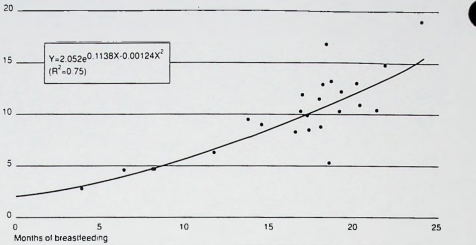
Previous analyses on postpartum contraception in developing countries have been based on various lengths of time after childbirth, including up to 24 months.[7] For several reasons, we defined the postpartum period in this analysis as up to two years (23 completed months) since the birth of the last child. First, the two-year time period encompasses a substantial proportion of women of reproductive age, from an average of 25% of women in lower fertility countries to an average of about 45% in higher fertility countries. Overall, the postpartum period used in this analysis also allows adequate time for the initiation of contraceptive use by a substantial proportion of women who had had a recent birth; thus, postpartum contraceptive behavior can be examined thoroughly.

Second, breastfeeding for long durations is the rule rather than the exception in most developing countries. According to the DHS data, the median duration of breastfeeding in the regions surveyed ranges from 12 months in Latin America and the Caribbean to 20 months in Sub-Saharan Africa. In some countries, weaning serves as a proximate marker for the initiation of contraceptive use after childbirth.[8]

Third, the longer the duration of breastfeeding, the longer the duration of amenorrhea, at least at the aggregate level.[9] Applying John Bongaarts's model of proximate determinants to DHS data confirmed this relationship (Figure 1), suggesting that each increase in duration of breastfeeding by one month increases the duration of postpartum amenorrhea by one-half to three-fourths of a month.

In addition to having given birth within 24 months prior to the study, women included in the sample had to have been currently married or in a consensual union and not pregnant at the time of the survey. A small proportion of women whose last pregnancy was ended by abortion was excluded from the study.

Figure 1. Median duration of postpartum amenorrhea, by median duration of breastfeeding, 25 DHS countries



Note: Y=Median duration of postpartum amenorrhea X=Median duration of breastfeeding

We classified the postpartum women into two categories of exposure to the risk of pregnancy: unexposed and exposed. Unexposed women included those who were amenorrheic or abstaining from sexual intercourse at the time of the survey; exposed women included those who had resumed menstruating since their last birth and who were not abstaining from sexual intercourse. In the analysis of survey data, the resumption of menses is generally used as an indicator of a woman's return to fertility. Contraceptive use in this analysis refers to use of a method at the time of the survey.

The classification of the postpartum women into two categories of exposure addresses behavioral and programmatic considerations. Behaviorally, evidence suggests that the return of menses after childbirth is an important signal for women to start using contraceptives[10]—a more important signal, in fact, than breastfeeding status.[11] Recent studies have shown that the probability of pregnancy during amenorrhea is low.[12] One study found that 6% of amenorrheic women were likely to be pregnant at the end of a year, while 17% of all breastfeeding women were likely to conceive.[13]

Programmatically, the initiation of use of reversible contraceptive methods, such as the pill, immediately after delivery may have either no impact or an adverse impact on fertility. Evidence from rural Bangladesh showed that the initiation of pill use immediately after childbirth can lead to shorter, not longer, birth intervals as a result of early abandonment of both contraceptive practice and breastfeeding.[14] A related consideration is the phenomenon referred to as the "double protection dilemma": If the duration of lactational

Table 1. Percentage distribution of postpartum women, by exposure to the risk of pregnancy, according to country, 1986–1989

Country	Exposed	Unexposed	Total
Asia	**57.5**	**42.5**	**100.0**
Indonesia	48.6	51.4	100.0
Sri Lanka	58.1	41.9	100.0
Thailand	65.9	34.1	100.0
Latin America/ Caribbean	**62.2**	**37.8**	**100.0**
Bolivia	44.7	55.3	100.0
Brazil	78.6	21.4	100.0
Colombia	73.2	26.8	100.0
Dominican Republic	68.8	31.2	100.0
Ecuador	55.8	44.2	100.0
Guatemala	37.3	62.7	100.0
Mexico	68.5	31.5	100.0
Peru	51.8	48.2	100.0
Trinidad & Tobago	80.9	19.1	100.0
North Africa	**59.4**	**40.6**	**100.0**
Egypt	58.0	42.0	100.0
Morocco	57.4	42.6	100.0
Tunisia	62.8	37.2	100.0
Sub-Saharan Africa	**32.6**	**67.4**	**100.0**
Botswana	45.0	55.0	100.0
Burundi	19.1	80.9	100.0
Ghana	27.6	72.4	100.0
Kenya	46.2	53.8	100.0
Liberia	31.2	68.8	100.0
Mali	29.0	71.0	100.0
Senegal	24.9	75.1	100.0
Togo	21.8	78.2	100.0
Uganda	36.3	63.7	100.0
Zimbabwe	45.0	55.0	100.0

Note: In this and subsequent tables, postpartum refers to women who are currently married, are not pregnant and have had a birth within 24 months before the survey; exposed refers to postpartum women who have resumed menses since last birth and are not abstaining. Because of rounding, figures may not add to 100. Regional averages are unweighted.

Table 2. Percentage distribution of postpartum women, by exposure to the risk of pregnancy and by method use, according to country

Country	Exposed							Unexposed							Total
	All methods	Pill	IUD	Inject-ables	Steril-ization*	Other	No method	All methods	Pill	IUD	Inject-ables	Steril-ization*	Other	No method	
Asia															
Indonesia	64.0	18.5	13.6	19.6	1.6	10.7	36.0	27.9	3.8	6.3	10.1	1.4	6.3	72.1	100.0
Sri Lanka	71.0	12.2	2.4	8.0	16.5	31.9	29.0	32.8	0.7	0.5	1.4	12.6	17.7	67.2	100.0
Thailand	82.0	24.7	12.9	18.6	20.8	5.1	18.0	38.5	2.5	6.6	10.4	17.3	1.5	61.5	100.0
Latin America/Caribbean															
Bolivia	41.2	3.5	5.3	1.3	2.9	28.2	58.8	7.8	0.0	0.7	0.1	1.0	5.9	92.2	100.0
Brazil	78.3	43.0	0.9	1.6	20.3	12.6	21.7	30.5	4.1	0.0	0.4	20.3	5.7	69.5	100.0
Colombia	81.5	27.6	15.1	5.9	12.2	20.8	18.5	25.3	4.1	3.0	0.0	5.8	12.4	74.7	100.0
Dominican Republic	65.7	22.3	6.4	0.0	26.3	10.6	34.3	26.4	4.0	0.5	0.0	17.2	4.8	73.6	100.0
Ecuador	55.0	12.5	15.6	1.8	10.7	14.3	45.0	13.0	0.9	2.5	0.2	5.9	3.4	87.0	100.0
Guatemala	28.8	8.7	2.2	0.9	5.8	11.2	71.2	5.1	0.3	0.1	0.3	2.3	2.0	94.9	100.0
Mexico	68.1	19.0	15.8	5.5	13.4	14.4	31.9	16.4	0.2	2.6	0.1	8.4	5.1	83.6	100.0
Peru	63.1	11.7	10.2	3.0	3.0	35.2	36.9	9.2	0.0	1.1	0.2	1.6	6.2	90.8	100.0
Trinidad & Tobago	75.7	23.1	5.2	1.7	6.6	39.1	24.3	36.5	2.1	1.0	3.1	8.3	21.9	63.5	100.0
North Africa															
Egypt	57.7	25.7	24.3	0.1	0.8	6.7	42.3	12.2	1.4	4.6	0.0	0.4	5.8	87.8	100.0
Morocco	57.1	42.3	3.1	0.9	0.8	10.0	42.9	6.5	1.9	0.6	0.1	0.5	3.5	93.5	100.0
Tunisia	65.3	15.8	27.7	1.0	4.3	16.5	34.7	9.7	0.7	2.2	0.2	2.8	3.7	90.3	100.0
Sub-Saharan Africa															
Botswana	45.8	24.2	8.0	7.1	1.0	5.6	54.2	14.5	5.7	1.4	4.5	1.4	1.6	85.5	100.0
Burundi	26.3	0.9	1.1	3.2	0.1	21.0	73.7	8.7	0.0	0.0	0.0	0.1	8.6	91.3	100.0
Ghana	26.4	4.9	0.5	0.5	0.0	20.5	73.6	9.4	0.4	0.1	0.1	0.5	8.3	90.6	100.0
Kenya	36.4	10.6	4.0	5.3	2.8	13.7	63.6	15.2	2.2	1.1	0.8	1.7	9.3	84.8	100.0
Liberia	11.6	8.6	1.3	0.0	0.0	1.8	88.4	0.7	0.3	0.0	0.0	0.2	0.2	99.3	100.0
Mali	5.8	1.7	0.3	0.0	0.0	3.7	94.2	5.7	0.1	0.0	0.0	0.0	5.5	94.3	100.0
Senegal	17.6	5.2	2.8	0.6	0.0	9.1	82.4	20.3	0.2	0.3	0.0	0.1	19.8	79.7	100.0
Togo	50.6	1.2	2.1	0.0	0.4	46.9	49.4	46.8	0.5	0.2	0.0	0.2	45.9	53.2	100.0
Uganda	8.1	2.7	0.3	0.6	0.4	4.2	91.9	1.9	0.3	0.1	0.2	0.3	1.1	98.1	100.0
Zimbabwe	68.2	51.1	1.1	0.0	0.6	15.5	31.8	50.7	37.4	0.5	0.2	0.4	12.3	49.3	100.0

*Sterilization includes male and female.

amenorrhea is very long, the introduction of contraceptives early in the postpartum period may have virtually no demographic impact, and a considerable proportion of the potential effect of contraceptive practice will be "wasted."[15]

Results

The proportion of exposed women ranged from an average of about one-third in Sub-Saharan Africa to almost two-thirds in Latin America and the Caribbean (Table 1). In the Sub-Saharan African countries studied, at least 55%—and in some countries more than 75%—of women who had given birth within the last two years were still unexposed to the risk of pregnancy. We found considerable variation in exposure to pregnancy risk among women in Sub-Saharan Africa and in Latin America and the Caribbean. Exposure status was associated largely with breastfeeding and to some extent with practices of postpartum abstinence.

Contraceptive Use

Contraceptive use was considerably lower among unexposed women than among exposed women. In the 25 countries surveyed, an average of only 19% of unexposed women were using a method of contraception, while more than 50% of exposed women were using a method. The ratio of contraceptive use of the unexposed group to the exposed was 0.38. Twelve percent of unexposed women and 41% of exposed women were using modern contraceptive methods (the pill, the IUD, injectables, implants, barrier methods or sterilization).

Not only was overall contraceptive use considerably lower among unexposed women compared with exposed women, but the methods used were markedly different. When we analyzed only those countries with at least 5% prevalence of each modern method, sterilization (female or male) appeared to be the most commonly used method by unexposed women. The pill was the predominant method among exposed women, followed by the IUD, sterilization and injectables.

Among exposed women (Table 2), the pill was used by at least 5% of the women in 19 of 25 countries. The proportions of women who were using the pill varied considerably among countries. Use of the pill was particularly high in Zimbabwe (51%), Brazil (43%) and Morocco (42%). The IUD was used by at least 5% of the women in 12 countries, most of which are in Asia, North Africa, and Latin America and the Caribbean. Use of the IUD by exposed women was more than 5% in only one country (Botswana) in Sub-Saharan Africa. Among the countries surveyed, the use of sterilization was limited almost exclusively to Asia and Latin America and the Caribbean; in Indonesia and Bolivia, however, it was not used at all. Injectables were used by 8–20% of exposed women in the three Asian countries surveyed, and by 6–8% of women in Colombia, Mexico, Botswana and Kenya.

Among unexposed women, sterilization was used by at least 5% of the women in eight of the 25 countries, and was particularly popular—used by 13–20%—in Brazil, the Dominican Republic, Thailand and Sri Lanka. Reversible methods were used by unexposed women in only a few countries. The IUD was used by an average of 6–7% of the women in Thailand and Indonesia, while injectables were used by an average of 10% of the women in these two countries. Botswana was the only other country where injectables were used by about 5% of unexposed women. The pill was used by at least 5% of unexposed women in only two countries—Zimbab-

we (37%) and Botswana (6%). Use of the pill in all other countries was negligible.

To examine when during the postpartum period women were more likely to use contraceptives, we compared women who were using the pill, the IUD, injectables or sterilization, at six different postpartum periods, by country. The proportion of unexposed women using reversible methods in each postpartum period was usually less than 5%, and so with few exceptions, use by exposed women was consistently and considerably higher than that of unexposed women in each time period. The data for exposed women are shown in Table 3.

Use of the pill by exposed women increased in Trinidad and Tobago, and Colombia after the third or the sixth month postpartum, and stabilized in subsequent postpartum months. In Liberia and Senegal, use of the pill increased after the sixth month postpartum, but decreased at later months. In a few countries—Zimbabwe, Brazil, Mexico, Peru and Thailand—the proportion of exposed women using the pill was at a high point in the first three months after birth, then declined at 4–6 months postpartum. Zimbabwe appeared to be a special case, in that the pill was used by as many as three-fourths of exposed women at 0–3 months postpartum.

Where IUD use was measurable, in about half of the 12 countries, its use among exposed women increased with time, particularly at 4–6 months; in the other countries, IUD use declined after 12 months. In Tunisia and Mexico, the IUD was used by a substantial proportion of exposed women. Its use among exposed women stabilized in Tunisia at 7–9 months postpartum.

Injectables were used by considerable proportions of exposed women in Thailand and Indonesia. In both countries, use of injectables was fairly constant during the postpartum period.

Sterilization among exposed women generally increased over time in all the countries where it was used by at least 3% of postpartum women. Sterilization was particularly high after nine months postpartum in Brazil, the Dominican Republic, Thailand and Sri Lanka.

The timing patterns for reversible methods used by more than 5% of unexposed women are shown in Table 4. The proportion of unexposed women in Zimbabwe who were using the pill increased with time postpartum. In Botswana, the only other country where the pill was used by at least 5% of the unexposed women, the trend was less distinct.

Table 3. Among postpartum women exposed to the risk of pregnancy, percentage using selected contraceptive methods, by country and duration since last birth

Country and months since last birth	Pill	IUD	Inject-ables	Steril-ization
ASIA				
Indonesia				
0–3	5.8	13.0	20.8	*
4–6	13.0	11.8†	19.9	*
7–9	12.8	7.6	29.9	*
10–12	17.0	13.1†	17.9	*
13–18	19.8	15.2†	17.3	*
19–23	23.6	17.2†	19.2	*
Sri Lanka				
0–3	0.0	*	10.9	9.6
4–6	10.6	*	5.9	4.7
7–9	11.0	*	9.4	7.9
10–12	15.7	*	9.6	9.5
13–18	9.1	*	7.3	22.9
19–23	15.7	*	8.0	21.7
Thailand				
0–3	28.2	5.5	20.2	18.2
4–6	17.0	10.2	23.3	9.6
7–9	25.8	17.1‡	17.2	10.5
10–12	23.7	16.4	13.8	19.6
13–18	27.7	10.5‡	17.3	25.0
19–23	23.0	14.3‡	21.4	23.5
LATIN AMERICA/CARIBBEAN				
Bolivia				
0–3	*	15.6	*	*
4–6	*	2.5	*	*
7–9	*	2.8	*	*
10–12	*	9.1	*	*
13–18	*	4.0	*	*
19–23	*	6.5	*	*
Brazil				
0–3	49.0	*	*	14.4
4–6	40.4	*	*	20.4
7–9	44.3	*	*	16.1
10–12	43.4	*	*	17.3
13–18	37.1	*	*	23.2
19–23	49.0	*	*	25.0
Colombia				
0–3	8.5	5.5	11.9	10.8
4–6	28.5	15.1	6.9	6.8
7–9	24.8	18.9	9.3	7.6
10–12	28.3	13.2	4.6	14.6
13–18	29.2	18.1	4.6	11.7
19–23	29.7	12.1	4.6	16.6
Dominican Republic				
0–3	29.2	6.8	*	13.1
4–6	31.7	3.1	*	21.2
7–9	18.9	6.8	*	21.3
10–12	26.7	6.7**	*	23.0
13–18	20.4	9.3**	*	26.8
19–23	16.1	5.0	*	39.3
Ecuador				
0–3	7.1	7.1	*	3.6
4–6	10.6	15.2	*	12.1
7–9	11.8	21.1	*	11.8
10–12	11.6	10.1	*	5.8
13–18	10.5	18.5	*	12.3
19–23	17.3	14.0	*	11.3
Guatemala				
0–3	36.4	*	*	0.0
4–6	4.9	*	*	9.8
7–9	14.1	*	*	4.7
10–12	6.3	*	*	3.1
13–18	9.6	*	*	6.9
19–23	5.2	*	*	5.2
Mexico				
0–3	23.8	10.6	2.0	6.8
4–6	13.9	25.0	6.0	13.0
7–9	15.3	13.1	10.1	9.7
10–12	11.9	20.7	3.1	12.6
13–18	15.7	14.8	5.3	14.5
19–23	28.6	11.0	4.3	17.3
Peru				
0–3	10.5	10.5	*	*
4–6	3.5	10.5	*	*
7–9	14.8	11.1	*	*
Country and months since last birth	**Pill**	**IUD**	**Inject-ables**	**Steril-ization**
Peru (cont.)				
10–12	9.1	13.6	*	*
13–18	13.6	9.5	*	*
19–23	13.5	8.7	*	*
Trinidad & Tobago				
0–3	10.7	3.6	*	0.0
4–6	12.5	7.5	*	0.0
7–9	26.8	1.6	*	3.1
10–12	25.8	4.5	*	7.6
13–18	24.1	6.3	*	5.4
19–23	25.8	6.2	*	14.4
NORTH AFRICA				
Egypt				
0–3	23.4	19.9	*	*
4–6	26.6	22.3	*	*
7–9	27.3	21.6	*	*
10–12	24.4	23.2	*	*
13–18	25.8	23.7	*	*
19–23	26.1	29.7	*	*
Morocco				
0–3	25.0	*	*	*
4–6	32.1	*	*	*
7–9	46.5	*	*	*
10–12	38.4	*	*	*
13–18	44.8	*	*	*
19–23	49.8	*	*	*
Tunisia				
0–3	11.1	19.0	*	*
4–6	14.3	13.5	*	*
7–9	13.1	32.3	*	*
10–12	20.2	32.5	*	*
13–18	16.7	27.2	*	*
19–23	16.4	35.4	*	*
SUB-SAHARAN AFRICA				
Botswana				
0–3	§§	§§	§§	*
4–6	§§	§§	§§	*
7–9	13.2	2.6	9.2	*
10–12	38.0	8.7	1.3	*
13–18	14.4	6.3	11.2	*
19–23	31.5	10.7	4.1	*
Ghana				
0–3	§	*	*	*
4–6	6.3	*	*	*
7–9	7.7	*	*	*
10–12	6.3	*	*	*
13–18	2.2	*	*	*
19–23	5.4	*	*	*
Kenya				
0–3	5.1	*	2.6	*
4–6	10.9	*	7.9	*
7–9	6.7	*	3.1	*
10–12	9.7	*	5.4	*
13–18	12.3	*	5.8	*
19–23	10.8	*	4.8	*
Liberia				
0–3	7.8	*	*	*
4–6	5.2	*	*	*
7–9	11.7	*	*	*
10–12	14.7	*	*	*
13–18	7.2	*	*	*
19–23	6.6	*	*	*
Senegal				
0–3	0.0	*	*	*
4–6	0.0	*	*	*
7–9	11.1	*	*	*
10–12	6.5	*	*	*
13–18	4.9	*	*	*
19–23	4.7	*	*	*
Zimbabwe				
0–3	75.0	*	*	*
4–6	62.2	*	*	*
7–9	51.3	*	*	*
10–12	52.5	*	*	*
13–18	44.5	*	*	*
19–23	52.3	*	*	*

*Not calculated because less than 5% of women were using the method †Includes 1.1%, 0.9%, 0.3% and 1.0% of implant users in 4–6, 10–12, 13–18 and 19–23 month intervals, respectively. ‡Includes 0.7, 0.8 and 3.2% of implant users in 7–9, 13–18 and 19–23 month intervals, respectively. §Number of cases fewer than 10 **Includes 1.1% and 0.3% of implant users for 10–12 and 13–18 month intervals, respectively

Table 4. Among postpartum women unexposed to the risk of pregnancy, percentage using selected contraceptive methods, by country, according to months since last birth

Method and country	Months since last birth					
	0–3	4–6	7–9	10–12	13–18	19–23
Pill						
Botswana	2.7	7.8	5.1	2.7	9.0	*
Zimbabwe	22.8	33.3	38.5	46.1	53.7	48.0
IUD						
Indonesia	3.4	8.2	7.9†	8.2†	9.9†	9.6†
Thailand	4.8	7.1	11.5	3.5	10.6†	3.2†
Injectables						
Indonesia	1.9	12.4	8.2	16.0	15.8	27.7
Thailand	6.2	9.9	3.8	16.5	22.0	41.8
Sterilization						
Brazil	16.3	26.1	29.4	29.1	22.7	0.0
Colombia	3.9	14.4	0.0	3.4	4.5	0.0
Dominican Republic	15.3	22.6	11.4	32.3	16.1	9.3
Ecuador	7.0	7.9	6.4	3.9	2.3	0.0
Mexico	12.1	5.9	5.4	4.7	7.3	0.0
Thailand	14.6	17.4	13.1	28.3	25.3	8.2
Trinidad & Tobago	6.9	18.2	0.0	*	*	*
Sri Lanka	8.1	8.1	18.4	17.9	21.6	23.0

*Number of cases fewer than 10. †Includes implant users.

Among unexposed women, IUD use was negligible in all countries studied except Thailand (3–12%) and Indonesia (3–10%).

Injectables were used by considerable proportions of unexposed women in Indonesia and Thailand, and use increased with time. The proportion of unexposed women using injectables increased sharply after nine months postpartum; at 19–23 months postpartum, use of injectables by unexposed women exceeded proportions among exposed women.

In the eight countries where sizable proportions of unexposed women used sterilization, they did so with equal (or greater) frequency than exposed women.

Table 5 shows the percentage of current users of modern methods and hormonal methods by whether they initiated use before or after the return of menses. In those countries for which data were available, the percentage of women who initiated using a modern method before menses returned was higher in Latin America and the Caribbean and Asia (27–57%, average of 42%), than in Sub-Saharan and North African countries (24–46%, average of 33%). The percentage of women who initiated contraceptive use during the same month menses returned (average of 18%) varied little among countries.*

In Latin America and the Caribbean and Asia, the higher percentage of women who initiated contraceptive use before the return of menses may be related to the high use of sterilization. When the analysis was restricted to hormonal methods—the pill, injectables and implants—only an average of one-fourth of the women in these regions initiated contraceptive use before the return of menses. In Thailand and Mexico, only about 10% of the women initiated hormonal contraceptive use before the first menses. Of all the countries for which data were available, Zimbabwe had the highest proportion of women (46%) who initiated the use of hormonal methods before the return of menses.

The proportion of women who initiated hormonal methods during the same month that menses returned was about one-fourth in Latin America and the Caribbean and Asia, but was considerably lower in the three Sub-Saharan African countries. The data in Table 5 clearly indicate that, on average, at least half of the women initiated use of hormonal contraceptives after the return of menses.

Reproductive Preferences

We classified the women's postpartum preferences for future childbearing into four categories: want no more children, want to space next pregnancy, want to have another child as soon as possible, and undecided. The first two categories include women with the potential need for contraceptives.†

Among women in need of contraceptives because they wanted no more children or wanted to space the next pregnancy, the highest proportion of women were unexposed and not using a method (38%); the lowest proportion of women were unexposed but using a contraceptive (9%). Approximately 32% of the women were exposed and using contraceptives, and 21% were exposed but not using a method.

Among women who were exposed to the risk of pregnancy but were not using a method, about 36% wanted no more children, about 36% wanted to space their next pregnancy, 16% wanted to have a child as soon as possible, and 12% were undecided about their next pregnancy. Latin America and the Caribbean had the

Table 5. Among postpartum women exposed to the risk of pregnancy, percentage distribution of current contraceptive users, by type of method and when use began, according to country

Country	Any modern method			Hormonal method only			Total
	Before menses	Menses month	After menses	Before menses	Menses month	After menses	
Asia	42.4	16.1	39.2	24.8	24.4	50.8	100.0
Indonesia	38.0	22.0	39.2	29.6	28.4	42.0	100.0
Sri Lanka	52.3	8.4	39.3	35.3	9.4	55.3	100.0
Thailand	36.8	24.0	39.2	9.6	35.3	55.0	100.0
Latin America							
Caribbean	41.5	17.9	40.6	22.9	23.8	53.4	100.0
Bolivia	39.9	11.2	48.9	33.2	15.2	51.7	100.0
Brazil	57.4	14.7	27.9	40.3	20.6	39.1	100.0
Colombia	34.6	24.4	41.0	18.9	26.4	54.7	100.0
Dominican Republic	54.3	16.0	29.7	28.6	21.6	49.8	100.0
Ecuador	40.8	14.3	44.8	15.3	22.4	62.4	100.0
Guatemala	42.9	21.8	35.3	19.3	29.8	50.9	100.0
Mexico	45.4	19.6	34.9	10.9	32.5	56.2	100.0
Peru	31.5	21.5	47.0	18.4	27.6	53.9	100.0
Trinidad & Tobago	26.9	17.6	55.5	20.9	17.3	61.9	100.0
Africa	32.9	13.9	53.3	29.7	15.0	55.4	100.0
Botswana	34.0	7.4	58.5	28.3	7.8	64.0	100.0
Kenya	24.2	16.8	59.0	19.0	18.9	62.1	100.0
Tunisia	27.6	19.5	52.9	25.1	20.5	54.4	100.0
Zimbabwe	45.6	11.8	42.6	46.4	12.7	40.9	100.0

Note: Any modern method includes the pill, the IUD, injectables, implants, barrier methods and sterilization; hormonal methods include the pill, injectables and implants. Regional averages are unweighted; because of rounding, figures may not add to 100.

*Among women who initiated contraceptive use in the same month as menses resumed, it was not possible to determine which event occurred first. Some women may have initiated contraceptive use before the resumption of menses because, based on past experience, they anticipated it, while others may have begun using contraceptives immediately after the first menses.

†Charles Westoff has made several refinements to the crude measure of unmet need (See: C. Westoff, "The Potential Demand for Family Planning: A New Measure of Unmet Need and Estimates for Five Latin American Countries," *International Family Planning Perspectives*, 14:45 1988). Because we defined the sample as not pregnant, currently in union and having recently given birth, many of the refinements suggested by Westoff are implicitly incorporated in our analysis of the contraceptive needs of postpartum women. Two elements of the refined measure that we did not include in our analysis are mistimed and unwanted last births among women who are pregnant or amenorrheic. In this regard, we may have slightly underestimated unmet needs.

Table 6. Percentage distribution of postpartum women exposed to the risk of pregnancy and not using contraceptives, by fertility preferences, according to country and months since last birth

Country and months since last birth	Want no more children	Want to space next birth	Want child soon	Undecided	Total
ASIA					
Indonesia					
0–23	28.0	48.6	9.6	13.8	100.0
0–3	17.6	48.6	10.2	23.5	100.0
7–9	31.1	45.2	5.9	17.8	100.0
13–18	24.0	51.8	8.6	15.6	100.0
Sri Lanka					
0–23	34.0	51.7	9.2	5.1	100.0
0–3	*	*	*	*	*
7–9	33.1	56.2	4.4	6.3	100.0
13–18	40.8	45.3	7.2	6.7	100.0
Thailand					
0–23	41.4	35.9	11.5	11.2	100.0
0–3	*	*	*	*	*
7–9	29.9	53.8	4.6	11.7	100.0
13–18	40.5	37.2	17.8	4.5	100.0
LATIN AMERICA/CARIBBEAN					
Bolivia					
0–23	74.1	14.3	8.0	3.6	100.0
0–3	*	*	*	*	*
7–9	57.9	24.7	7.9	9.5	100.0
13–18	73.7	16.1	7.4	2.6	100.0
Brazil					
0–23	56.6	18.6	20.4	4.4	100.0
0–3	61.2	23.5	7.7	7.6	100.0
7–9	62.0	11.3	14.2	12.5	100.0
13–18	59.4	15.3	19.9	5.4	100.0
Colombia					
0–23	60.7	26.0	11.1	2.2	100.0
0–3	*	*	*	*	*
7–9	67.5	27.8	4.7	0.0	100.0
13–18	48.2	26.4	19.5	5.9	100.0
Dominican Republic					
0–23	39.7	35.4	20.3	4.6	100.0
0–3	28.6	54.2	7.6	9.6	100.0
7–9	57.9	28.6	12.6	0.9	100.0
13–18	43.0	31.5	22.5	3.0	100.0
Ecuador					
0–23	56.0	30.2	7.7	6.1	100.0
0–3	57.9	42.1	0.0	0.0	100.0
7–9	56.7	33.3	6.7	3.3	100.0
13–18	51.5	29.4	10.3	8.8	100.0
Guatemala					
0–23	35.1	34.4	13.7	16.8	100.0
0–3	*	*	*	*	*
7–9	31.6	50.0	15.8	2.6	100.0
13–18	33.1	35.9	14.5	16.5	100.0
Mexico					
0–23	48.8	20.6	9.5	21.1	100.0
0–3	51.4	13.6	6.2	28.8	100.0
7–9	36.2	27.5	24.6	11.7	100.0
13–18	50.9	21.4	3.3	24.4	100.0
Peru					
0–23	71.7	17.3	8.1	2.9	100.0
0–3	*	*	*	*	*
7–9	76.2	14.3	4.8	4.7	100.0
13–18	73.8	15.4	9.2	1.6	100.0
Trinidad & Tobago					
0–23	51.5	26.3	12.1	10.1	100.0
0–3	*	*	*	*	*
7–9	56.3	25.0	12.5	6.2	100.0
13–18	40.7	33.3	11.1	14.9	100.0
NORTH AFRICA					
Egypt					
0–23	42.1	21.6	19.2	17.1	100.0
0–3	39.2	38.1	12.4	10.3	100.0
Egypt (cont.)					
7–9	40.3	25.2	23.3	11.2	100.0
13–18	43.1	17.7	22.4	16.8	100.0
Morocco					
0–23	30.3	33.1	24.7	11.9	100.0
0–3	29.3	44.8	15.5	10.4	100.0
7–9	30.0	50.0	13.3	6.7	100.0
13–18	36.9	22.8	26.2	14.1	100.0
Tunisia					
0–23	36.0	34.7	21.3	8.0	100.0
0–3	29.4	50.0	14.7	5.9	100.0
7–9	40.9	38.6	9.1	11.4	100.0
13–18	33.3	34.4	25.8	6.5	100.0
SUB-SAHARAN AFRICA					
Botswana					
0–23	28.0	40.6	19.5	11.9	100.0
0–3	*	*	*	*	*
7–9	24.5	37.7	37.7	0.0	100.0
13–18	30.2	43.4	16.0	10.4	100.0
Burundi					
0–23	22.7	51.4	20.2	5.7	100.0
0–3	9.2	90.8	0.0	0.0	100.0
7–9	9.1	84.5	5.5	0.9	100.0
13–18	24.0	48.0	20.4	7.6	100.0
Ghana					
0–23	16.7	54.7	21.3	7.3	100.0
0–3	*	*	*	*	*
7–9	8.0	80.0	8.0	4.0	100.0
13–18	17.0	56.6	22.6	3.8	100.0
Kenya					
0–23	37.1	40.7	12.6	9.6	100.0
0–3	28.2	57.9	8.5	5.4	100.0
7–9	35.1	43.5	7.0	14.4	100.0
13–18	37.7	40.7	14.6	7.0	100.0
Liberia					
0–23	12.9	31.7	38.3	17.1	100.0
0–3	16.9	33.7	39.8	9.6	100.0
7–9	7.3	33.8	39.4	19.5	100.0
13–18	16.8	31.6	30.6	21.2	100.0
Mali					
0–23	14.4	31.7	40.7	13.2	100.0
0–3	0.0	46.2	39.6	14.2	100.0
7–9	16.8	40.0	32.0	9.2	100.0
13–18	13.4	32.9	37.1	16.6	100.0
Senegal					
0–23	13.0	28.8	18.2	39.8	100.0
0–3	*	*	*	*	*
7–9	25.0	41.7	16.7	0.0	100.0
13–18	14.3	25.5	19.4	40.8	100.0
Togo					
0–23	12.6	51.3	29.4	6.7	100.0
0–3	*	*	*	*	*
7–9	15.4	61.5	15.4	7.7	100.0
13–18	7.5	62.5	20.0	10.0	100.0
Uganda					
0–23	12.4	34.4	49.3	3.9	100.0
0–3	22.6	33.8	35.2	8.4	100.0
7–9	17.3	38.7	40.7	3.3	100.0
13–18	7.7	28.9	56.3	7.1	100.0
Zimbabwe					
0–23	27.0	37.8	27.0	8.2	100.0
0–3	*	*	*	*	*
7–9	*	*	*	*	*
13–18	32.8	36.1	19.7	9.8	100.0

*Number of cases fewer than 10

highest proportion of women who wanted no more children (55%), and Sub-Saharan Africa had the lowest proportion (20%), with wide variation within each region. Among all countries surveyed, Peru and Bolivia had the largest proportions (over 70%) of women who wanted no more children.

In contrast to the proportions of women who wanted no more children, the proportions of women who wanted to space their next pregnancy varied little among regions. In Asia and Sub-Saharan Africa, an average of 40% of the women wanted to space their next pregnancy, while in North Africa and Latin America and the Caribbean the average was 28%. In all countries except Egypt, Mexico, Peru and Bolivia, at least one-fourth of the women wanted to space their next pregnancy.

Regarding women who wanted to have another child as soon as possible, there was less intraregional variation in North Africa and Asia than there was in the other

two regions. In Sub-Saharan Africa, the proportions ranged from 12% to as high as 49%, and in Latin America and the Caribbean, the proportions ranged from 8% to 20%.

Table 6 shows the potential demand for contraceptives among women who were exposed to the risk of pregnancy but were not using a method, at three different postpartum periods (0–3, 7–9 and 13–18 months) as well as for the entire postpartum period (0–23 months). For space considerations, the alternate time intervals (4–6, 10–12 and 18–23) are not shown in Table 6.

The difference between women's future childbearing preferences in the immediate postpartum period (0–3 months) and in subsequent periods is of particular interest. Data in the first column of Table 6 indicate that in the majority of the countries, women in the immediate postpartum period were not necessarily more likely to want no more children than women interviewed during later postpartum months. In fact, the proportion of women in subsequent periods (7–9 and 13–18 months postpartum) who indicated that they wanted no more children was higher than or equal to that of women in the immediate postpartum period among nine of the 13 countries for which data were available. Further, even in the two countries, Liberia and Mexico, where the proportion of women who wanted no more children decreased in the 7–9 month period, the proportion increased in later months. In only two countries, Uganda and Ecuador, were the proportions of women who wanted no more children consistently lower in later months than in the immediate postpartum period.

These findings challenge the notion that women's motivation to control fertility is highest during the immediate postpartum period, at least among postpartum women who wanted no more children. However, the differences observed in women's motivation at different points postpartum could reflect differences in the compositions of the populations. For example, women who wanted to have many children might not have been included in the 13–18 month postpartum cohort because they had already become pregnant again.

A contrasting pattern emerged among women who wanted to space the next pregnancy (Table 6, second column). In nine of the 13 countries for which data were available, the proportion of women in the immediate postpartum period who indicated that they wanted to space their pregnancy was consistently higher than or equal to the proportion of women in subsequent months who wanted to space their next pregnancy. Mexico was the only country in which the proportion of women who wanted to space their pregnancy was lower at 0–3 months than in subsequent months. In two countries, Uganda and Morocco, the proportion of women at 7–9 months who wanted to space their next pregnancy was higher than the proportion of women at 0–3 months, but even in these countries the proportion decreased at 13–18 months. Indonesia was the only country in which the proportion of women who wanted to space their next pregnancy was the highest at 13–18 months. The data suggest that women who wanted to space their next pregnancy were more motivated to control their fertility in the immediate postpartum period than were women who wanted no more children.

Table 7. Percentage of postpartum women who received perinatal care from trained health care providers, by type of care, according to country

Country	Prenatal	Delivery	Postnatal*
Asia	**83.8**	**66.6**	**88.1**
Indonesia	u	38.7	u
Sri Lanka	34.1	88.4	94.1
Thailand	83.5	72.1	82.1
Latin America/ Caribbean	**69.1**	**64.7**	**58.5**
Bolivia	55.9	43.9	46.4
Brazil	39.5	u	77.7
Colombia	83.1	72.4	80.7
Dominican Republic	97.3	90.3	15.9
Ecuador	75.5	63.9	u
Guatemala	39.9	27.5	48.5
Mexico	74.2	70.8	u
Peru	58.0	49.9	63.9
Trinidad & Tobago	98.9	99.1	76.2
North Africa	**53.2**	**45.1**	**75.3**
Egypt	62.2	37.5	62.0
Morocco	26.5	27.5	74.2
Tunisia	70.9	70.4	89.8
Sub-Saharan Africa	**75.8**	**43.1**	**56.7**
Botswana	93.1	76.0	91.5
Burundi	66.9	17.0	58.4
Ghana	86.3	40.0	50.9
Kenya	92.8	50.3	83.0
Liberia	84.0	55.8	42.3
Mali	25.6	18.1	16.7
Senegal	44.5	20.7	35.3
Togo	82.0	44.1	u
Uganda	90.9	37.8	43.2
Zimbabwe	92.0	71.4	89.3

*Refers to at least one immunization (tuberculosis, polio, diphtheria or measles) for children 6–23 months old at the time of the survey. Note: u=unavailable. Regional averages are unweighted.

Contact with Health Care Providers

One indicator of a postpartum woman's contact with trained health care providers that may be used to develop or expand postpartum family planning services is whether the woman gave birth in a hospital. The higher the proportion of women delivering in hospitals, the greater the number of potential family planning acceptors. However, if a hospital-based program does not give women any information or counseling on family planning options before delivery, a postpartum program may not be acceptable or effective. If information or counseling on postpartum contraception were provided prenatally, a hospital-based program could be very effective. Therefore, the frequency of contact between a woman and a health care provider during the prenatal period is a second indicator of the opportunity to offer postpartum contraceptive services. The third opportunity to provide contraceptives is during the postnatal period, when child immunization can be used as a proxy for a woman's access to health care providers.

Table 7 includes data on women's contact with health care providers during three phases—the prenatal period, at delivery and the postnatal period. On average, about 70% of the women reported having had contact with health care providers during the prenatal period. In 12 countries, at least 80% of the women had had contact prenatally. In only a few countries—Senegal, Mali, Brazil, Morocco and Guatemala—the proportion of women who had had prenatal contact with health care providers was less than 50%.

The proportions of women who had had contact with health care providers during delivery were high in the Asian and Latin American samples. In these two regions, about two-thirds of the women had delivered in hospitals, and in only a few countries—Bolivia, Guatemala and Indonesia—less than 50% of the women had done so. Although the overall percentage of women who had had contact with health care providers during delivery was lower in Sub-Saharan Africa and North Africa, a few countries—Zimbabwe, Botswana, and Tunisia—had percentages similar to those in the other two regions. At the same time, two countries in the Sub-Saharan region—Burundi and Mali—had the smallest proportion of women (less than 20%) reporting hospital deliveries.

In a majority of the countries, the proportion of women who had had contact with health care providers during the postnatal period was generally lower than that of the prenatal period. The proportion of women who had had postnatal contact was particularly low (less than 20%) in Mali and the Dominican Republic.

The number of prenatal and postnatal contacts with trained health care providers for each woman was unknown. Moreover, the same women were not necessarily represented in all three contact categories; it is quite probable that some women had had only one of the three types of contact, while others may have had two or three. In general, however, the data in Table 7 show that the proportions of postpartum women who had had contact with trained health care personnel in the prenatal or postnatal periods were not necessarily lower than the proportions who had had contact during delivery. In fact, in several countries, the proportions of women who had had prenatal and postnatal contact were higher than the proportion of women who had had contact during delivery. These results challenge the notion that women are more likely to have contact with health care providers at the time of delivery than before or after it.

Discussion

The DHS data analyzed in this paper offer a comparative perspective on the contraceptive behavior of postpartum women from a number of socioeconomically and culturally diverse countries. These data support some previous research findings and provide empirical evidence for previous hypotheses.

Although a relatively large number of countries included in the sample are from Latin America and the Caribbean and Sub-Saharan African regions, only three countries each are from North Africa and from Asia. The countries in the latter two regions do not necessarily represent their regions; for example, all three Asian countries included have experienced rapid fertility decline. The sample excludes large countries, such as India and Pakistan, that have lower rates of contraceptive prevalence. Hence, the regional averages, particularly for these two regions, should not be considered representative.

Very little direct information on attitudes regarding postpartum contraception was available in the data analyzed. No direct information was available on when during the postpartum period women preferred to use contraceptives and what methods they preferred using. Instead, most of the analysis focused on behavior. The contraceptive behavior observed probably reflects both the family planning program characteristics and the women's actual preferences. However, because of a lack of attitudinal data, we cannot determine to what extent behavior was influenced by the program characteristics and by women's choices. Winikoff and Mensch cautioned against making inferences about "underlying desires" regarding postpartum contraception based on the "analysis of behavior."[16] The World Health Organization's Human Reproduction Program hopes to fill this gap by supporting postpartum modules in several future Demographic and Health Surveys.[17]

The focus on current contraceptive use may have resulted in misclassification of some women. The use of injectables, for example, leads to amenorrhea among a significant proportion of the users.[18] Classifying as amenorrheic women who were using injectables would exaggerate the proportion of unexposed women using contraceptives. However, the potential effect of this kind of misclassification would be small, since injectable contraceptives are used by a significant proportion of women in only a few countries.

Another potential source of misclassification involves the separation of women into exposed and unexposed categories. Current menstrual status is used as one of the criteria for this classification, but it is not always a reliable indicator of fertility, especially when women have difficulty distinguishing between the end of lochia (bleeding after delivery) and the return of menstrual bleeding. This confusion could result in an overestimation of the proportion of exposed women. On the other hand, many women who experience resumption of menses, especially within six months after delivery, have anovulatory cycles.[18] Hence, the resumption of menses does not necessarily imply fertility, especially when menses returns within six months postpartum. However, the average duration of amenorrhea was generally twice that length in several of the countries studied.

Endocrinological studies have shown that ovulation can occur prior to menstruation in both breastfeeding and bottlefeeding mothers.[20] Generally, though, the earlier a woman experiences menses, the less likely that the bleeding has been preceded by ovulation, and the earlier the first ovulation occurs, the less likely that the woman will have had sufficient progesterone production to sustain a pregnancy.[21]

If, as suggested, menstrual status after the first six months postpartum is a more reliable indicator of fertility than before the first six months postpartum,[22] some women, especially those in the immediate postpartum periods, may not really be exposed to the risk of pregnancy. One way to refine the definition of exposed women might be to include only those who have resumed menses, are at least six months postpartum and are not abstaining. This classification method would have reduced the proportions of exposed women shown in Tables 1 and 2; in view of this, the proportions reported in the tables should be considered upper-bound estimates. For this study, such estimates were desirable, in order to determine the maximum proportion of unexposed women who were using contraceptives.

The status of postpartum women with regard to exposure to the risk of pregnancy is affected by the time since childbirth: Unexposed women tend to have shorter average times since delivery than exposed women. Contraceptive use and method choice may be affected by this time factor. The potential effect of any confounding may be minimized by the application of life-table techniques; however, previous research has shown that method choice is not affected by the length of time since delivery.[23] Further, in our analysis, data on contraceptive use were examined by time since childbirth, comparing exposed groups with unexposed groups. The results showed that the patterns of contraceptive use were different between exposed women and unexposed women, regardless of the time since childbirth.

The determinants of postpartum contraceptive behavior were not examined in our analysis. Women's socioeconomic status and family life-cycle stage are no doubt important covariates affecting contraceptive choice and behavior. Equally important are the effects of the family planning program's characteristics and policies, which require analysis of different types of information than standard survey data.

Conclusions

Despite some limitations of the data and analysis, our findings about the patterns of contraceptive use among postpartum women in developing countries have implications for program design and implementation. First and foremost, the data clearly show that reversible modern methods of contraception are not used indiscriminately by unexposed women. By and large, we found that the women using postpartum contraceptives were those who were exposed to the risk of pregnancy. At the same time, the results also suggest that in some countries refinements in the delivery of postpartum contraceptive services may be desirable. It is not generally well recognized that relatively few women need contraceptive protection soon after a childbirth. In Zimbabwe and Botswana, for example, service delivery

could be refined to minimize double protection among unexposed women.

At least half of the postpartum women appeared to initiate hormonal contraception after the resumption of menses. Our results suggest that the previous findings from Mexico[23] and Thailand[25] are generally applicable to a large number of countries. In a few countries, however program refinements may be needed with respect to distribution of the pill to unexposed women. At least one-third of the postpartum women in Zimbabwe, Brazil, Bolivia and Sri Lanka initiated use of hormonal methods long before the resumption of menses. Use of the pill by unexposed women results in double contraceptive protection during lactational infertility and may produce a shorter interval between pregnancies than if the two kinds of protection were sequenced instead of simultaneous.

An average of only about one-fifth of the postpartum women in the countries studied were exposed to the risk of pregnancy within two years of giving birth as a result of not using contraceptives. Our results on women who want no more children challenge the notion that motivation to use contraceptives is highest in the immediate postpartum period. However, a larger proportion of women in the immediate postpartum period than in the later postpartum period wanted to space their next pregnancy, presumably because some women in the later postpartum months would like to become pregnant.

Our results also question the notion that delivery is the only time women come in contact with health care providers. The proportion of women who had been in contact with providers at least once in a prenatal or postnatal period was equal to or higher than the proportion who had had contact during hospital deliveries. Contact during the prenatal period provides an opportunity to inform and counsel women about their postpartum contraceptive options before they encounter health care providers for delivery. Prenatal counseling is critical for the adoption of permanent contraceptives and could help prevent postoperative regret over sterilization;[26] it is also important for the immediate postplacental insertion of IUDs, in that it allows a woman to make a well-informed decision prior to labor, under less stressful circumstances.[27] Simply put, a good postpartum program should begin prenatally.

Although the medical safety of tubal sterilization, particularly if performed within seven days of the delivery, has been established,[28] the extent to which programs can accommodate immediate tubal sterilization is not clear. In many developing countries where the maternity hospitals and facilities are limited, the demand for this service can easily exceed the supply. Furthermore, it may be medically unsafe to perform tubal sterilization on the delivery table. Access to a separate operating theater adjacent to the delivery room is required for tubal sterilization. As for IUDs, although it is technically safe to insert the devices during the immediate postpartum period,[29] expulsions are known to be more frequent in the immediate postpartum stage than at later stages.[30] Moreover, as with sterilization, it may not be feasible to insert IUDs at the time of delivery.

Hormonal implants and injectables are normally not advised for use in the immediate postpartum period, their medical safety, especially the effect on lactation and the infant, has not yet been established. Even if their medical safety is established, these methods will have little programmatic impact because of double protection in countries where lactational amenorrhea is long. Similarly, even though the minipill has been established as medically safe for use while breastfeeding,[31] its use in the immediate postpartum period may not be desirable from a programmatic perspective, as shown by the data for Zimbabwe and Bangladesh. The immediate use of barrier methods, although known to be medically safe for women in the immediate postpartum period, will also have little demographic impact if they are providing redundant protection during amenorrhea. Double protection is not currently a widespread problem, however.

One important behavioral factor that interacts with all aspects of postpartum contraceptive use, and one that is gaining appreciation, is breastfeeding. Efforts to improve the postpartum delivery of family planning services may be most successful if providers fully integrate it with breastfeeding.[32] Even when the postpartum period is considered two years long, about 80% of the need for postpartum family planning is met without contraceptives, through lactational amenorrhea or abstinence. In addition, during this time, women have prenatal and postnatal contacts with health care providers, who can use these opportunities to deliver family planning information, counseling and services. These findings suggest that a different programmatic approach than has been used in previous postpartum contraceptive service delivery efforts may be needed to advise women intelligently and sensibly when to initiate contraceptive use and which method to use.

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Resumen

Este estudio realizado a mujeres durante el periodo de postparto se basa en datos recogidos por las Encuestas de Demografía y Salud (EDS) realizadas en 25 países en desarrollo y revela que la proporción de mujeres expuestas al riesgo del embarazo durante el periodo de los dos años posteriores al parto, varía entre un tercio en el Africa Subsahariana a aproximadamente dos tercios en América Latina y el Caribe. Más de la mitad de las mujeres que se encuentran en el periodo postparto, actualmente usan anticonceptivos. Las mujeres expuestas al riesgo del embarazo son más proclives que las mujeres no expuestas a utilizar métodos anticonceptivos reversibles, generalmente la píldora. Entre las mujeres que no están expuestas al riesgo del embarazo debido a la abstinencia o a la amenorrea relacionada con la lactancia, el 19% utiliza un método anticonceptivo, generalmente la esterilización. La proporción de usuarias que comienzan a utilizar un método moderno antes del regreso de la menstruación varía entre el 27% y 57% en los países de América Latina y el Caribe y Asia, y del 24% al 46% en los países africanos. Es menor la proporción de las usuarias de anticonceptivos hormonales que inician su uso antes de la reanudación del período menstrual. Aproximadamente una quinta parte de las mujeres expuestas no utilizan ningún método anticonceptivo. De este grupo más de la tercera parte no desean tener más hijos y otro tanto quieren espaciar su próximo embarazo.

Résumé

Cette étude de femmes post-partum, basée sur des données tirées des Enquêtes démographiques et de santé dans 25 pays en développement, a révélé que la proportion de femmes exposées au risque de grossesse dans les deux ans suivant l'accouchement varie entre un tiers en Afrique subsaharienne et près des deux tiers en Amérique latine et dans les Antilles. Plus de la moitié des femmes post-partum font couramment usage de contraceptifs. Les femmes exposées au risque de grossesse sont plus susceptibles que les femmes non exposées d'utiliser des méthodes réversibles, généralement la pilule. Parmi les femmes non exposées au risque de grossesse par suite d'abstinence ou d'aménorrhée liée à l'allaitement, 19% utilisent une méthode contraceptive, généralement la stérilisation. La proportion d'utilisatrices de contraceptifs qui commencent à utiliser une méthode moderne avant la reprise des menstruations varie entre 27% et 57% parmi les pays d'Amérique latine, des Antilles et d'Asie, et entre 24% et 46% parmi les pays africains. Des proportions plus faibles d'utilisatrices de contraceptifs hormonaux commencent à utiliser ceux-ci avant la reprise des menstruations. Environ 20% des femmes exposées n'utilisent aucun moyen contraceptif. Au sein de ce groupe, plus du tiers ne veulent plus d'enfants et un autre tiers désirent retarder la grossesse subséquente.

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References and Resources

Evaluation

Pretest/Posttest Questionnaire and Participant Evaluation

Instructions for Presenters

Pretest and Posttest Questionnaire

This questionnaire should be given before the training session to ascertain knowledge level of the audience. This same instrument should also be given afterward to assess how much the audience learned from the presentation.

The following steps are recommended when giving the pretest:

- ___ clarify any terms that may not be familiar to the participants
- ___ do not tell the participants that there will be a test again after the presentation (to avoid biasing the results of the posttest)
- ___ remain in the room during the test
- ___ ask the participants to fill out the questionnaires individually
- ___ check responses against answer sheet.

Participant Evaluation

Ask audience members to complete a form after each training session. The comments from the audience may be useful in planning future presentations.

We would appreciate your sending to us any suggestions for improving the module based on comments from the participants, or your experience as a presenter. In addition, we are interested in knowing whether you found the pretest/posttest to be useful. Please return completed evaluation forms, pretest/posttest results and other comments to:

CTU Modules Project Administrator
Family Health International
P.O. Box 13950
Research Triangle Park, NC 27709 USA

Contraception after Pregnancy: Questionnaire

Participant number (if applicable): _____ **Age:** _____ **Sex:** _____

Occupation (check one): Physician ____ **Other provider** ____ **Program manager** ____

Policy-maker ____ **Student** ____ **Other (please specify)** _____

1. The following statements relate to contraception after pregnancy. Please indicate whether each statement is **True (T)** or **False (F)**.

T F All hormonal contraceptives have a negative effect on milk production.

T F All nonhormonal contraceptive methods can be initiated immediately after childbirth.

T F Lactational amenorrhea method (LAM) provides more than 98 percent protection from pregnancy.

T F There is no difference in the technique for inserting an IUD immediately after delivery and inserting it six months later.

T F Children are more likely to survive if born two or more years after the preceding birth.

T F Nonbreastfeeding women postpartum should wait three months before beginning contraception.

T F All contraceptive methods can be started immediately after uncomplicated first- or second-trimester abortions.

T F IUDs should not be inserted after abortion in cases where infection is suspected.

T F IUDs should never be inserted earlier than four weeks postpartum.

T F Sterilization is safe to perform immediately after abortion, even if the woman is hemorrhaging.

T F Postabortion counseling increases contraceptive use.

2. LAM is considered to be a very effective method of contraception for up to:
   - ____ three months postpartum
   - ____ six months postpartum
   - ____ nine months postpartum
   - ____ 12 months postpartum

3. IUD insertion can be performed... Check (√) all that apply.
   - ____ immediately after delivery of the placenta
   - ____ within the first 48 hours postpartum
   - ____ within the first 72 hours postpartum
   - ____ within the first week after delivery
   - ____ six weeks after delivery
   - ____ at any time

4. IUD expulsion rates are:
   - ____ higher for postpartum insertions
   - ____ higher for interval insertions
   - ____ the same for both postpartum and interval insertions

5. The best time to perform sterilization postpartum is:
   - ____ immediately after delivery
   - ____ 48 hours after delivery
   - ____ one week after delivery
   - ____ four weeks after delivery

6. Male sterilization is considered effective:
   - ____ immediately after procedure
   - ____ four weeks after procedure
   - ____ six weeks after procedure
   - ____ 12 weeks after procedure

7. Contraceptive methods that can be initiated by breastfeeding women immediately after delivery include... Check (√) all that apply.

____ condoms
____ diaphragms
____ periodic abstinence
____ DMPA
____ IUDs
____ Combined oral contraceptives (COCs)
____ female sterilization

8. Contraceptive methods that should not be initiated by nonbreastfeeding women immediately after delivery include... Check (√) all that apply.

____ condoms
____ diaphragms
____ periodic abstinence
____ DMPA
____ IUDs
____ Combined oral contraceptives (COCs)
____ female sterilization

9. Fertility will most likely return earliest for:

____ nonbreastfeeding women postpartum
____ breastfeeding women postpartum
____ women postabortion

10. Diaphragms and cervical caps can be fitted immediately for:

____ nonbreastfeeding women postpartum
____ breastfeeding women postpartum
____ women after second-trimester abortion
____ all of the above
____ none of the above

11. Please circle **A** or **D** to indicate if you **agree (A)** or **disagree (D)** with the following statements.

A **D** During childbirth is a good time to talk to a woman about sterilization.

A **D** Prenatal visits provide good opportunities for talking with women about family planning.

A **D** A woman should be encouraged to discontinue breastfeeding three months after giving birth to enable her to use a hormonal contraceptive method.

A **D** Health-care providers should encourage women to fully breastfeed.

A **D** HIV-positive women should never breastfeed.

Contraception after Pregnancy: Questionnaire Answer Key

1. The following statements relate to contraception after pregnancy. Please indicate whether each statement is **True (T)** or **False (F)**.

   T (F) All hormonal contraceptives have a negative effect on milk production.

   T (F) All nonhormonal contraceptive methods can be initiated immediately after childbirth.

   (T) F Lactational amenorrhea method (LAM) provides more than 98 percent protection from pregnancy.

   T (F) There is no difference in the technique for inserting an IUD immediately after delivery and inserting it six months later.

   (T) F Children are more likely to survive if born two or more years after the preceding birth.

   T (F) Nonbreastfeeding women postpartum should wait three months before beginning contraception.

   T (F) All contraceptive methods can be started immediately after uncomplicated first- or second-trimester abortions.

   (T) F IUDs should not be inserted after abortion in cases where infection is suspected.

   T (F) IUDs should never be inserted earlier than four weeks postpartum.

   T (F) Sterilization is safe to perform immediately after abortion, even if the woman is hemorrhaging.

   (T) F Postabortion counseling increases contraceptive use.

2. LAM is considered to be a very effective method of contraception for up to:

___ three months postpartum
√ six months postpartum
___ nine months postpartum
___ 12 months postpartum

3. IUD insertion can be performed... Check (√) all that apply.

√ immediately after delivery of the placenta
√ within the first 48 hours postpartum
___ within the first 72 hours postpartum
___ within the first week after delivery
√ six weeks after delivery
___ at any time

4. IUD expulsion rates are:

√ higher for postpartum insertions
___ higher for interval insertions
___ the same for both postpartum and interval insertions

5. The best time to perform sterilization postpartum is:

___ immediately after delivery
√ 48 hours after delivery
___ one week after delivery
___ four weeks after delivery

6. Male sterilization is considered effective:

___ immediately after procedure
___ four weeks after procedure
___ six weeks after procedure
√ 12 weeks after procedure

7. Contraceptive methods that can be initiated by breastfeeding women immediately after delivery include... Check (√) all that apply.

- √ condoms
- ___ diaphragms
- ___ periodic abstinence
- ___ DMPA
- √ IUDs
- ___ Combined oral contraceptives (COCs)
- √ female sterilization

8. Contraceptive methods that should not be initiated by nonbreastfeeding women immediately after delivery include... Check (√) all that apply.

- ___ condoms
- √ diaphragms
- ___ periodic abstinence
- ___ DMPA
- ___ IUDs
- √ Combined oral contraceptives (COCs)
- ___ female sterilization

9. Fertility will most likely return earliest for:

- ___ nonbreastfeeding women postpartum
- ___ breastfeeding women postpartum
- √ women postabortion

10. Diaphragms and cervical caps can be fitted immediately for:

- ___ nonbreastfeeding women postpartum
- ___ breastfeeding women postpartum
- ___ women after second-trimester abortion
- ___ all of the above
- √ none of the above

11. Please circle **A** or **D** to indicate if you **agree (A)** or **disagree (D)** with the following statements.

A (**D**) During childbirth is a good time to talk to a woman about sterilization.

(**A**) **D** Prenatal visits provide good opportunities for talking with women about family planning.

A (**D**) A woman should be encouraged to discontinue breastfeeding three months after giving birth to enable her to use a hormonal contraceptive method.

(**A**) **D** Health-care providers should encourage women to fully breastfeed.

A (**D**) HIV-positive women should never breastfeed.

Participant Evaluation

Contraception after Pregnancy

Please answer the questions below after the *Contraceptive Technology Update* presentation on Contraception after Pregnancy. Family Health International will use this information to help improve future presentations.

Please tell us a little about yourself.

Name (optional) _____

Address (optional) _____

_____

_____

Phone (optional) _____ **Fax** (optional) _____ **E-mail** (optional) _____

What are your current job responsibilities? (Please mark all that apply.)

___ policy-maker
___ program manager
___ practicing doctor
___ practicing nurse/nurse midwife
___ nonmedical clinic personnel
___ other (specify)_____
___ community health worker
___ medical faculty
___ student (medical, nursing, midwifery)
___ health educator
___ pharmacist

Please tell us what you think about the presentation.

Did the presentation address what you consider to be the most important programmatic and clinical issues on the topic? (Please mark one box.) ☐ Yes ☐ No

What, if any, additional information do you think should have been covered? (Please specify.)

_____

_____

What, if any, part of the presentation should have been excluded? (Please specify.)

_____

_____

How familiar were you with the information in the module prior to this presentation?

(Please mark one box.)

☐ Very familiar ☐ Somewhat familiar ☐ Not at all familiar

Which two presentation messages do you think will be the most useful to you?

1. _____

2. _____

Please continue on next page.

How did you benefit from attending this presentation? (Please mark all that apply.)

___ learned more about the need for contraception after pregnancy
___ learned more about the timing of initiation of contraceptive methods after pregnancy
___ verified existing knowledge
___ gained a new perspective related to contraception after pregnancy
___ increased confidence in providing contraception after pregnancy
___ did not benefit
___ other (specify)_____

Based on the information presented today, would you consider making any changes to your professional practice? ☐ Yes ☐ No

If Yes, what changes would you consider?

If No, why would you not consider making any changes?

_____

_____

Please respond to each of the following statements by circling the answer that best describes your feelings.

The information presented was relevant to my job.

Strongly agree Agree Disagree Strongly disagree

The slides and other visual aids enhanced my understanding of the presentation content.

Strongly agree Agree Disagree Strongly disagree

The training activities enhanced my understanding of the presentation content (if applicable).

Strongly agree Agree Disagree Strongly disagree

The presentation was too technical.

Strongly agree Agree Disagree Strongly disagree

The duration of the presentation was too long.

Strongly agree Agree Disagree Strongly disagree

Please rate the following presentation components as either excellent (A), good (B), fair (C), or poor (D). If the presenter did not use a particular component, please indicate "not applicable" or "NA".

	Rating (A, B, C, D or NA)	Comments
35 mm slides/transparencies	_____	_____
fact sheet handout	_____	_____
audience note pages	_____	_____
scientific articles	_____	_____
pretest/posttest	_____	_____
training activities	_____	_____
other (specify)	_____	_____

Please add any additional comments or suggestions.

_____

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_____

Thank you for your assistance. Please return completed form to: CTU Modules Project Administrator
Family Health International
P.O. Box 13950
Research Triangle Park, NC 27709 USA

Audience Handouts

WH 3A.5

Contraception after Pregnancy

The initiation and use of a contraceptive method after delivery or abortion. Method should be initiated before fertility returns.

Contraceptive Options after Childbirth

Breastfeeding Is Important

- Breastfed infants have lower mortality rates than those who are not breastfed
- International Planned Parenthood Federation recommends that:
  - health-care providers encourage full breastfeeding
  - breastfeeding not be discontinued to initiate a contraceptive method
  - the method not adversely affect breastfeeding or infant health
- When the mother is HIV-positive:
  - risk to the infant can be *eliminated* if a safe, ongoing and clean method of bottlefeeding is available
  - risk to the infant may be *reduced* if breastfeeding is limited to the first 6 months

Breastfeeding Women: *Nonhormonal Methods*

All nonhormonal contraceptive methods can be used safely by breastfeeding women

- No interference with breastfeeding
- No effect on the quality or quantity of breastmilk
- No effect on infant growth and development

Breastfeeding Women: *Progestin-Only Methods*

- Progestin-only methods include:
  - progestin-only pills (POPs)
  - progestin-only injectables (DMPA, NET-EN)
  - implants (Norplant)
  - levonorgestrel intrauterine system (LNg IUS)
- No effect on breastfeeding, breastmilk production or infant growth and development
- WHO recommends delay of 6 weeks because very young infants may be at risk to exposure to the hormone

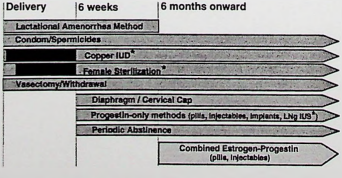
Breastfeeding women who have unprotected intercourse can safely use POPs for emergency contraception

Breastfeeding Women: *Combined Estrogen-Progestin Methods*

- Combined methods include:
  - combined oral contraceptives (COCs)
  - monthly injectables (Mesigyna, Cyclofem)
- Not to be used during first 6 weeks postpartum due to effect on establishment of lactation
- Not recommended during first 6 months postpartum due to decrease in milk production
- Can be used at 6 months postpartum, but not a preferred option

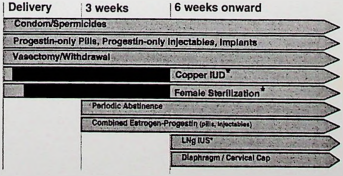
Breastfeeding women who have unprotected intercourse can safely use COCs for emergency contraception

Method Initiation for Breastfeeding Women



** can be initiated 4 - 6 weeks if uterus has returned to normal size*

Method Initiation for Nonbreastfeeding Women Postpartum



** can be initiated 4 - 6 weeks if uterus has returned to normal size*

Contraceptive Options after Abortion

Women regain fertility 2 - 4 weeks after abortion

Uncomplicated First-Trimester Abortion: *Contraceptive Options*

- Induced abortion: any method can be used immediately *except*:
  - diaphragm or cervical cap: delay 4 - 6 weeks
- Spontaneous abortion: any method can be used immediately
  - diaphragm or cervical cap: 4 - 6 week delay may be necessary in some cases

Uncomplicated Second-Trimester Abortion: *Contraceptive Options*

- Induced and spontaneous abortion: any method can be used immediately *except*:
  - diaphragm or cervical cap: delay 4 - 6 weeks
  - IUD: delay insertion 4 - 6 weeks unless provider is trained in insertion immediately after abortion
  - female sterilization: easier to perform if delayed until uterus returns to normal position

Complicated Abortion: *Infection*

- If infection is present or suspected, delay female sterilization and IUD insertion
- Follow guidelines for uncomplicated abortion for initiation of all other methods
- Advise client to avoid intercourse until infection is resolved
  - use condoms if intercourse is not avoided

Complicated Abortion: *Genital Trauma*

- If genital trauma exists, delay:
  - female sterilization, unless performed during required surgery
  - IUD insertion
  - female barrier methods and spermicides (depending on extent and location of injury)
- Follow guidelines for uncomplicated abortion for initiation of all other methods

Complicated Abortion: *Hemorrhage and Severe Anemia*

- Delay methods that increase or maintain short-term blood loss (female sterilization, IUD)
- Follow guidelines for uncomplicated abortion for initiation of all other methods

R. Lord

R. Lord

R. Lord

Contraceptive Counseling of Women after Abortion

Women who have undergone abortion should be treated with respect

Counseling can help women:

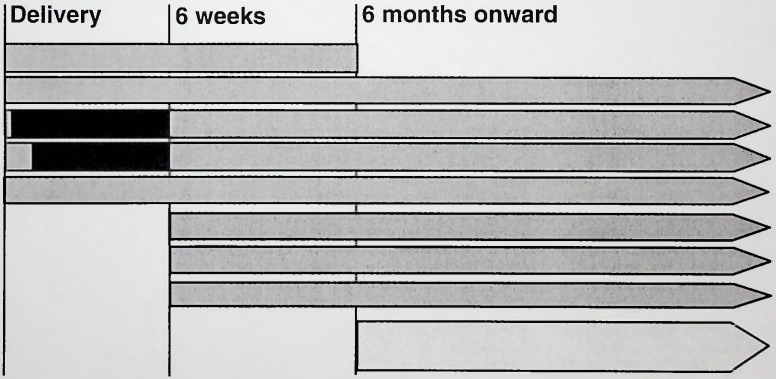
- identify factors that led to abortion
- make informed choice of contraceptive method
- choose highly effective method when pregnancy is life threatening
- become aware of emergency contraception
- understand implications for future fertility

Counseling the Partners of Clients after Abortion

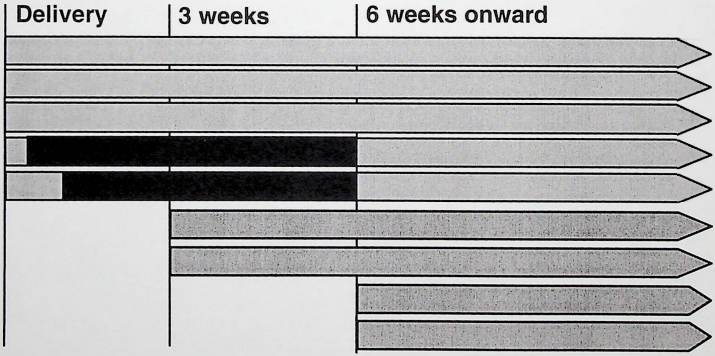
- Counseling male partners of abortion clients can increase their support for contraception
- Egyptian study found that husband's support for family planning was strongest predictor of client's use of contraception
- Counseling male partners may also increase awareness and use of vasectomy or male condoms

Source: Abdel-Tawab N., 1999.

Slide 34 Activity:
Method Initiation for Breastfeeding Women



Slide 35 Activity: *Method Initiation for Nonbreastfeeding Women Postpartum*



Patient Scenarios

The following patient scenarios are to be used for the Slide 48 Activity in the narrative. Make copies and cut them so that each question is on an individual strip of paper. Distribute them to the participants. An Answer Key follows.

---

1. A 20-year-old woman is two-weeks postpartum after giving birth to her first child. She is generally healthy and is breastfeeding. She possibly wants more children. What contraceptive methods can she initiate at this time?

---

2. A 32-year-old woman is immediately postpartum after giving birth by cesarean section. This is her fourth healthy child. She is generally healthy and is planning to breastfeed. What contraceptive methods can she initiate at this time?

---

3. A 23-year-old woman is six-weeks postpartum after giving birth to her second child, who died soon after delivery. She had a difficult pregnancy and is not planning to have another child soon. What contraceptive methods can she initiate at this time?

---

4. A 26-year-old woman is four-months postpartum after giving birth to her first child. She is breastfeeding, and both mother and child are healthy. She wants to postpone her next pregnancy for a few years. What contraceptive methods can she initiate at this time?

5. A 28-year-old woman is two-weeks postpartum with her third child. She is breast-feeding but does not want to rely on LAM. She wants to use another method and feels strongly about not having more children. What contraceptive methods can she initiate at this time?

---

6. A 29-year-old woman experienced a first-trimester uncomplicated miscarriage two weeks ago. She would like to get pregnant again but wants to delay it for a few months. What contraceptive methods can she initiate at this time?

---

7. A 36-year-old woman underwent a second-trimester abortion one week ago, complicated by an infection which has not yet completely resolved. She does not want any more children. What contraceptive methods can she initiate at this time?

Patient Scenarios (Answer Key)

1. A 20-year-old woman is two-weeks postpartum after giving birth to her first child. She is generally healthy and is breastfeeding. She possibly wants more children. What contraceptive methods can she initiate at this time?

A: LAM, condoms, spermicides or withdrawal.

2. A 32-year-old woman is immediately postpartum after giving birth by cesarean section. This is her fourth healthy child. She is generally healthy and is planning to breastfeed. What contraceptive methods can she initiate at this time?

A: LAM, condoms, spermicides, copper IUD, withdrawal, female sterilization (if discussed and consent given in advance) or vasectomy (if discussed and consent given in advance).

3. A 23-year-old woman is six-weeks postpartum after giving birth to her second child, who died soon after delivery. She had a difficult pregnancy and is not planning to have another child soon. What contraceptive methods can she initiate at this time?

A: She may be interested in a long-term method such as progestin-only or combined injectables, implants, copper IUD or LNg IUS. Other appropriate methods include progestin-only or combined pills, withdrawal, periodic abstinence, condoms, spermicides, diaphragm or cervical cap.

4. A 26-year-old woman is four-months postpartum after giving birth to her first child. She is breastfeeding, and both mother and child are healthy. She wants to postpone her next pregnancy for a few years. What contraceptive methods can she initiate at this time?

A: She may be interested in a long term method such as progestin-only injectables, implants, copper IUD or LNg IUS. Other appropriate methods include progestin-only pills, withdrawal, periodic abstinence, condoms, spermicides, diaphragm or cervical cap.

5. A 28-year-old woman is two-weeks postpartum with her third child. She is breast-feeding but does not want to rely on LAM. She wants to use another method and feels strongly about not having more children. What contraceptive methods can she initiate at this time?

A: Until she is six-weeks postpartum, the only methods she may use are condoms, spermicides, withdrawal or vasectomy (if discussed and consent given in advance). At six weeks, female sterilization may be initiated (if discussed and consent given in advance), as well as other long-term methods such as injectables, implants, copper IUD or LNg IUS.

6. A 29-year-old woman experienced a first-trimester uncomplicated miscarriage two weeks ago. She would like to get pregnant again but wants to delay it for a few months. What contraceptive methods can she initiate at this time?

A: Condoms, spermicides, progestin-only pills, combined pills, withdrawal or periodic abstinence.

7. A 36-year-old woman underwent a second-trimester abortion one week ago, complicated by an infection which has not yet completely resolved. She does not want any more children. What contraceptive methods can she initiate at this time?

A: Condoms, spermicides, progestin-only pills, injectables or implants, combined pills or injectables, withdrawal, periodic abstinence or vasectomy (if discussed and consent given in advance). Once the infection is resolved and it has been at least six weeks since the procedure, she may choose to use other long-term methods such as female sterilization (if discussed and consent given in advance), copper IUD or LNg IUS.

Audience Notes

1.

Contraception after Pregnancy

2.

Topics to Be Covered

- Contraception after pregnancy: Overview
- Contraceptive options after childbirth
- Contraceptive options after abortion

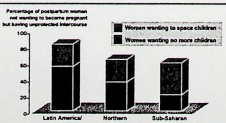
3.

Contraception after Pregnancy: *Overview*

- Unmet need for contraception
- Integration with other health services
- Characteristics of effective services
- Counseling

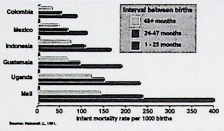
4.

Unmet Need: *Fertility Preferences of Women Postpartum*



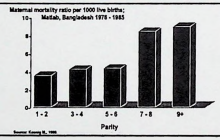
5.

Birth Spacing Saves Infant Lives



6.

Family Planning Can Reduce Maternal Mortality



7.

Family Planning Can Reduce Abortion-Related Deaths

	Number of Unsafe Abortions Annually	Risk of Death from Abortion
Worldwide	20,000,000	1 in 300
Asia	9,240,000	1 in 250
Africa	3,740,000	1 in 150

8.

Contraception after Pregnancy: *Definition and Return to Fertility*

The initiation and use of a contraceptive method after childbirth or abortion. Ideally, initiated before fertility returns.

Return to fertility:	
After childbirth	
Not breastfeeding	Occurs as early as 4 weeks postpartum
Fully breastfeeding	May be delayed until 6 months postpartum and possibly later.
After abortion	Occurs as early as 2 weeks after procedure

9.

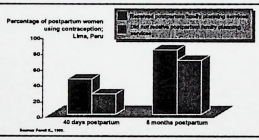
Integration of Services: *Health-Care Contacts*

The period during and soon after pregnancy can be a unique opportunity for providers to offer family planning information and services

Childbirth	Abortion
Prenatal visits	Before procedure
Following delivery	Following procedure
Postpartum/ infant health visits	When treated for complications

10.

Integration of Services Can Increase Contraceptive Prevalence



11.

Integration of Services: *Facilities*

Facilities adding contraceptive services after pregnancy should have:

- private area for counseling
- private area where methods can be provided
- supply of contraceptives and place to store them

12.

Effective Services after Pregnancy

Effective services include:

- offering a variety of contraceptive methods
- training all levels of providers in clinical skills and counseling

13.

Training of Providers

Providers of contraceptive services can benefit from training in:

- communication skills
- how to be reasonably sure a woman is not pregnant
- how to help women make voluntary informed choices
- characteristics of contraceptive methods and their initiation time following childbirth or abortion

Staff should know where to refer for methods not provided on-site

14.

Contraceptive Counseling after Pregnancy

Counseling can help client make an informed choice

To help client select a method, providers should:

- help to assess her reproductive goals, discussing short- and long-term contraceptive needs
- provide brief, clear, accurate information about all methods of interest to client

15.

Contraceptive Counseling after Pregnancy (cont'd)

After client selects a method, provider should discuss:

- chosen method in detail
- the availability of emergency contraception
- condom use, if client is at risk for STDs/HIV

Counsel male partners, if appropriate

16.

Contraception for HIV-Positive Women after Pregnancy

HIV-positive women especially need to know:

- the correct and consistent use of male and female condoms can prevent STD/HIV transmission
- using another contraceptive in addition to a condom (dual method use) reduces the chance of pregnancy, thus avoiding HIV transmission to a child

17.

Contraceptive Options After Childbirth

- Importance of breastfeeding
- Contraceptive options for breastfeeding women
- Timing of method initiation for breastfeeding women
- Timing of method initiation for nonbreastfeeding women

18.

Breastfeeding Is Important

- Breastfed infants have lower mortality rates than those who are not breastfed
- International Planned Parenthood Federation recommends that:
  - health-care providers encourage full breastfeeding
  - breastfeeding not be discontinued to initiate a contraceptive method
  - the method not adversely affect breastfeeding or infant health

19.

Breastfeeding When the Mother is HIV-Positive

- Average risk of acquiring HIV through breastmilk is at least 16%
- According to WHO:
  - risk can be *eliminated* if a safe, ongoing and clean alternative method of bottlefeeding is available
  - risk may be *reduced* if breastfeeding is limited to the first 6 months

Providers can help these mothers decide whether the risks of breastfeeding outweigh the proven benefits

20.

Contraceptive Options for Breastfeeding Women

- Nonhormonal methods
- Progestin-only methods
- Combined estrogen-progestin methods

21.

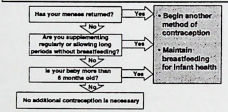
Breastfeeding Women: *Nonhormonal Methods*

All nonhormonal contraceptive methods can be used safely by breastfeeding women

- No interference with breastfeeding
- No effect on the quality or quantity of breastmilk
- No effect on infant growth and development

22.

Nonhormonal Methods: *Lactational Amenorrhea Method (LAM)*



23.

Nonhormonal Methods: *Barrier Methods*

- *Condoms* are highly effective at preventing pregnancy and STDs/HIV when used consistently and correctly
- *Male* and *female condoms* and *spermicides* can be used immediately postpartum
- *Diaphragm* and *cervical cap* use must be delayed until 6 weeks postpartum

24.

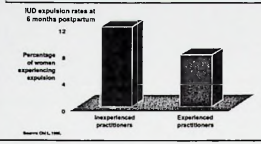
Nonhormonal Methods: *Copper IUDs*

- Specially trained providers can safely insert IUDs:
  - immediately after delivery of the placenta
  - during cesarean section
  - within 48 hours of childbirth
- If not inserted within 48 hours, delay 4 - 6 weeks

Clients should be counseled that postpartum IUD insertions have higher expulsion rates than do interval insertions

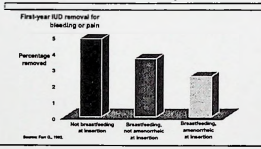
25.

Copper IUDs: *Experience and Training Reduce Expulsion Rate*



26.

Copper IUDs: *Removal Rates Lower for Breastfeeding Women*



27.

Nonhormonal Methods: *Periodic Abstinence*

- Abstaining from intercourse during woman's fertile time
- Can be difficult to use while breastfeeding because signs of fertility may be absent or hard to interpret

28.

Nonhormonal Methods: *Withdrawal*

- Presumably more effective when woman is fully breastfeeding and fertility is reduced
- Pregnancy rates for nonbreastfeeding women range from 4% - 21%

29.

Nonhormonal Methods: *Female Sterilization*

- Ideally performed within 48 hours after delivery
- May be performed immediately following delivery or during cesarean section
- If not performed within 1 week of delivery, delay 4 to 6 weeks

Thoroughly counsel clients in advance and obtain informed consent

30.

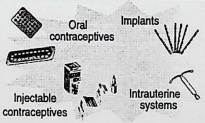
Nonhormonal Methods: *Male Sterilization*

- Not effective until after 12 weeks or 20 ejaculations
- Can be timed to coincide with the postpartum period when fertility is reduced or abstinence may be practiced

Clients should be thoroughly counseled in advance and give informed consent

31.

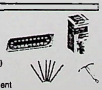
Breastfeeding Women: *Hormonal Methods*



32.

Breastfeeding Women: *Progestin-Only Methods*

- Progestin-only methods include:
  - progestin-only pills (POPs)
  - progestin-only injectables (DMPA, NET-EN)
  - implants (Norplant)
  - levonorgestrel intrauterine system (LNg IUS)
- No effect on breastfeeding, breastmilk production or infant growth and development
- WHO recommends delay of 6 weeks because very young infants may be at risk of exposure to the progestin



Breastfeeding women who have unprotected intercourse can safely use POPs for emergency contraception

33.

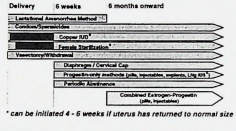
Breastfeeding Women: *Combined Estrogen-Progestin Methods*

- Combined methods include:
  - combined oral contraceptives (COCs)
  - monthly injectables (Mesigyna, Cyclofem)
- Not to be used during first 6 weeks postpartum due to effect on establishment of lactation
- Not recommended during first 6 months postpartum due to decrease in milk production
- Can be used at 6 months postpartum, but not a preferred option

Breastfeeding women who have unprotected intercourse can safely use COCs for emergency contraception

34.

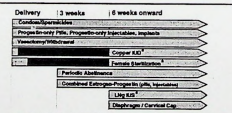
Method Initiation for Breastfeeding Women



** can be initiated 4 - 6 weeks if uterus has returned to normal size*

35.

Method Initiation for Nonbreastfeeding Women Postpartum



** can be initiated 4 - 6 weeks if uterus has returned to normal size*

36.

Contraceptive Options After Abortion

- Types of abortion
- Contraceptive need after abortion
- Uncomplicated abortion
- Complicated abortion
- Provider training
- Counseling

37.

Types of Abortion

Induced	Spontaneous (miscarriage)

- Contraceptive needs may differ
- Those who want to avoid pregnancy have the same contraceptive options

38.

Contraceptive Need after Abortion

- Women regain fertility 2 - 4 weeks after abortion
- To avoid another pregnancy, contraception should be initiated as soon as possible after abortion

39.

Uncomplicated First-Trimester Abortion: *Contraceptive Options*

- Induced and spontaneous abortion: any method can be used immediately *except:*
  - diaphragm or cervical cap: delay of 4 - 6 weeks may be necessary in some cases

40.

Uncomplicated Second-Trimester Abortion: *Contraceptive Options*

- Induced and spontaneous abortion: any method can be used immediately *except:*
  - diaphragm or cervical cap: delay 4 - 6 weeks
  - IUD: delay insertion 4 - 6 weeks unless provider is trained in insertion immediately after abortion
  - female sterilization: easier to perform if delayed until uterus returns to normal position

41.

Complicated Abortion:
Contraceptive Issues

Complications that can affect contraceptive choice include:

- infection
- trauma to genital tract
- hemorrhage, leading to severe anemia

2 or more complications can occur concurrently

42.

Complicated Abortion: *Infection*

- If infection is present or suspected, delay:
  - female sterilization
  - IUD insertion
- Follow guidelines for uncomplicated abortion for initiation of all other methods
- Advise client to avoid intercourse until infection is resolved
  - use condoms if intercourse is not avoided

43.

Complicated Abortion:
Genital Trauma

- If genital trauma exists, delay:
  - female sterilization, unless performed during required surgery
  - IUD insertion
  - female barrier methods and spermicides (depending on extent and location of injury)
- Follow guidelines for uncomplicated abortion for initiation of all other methods

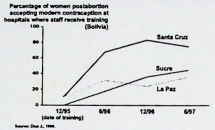
44.

Complicated Abortion:
Hemorrhage and Severe Anemia

- Delay methods that increase or maintain short-term blood loss
  - female sterilization
  - IUD
- Follow guidelines for uncomplicated abortion for initiation of all other methods

45.

Training and Counseling Increase Contraceptive Acceptance



46.

Contraceptive Counseling of Women after Abortion

Women who have undergone abortion should be treated with respect

Counseling can help women:

- identify factors that led to abortion
- make informed choice of contraceptive method
- choose highly effective method when pregnancy is life threatening
- become aware of emergency contraception
- understand implications for future fertility

47.

Counseling the Partners of Clients after Abortion

- Counseling male partners of abortion clients can increase their support for contraception
- Egyptian study found that husband's support for family planning was strongest predictor of client's use of contraception
- Counseling male partners may also increase awareness and use of vasectomy or male condoms

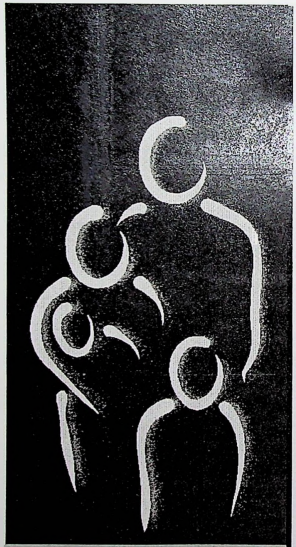
48.

Contraception after Pregnancy: *Conclusion*

After pregnancy, many women want to delay or avoid getting pregnant again

- Providing family planning to women for use after pregnancy can save lives and improve health and quality of life
- Many contraceptive methods can be used soon after pregnancy
- Integrating contraceptive services into maternal and child health services can be highly effective

Slides



Contraceptive Technology Update Series

Contraception after Pregnancy

Topics to Be Covered

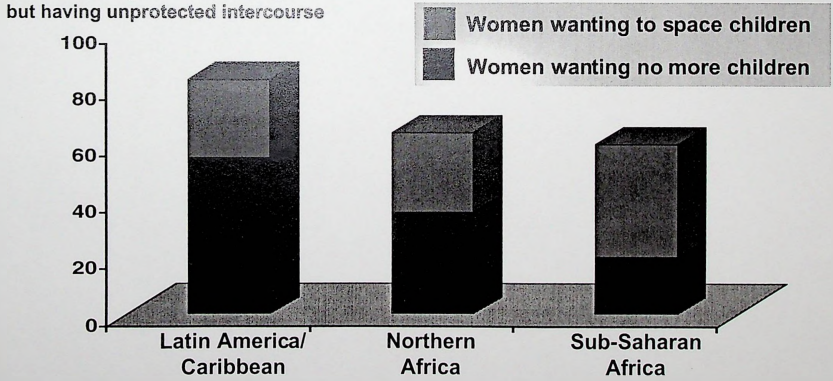
- Contraception after pregnancy: Overview
- Contraceptive options after childbirth
- Contraceptive options after abortion

Contraception after Pregnancy: *Overview*

- Unmet need for contraception
- Integration with other health services
- Characteristics of effective services
- Counseling

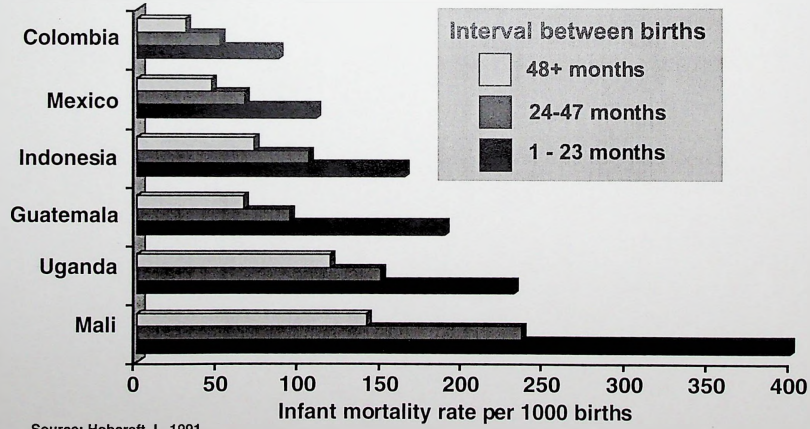
Unmet Need: *Fertility Preferences of Women Postpartum*

Percentage of postpartum women not wanting to become pregnant but having unprotected intercourse



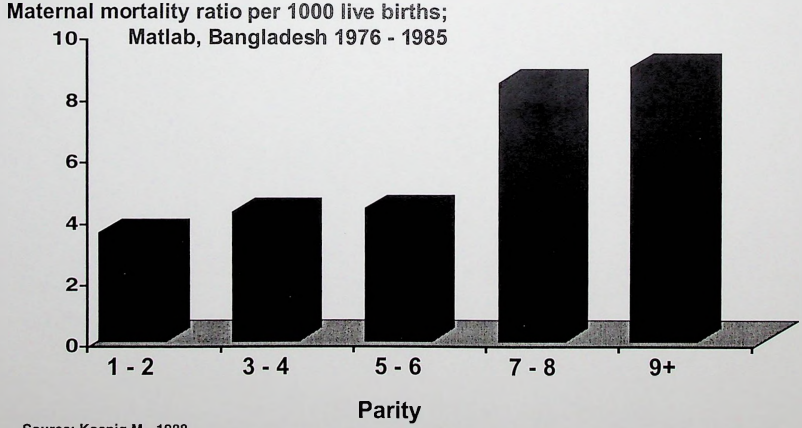
Source: Thapa S., 1992.

Birth Spacing Saves Infant Lives



Source: Hobcraft J., 1991.

Family Planning Can Reduce Maternal Mortality



Source: Koenig M., 1988.

Family Planning Can Reduce Abortion-Related Deaths

	Number of Unsafe Abortions Annually	Risk of Death from Abortion
Worldwide	20,000,000	1 in 300
Asia	9,240,000	1 in 250
Africa	3,740,000	1 in 150

Source: WHO, 1993.

Contraception after Pregnancy: *Definition and Return to Fertility*

The initiation and use of a contraceptive method after childbirth or abortion.
Ideally, initiated before fertility returns.

Return to fertility:	
After childbirth	
Not breastfeeding	**Occurs as early as 4 weeks postpartum**
Fully breastfeeding	**May be delayed until 6 months postpartum and possibly later**
After abortion	**Occurs as early as 2 weeks after procedure**

Integration of Services: *Health-Care Contacts*

The period during and soon after pregnancy can be a unique opportunity for providers to offer family planning information and services

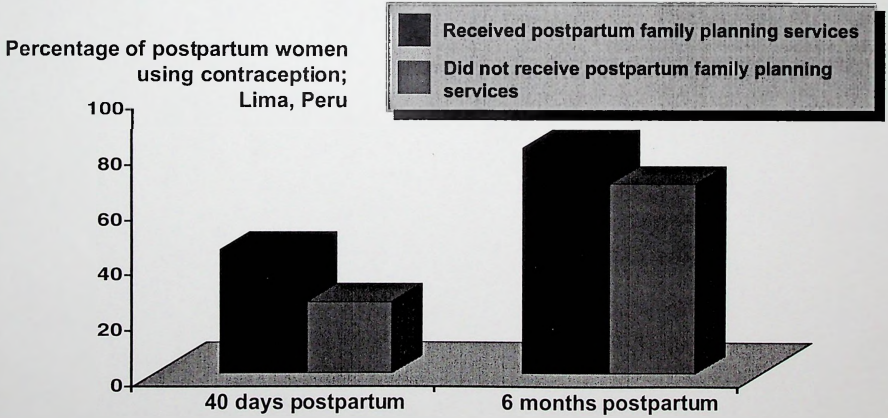
Childbirth

- Prenatal visits
- Following delivery
- Postpartum/ infant health visits

Abortion

- Before procedure
- Following procedure
- When treated for complications

Integration of Services Can Increase Contraceptive Prevalence

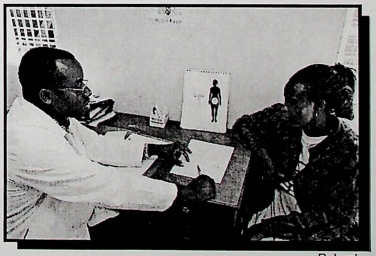


Source: Foreit K., 1993.

Integration of Services: *Facilities*

Facilities adding contraceptive services after pregnancy should have:

- private area for counseling
- private area where methods can be provided
- supply of contraceptives and place to store them



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Effective Services after Pregnancy

Effective services include:

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- offering a variety of contraceptive methods
- training all levels of providers in clinical skills and counseling

Training of Providers

Providers of contraceptive services can benefit from training in:

- communication skills
- how to be reasonably sure a woman is not pregnant
- how to help women make voluntary informed choices
- characteristics of contraceptive methods and their initiation time following childbirth or abortion

Staff should know where to refer for methods not provided on-site

Contraceptive Counseling after Pregnancy

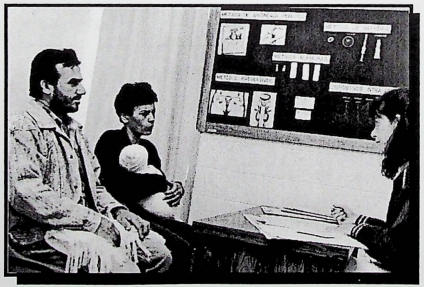
Counseling can help client make an informed choice

To help client select a method, providers should:

- help to assess her reproductive goals, discussing short- and long-term contraceptive needs
- provide brief, clear, accurate information about all methods of interest to client

Contraceptive Counseling after Pregnancy (cont'd)

After client selects a method, provider should discuss:



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- chosen method in detail
- the availability of emergency contraception
- condom use, if client is at risk for STDs/HIV

Counsel male partners, if appropriate

Contraception for HIV-Positive Women after Pregnancy

HIV-positive women especially need to know:

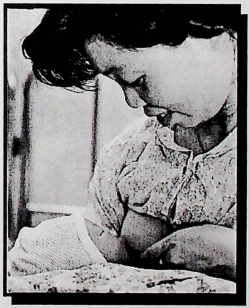
- the correct and consistent use of male and female condoms can prevent STD/HIV transmission
- using another contraceptive in addition to a condom (dual method use) reduces the chance of pregnancy, thus avoiding HIV transmission to a child

Contraceptive Options after Childbirth

- Importance of breastfeeding
- Contraceptive options for breastfeeding women
- Timing of method initiation for breastfeeding women
- Timing of method initiation for nonbreastfeeding women

Breastfeeding Is Important

- Breastfed infants have lower mortality rates than those who are not breastfed
- International Planned Parenthood Federation recommends that:
  - health-care providers encourage full breastfeeding
  - breastfeeding not be discontinued to initiate a contraceptive method
  - the method not adversely affect breastfeeding or infant health



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Sources: WHO, 2000; IPPF, 1990.

Breastfeeding When the Mother is HIV-Positive

- Average risk of acquiring HIV through breastmilk is at least 16%
- According to WHO:
  - risk can be *eliminated* if a safe, ongoing and clean alternative method of bottlefeeding is available
  - risk may be *reduced* if breastfeeding is limited to the first 6 months

Providers can help these mothers decide whether the risks of breastfeeding outweigh the proven benefits

Source: Nduati R., 2000.

Contraceptive Options for Breastfeeding Women

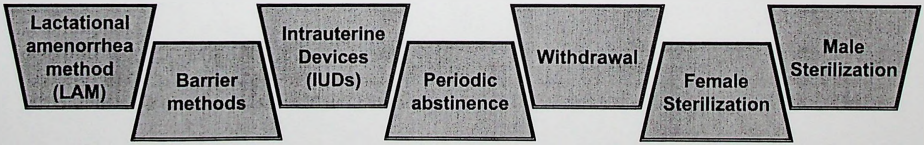
- Nonhormonal methods
- Progestin-only methods
- Combined estrogen-progestin methods

World Health Organization

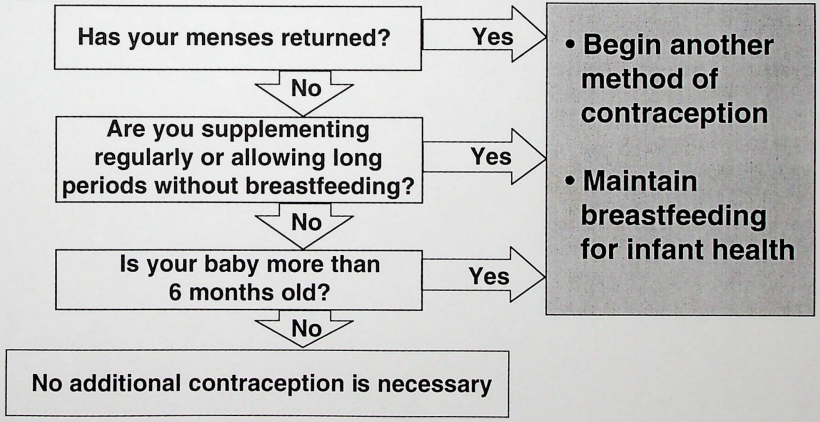
Breastfeeding Women: *Nonhormonal Methods*

All nonhormonal contraceptive methods can be used safely by breastfeeding women

- No interference with breastfeeding
- No effect on the quality or quantity of breastmilk
- No effect on infant growth and development



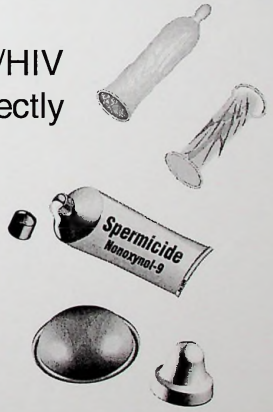
Nonhormonal Methods: *Lactational Amenorrhea Method (LAM)*



Source: Institute for Reproductive Health, 1994.

Nonhormonal Methods: *Barrier Methods*

- *Condoms* are highly effective at preventing pregnancy and STDs/HIV when used consistently and correctly
- *Male* and *female condoms* and *spermicides* can be used immediately postpartum
- *Diaphragm* and *cervical cap* use must be delayed until 6 weeks postpartum

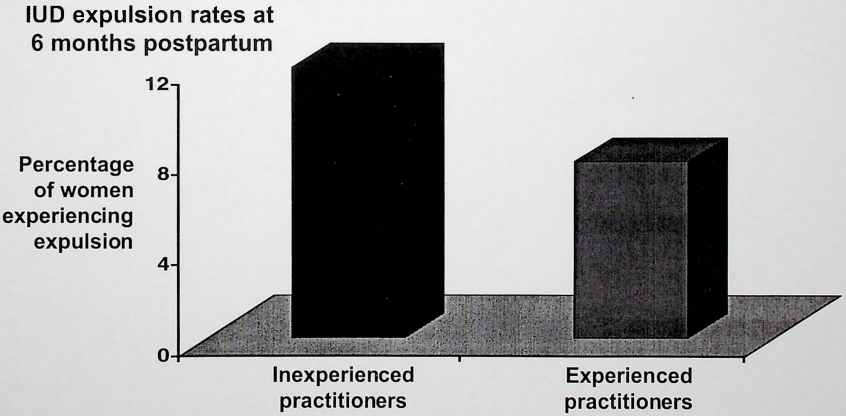


Nonhormonal Methods: *Copper IUDs*

- Specially trained providers can safely insert IUDs:
  - immediately after delivery of the placenta
  - during cesarean section
  - within 48 hours of childbirth
- If not inserted within 48 hours, delay 4 - 6 weeks

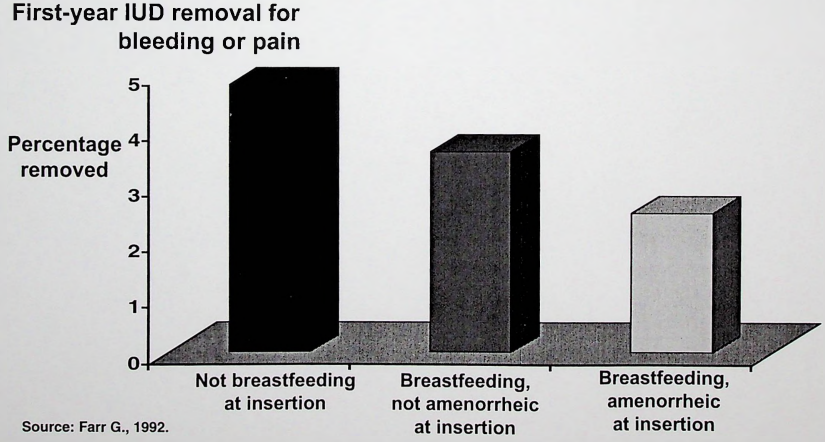
Clients should be counseled that postpartum IUD insertions have higher expulsion rates than do interval insertions

Copper IUDs: *Experience and Training Reduce Expulsion Rate*



Source: Chi I., 1985.

Copper IUDs: *Removal Rates Lower for Breastfeeding Women*



Source: Farr G., 1992.

Nonhormonal Methods: *Periodic Abstinence*

- Abstaining from intercourse during woman's fertile time
- Can be difficult to use while breastfeeding because signs of fertility may be absent or hard to interpret

Nonhormonal Methods: *Withdrawal*

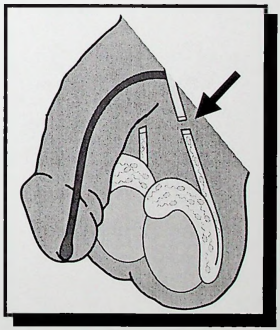
- Presumably more effective when woman is fully breastfeeding and fertility is reduced
- Pregnancy rates for nonbreastfeeding women range from 4% - 21%

Source: Debusschere R., 1980.

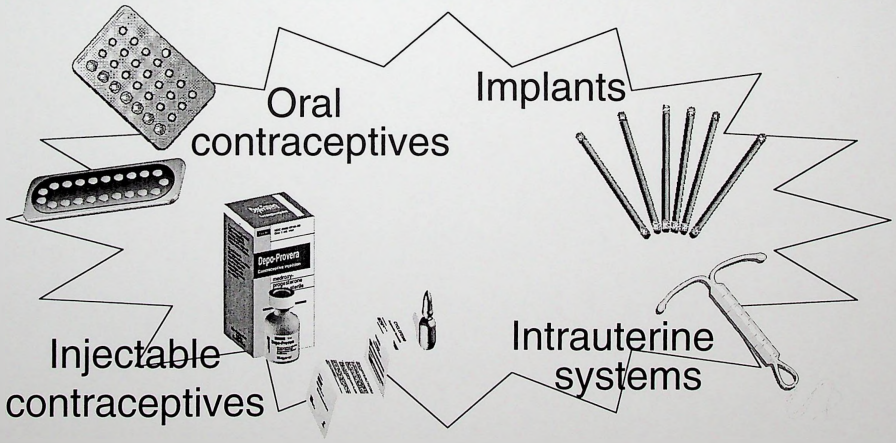
Nonhormonal Methods: *Male Sterilization*

- Not effective until after 12 weeks or 20 ejaculations
- Can be timed to coincide with the postpartum period when fertility is reduced, or abstinence may be practiced

Thoroughly counsel clients in advance and obtain informed consent

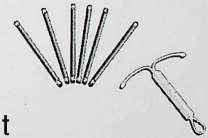


Breastfeeding Women:
Hormonal Methods



Breastfeeding Women: *Progestin-Only Methods*

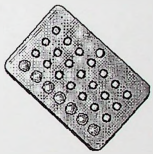
- Progestin-only methods include:
  - progestin-only pills (POPs)
  - progestin-only injectables (DMPA, NET-EN)
  - implants (Norplant)
  - levonorgestrel intrauterine system (LNg IUS)



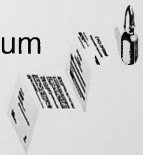
- No effect on breastfeeding, breastmilk production or infant growth and development
- WHO recommends delay of 6 weeks because very young infants may be at risk of exposure to the progestin

Breastfeeding women who have unprotected intercourse can safely use POPs for emergency contraception

Breastfeeding Women: *Combined Estrogen-Progestin Methods*

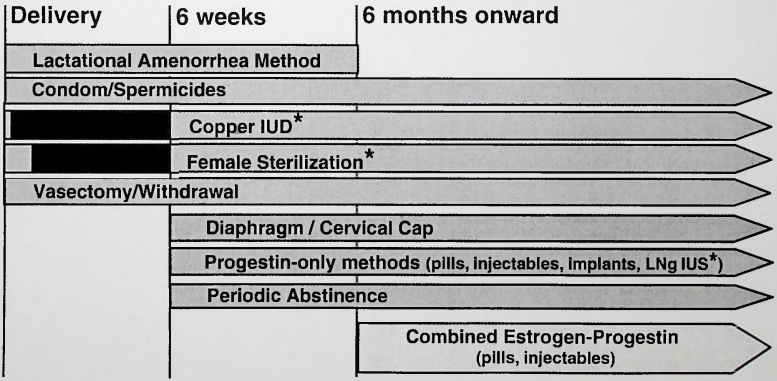


- Combined methods include:
  - combined oral contraceptives (COCs)
  - monthly injectables (Mesigyna, Cyclofem)
- Not to be used during first 6 weeks postpartum due to effect on establishment of lactation
- Not recommended during first 6 months postpartum due to decrease in milk production
- Can be used at 6 months postpartum, but not a preferred option



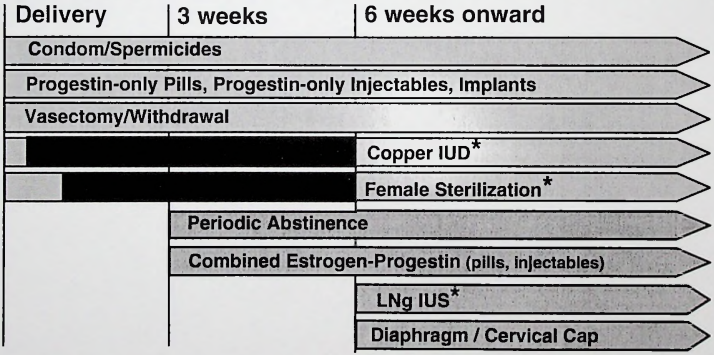
Breastfeeding women who have unprotected intercourse can safely use COCs for emergency contraception

Method Initiation for Breastfeeding Women



** can be initiated 4 - 6 weeks if uterus has returned to normal size*

Method Initiation for Nonbreastfeeding Women Postpartum



** can be initiated 4 - 6 weeks if uterus has returned to normal size*

Contraceptive Options after Abortion

- Types of abortion
- Contraceptive need after abortion
- Uncomplicated abortion
- Complicated abortion
- Provider training
- Counseling

Types of Abortion

Induced

Spontaneous
(miscarriage)

- Contraceptive needs may differ
- Those who want to avoid pregnancy have the same contraceptive options

Contraceptive Need after Abortion

- Women regain fertility 2 - 4 weeks after abortion
- To avoid another pregnancy, contraception should be initiated as soon as possible after abortion

Uncomplicated First-Trimester Abortion: *Contraceptive Options*

- Induced and spontaneous abortion: any method can be used immediately *except:*
  - diaphragm or cervical cap: delay of 4 - 6 weeks may be necessary in some cases

Uncomplicated Second-Trimester Abortion: *Contraceptive Options*

- Induced and spontaneous abortion: any method can be used immediately *except:*
  - diaphragm or cervical cap: delay 4 - 6 weeks
  - IUD: delay insertion 4 - 6 weeks unless provider is trained in insertion immediately after abortion
  - female sterilization: easier to perform if delayed until uterus returns to normal position

Complicated Abortion: *Contraceptive Issues*

Complications that can affect contraceptive choice include:

- infection
- trauma to genital tract
- hemorrhage, leading to severe anemia

2 or more complications can occur concurrently

Complicated Abortion: *Infection*

- If infection is present or suspected, delay:
  - female sterilization
  - IUD insertion
- Follow guidelines for uncomplicated abortion for initiation of all other methods
- Advise client to avoid intercourse until infection is resolved
  - use condoms if intercourse is not avoided

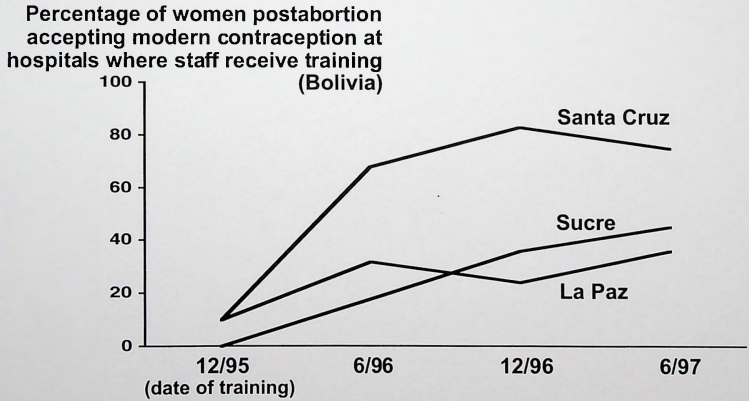
Complicated Abortion: *Genital Trauma*

- If genital trauma exists, delay:
  - female sterilization, unless performed during required surgery
  - IUD insertion
  - female barrier methods and spermicides (depending on extent and location of injury)
- Follow guidelines for uncomplicated abortion for initiation of all other methods

Complicated Abortion: *Hemorrhage and Severe Anemia*

- Delay methods that increase or maintain short-term blood loss
  - female sterilization
  - IUD
- Follow guidelines for uncomplicated abortion for initiation of all other methods

Training and Counseling Increase Contraceptive Acceptance



Source: Diaz J., 1999.

Contraceptive Counseling of Women after Abortion

Women who have undergone abortion should be treated with respect

Counseling can help women:

- identify factors that led to abortion
- make informed choice of contraceptive method
- choose highly effective method when pregnancy is life threatening
- become aware of emergency contraception
- understand implications for future fertility

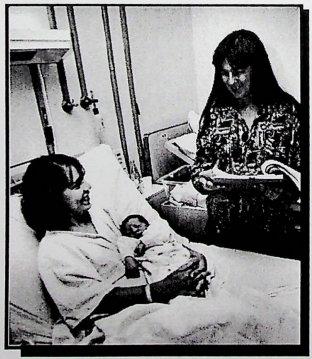
Counseling the Partners of Clients after Abortion

- Counseling male partners of abortion clients can increase their support for contraception
- Egyptian study found that husband's support for family planning was strongest predictor of client's use of contraception
- Counseling male partners may also increase awareness and use of vasectomy or male condoms

Source: Abdel-Tawab N., 1999.

Contraception after Pregnancy: *Conclusion*

After pregnancy, many women want to delay or avoid getting pregnant again



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- Providing family planning to women for use after pregnancy can save lives and improve health and quality of life
- Many contraceptive methods can be used soon after pregnancy
- Integrating contraceptive services into maternal and child health services can be highly effective

Narrative

Contraception after Pregnancy

Suggested Narrative

Introductory note to the presenter: *This presentation will familiarize health professionals with contraception after pregnancy; that is, contraception after childbirth or abortion. It is divided into three sections. The first section contains general introductory information, including a discussion of the unmet need for contraceptive services after pregnancy, the rationale for integrating these services with other health services, and characteristics of effective contraceptive services following pregnancy. The second section contains information about the contraceptive methods most appropriate for both breastfeeding and nonbreastfeeding women postpartum and the timing of initiation of these various methods. The third and final section discusses the contraceptive methods appropriate for women who have had spontaneous (miscarriage) or induced abortions (either uncomplicated or complicated), and ways to improve family planning services for women following abortion.*

Depending upon the background and needs of your audience, you may decide to use some or all of the slides or supplement them with information relevant to your local situation.

Items found in shaded boxes are suggestions for activities and discussion questions that you may wish to use with your audience. Including some or all of these elements can help your presentation become more interactive, enhancing the learning process. In some cases when activities are used, you may find that slides covering the same material may be omitted.

Regardless of whether or not you include the participatory activities, be sure to familiarize yourself with the contents prior to your presentation. At the beginning of the presentation, inform your audience about the organization of your presentation and how you would like to structure →

the discussion (i.e., take questions during the presentation or wait until the end). If you plan to include participatory activities, make sure your audience is aware of this. Depending on how much information you decide to use, you may want to break the presentation into two or more sessions. In its entirety, the presentation takes 1 1/2 to 2 hours to complete without the participatory activities and 2 to 2 1/2 hours when they are included.

Throughout the narrative, there are notes to the presenter, similar to this one, that may enhance your presentation. ■

Section I.
Contraception after Pregnancy

Slide 1

Contraception after Pregnancy

This presentation is part of a series of training modules produced by Family Health International. In this module, we will discuss contraception after pregnancy, which includes contraception after childbirth or abortion.

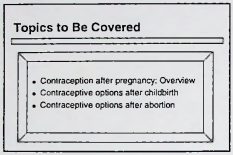
The contraceptive needs of many women remain unmet after pregnancy. This often has a negative impact on the health and quality of life of women and children. ■

Opening Activity – The Question Tree

Before you begin: *Draw a picture of a tree on a piece of flip chart paper and hang it on a nearby wall with pins or tape. Provide small pieces of paper on which participants can write their questions.*

- *Tell participants that you would like to create a Question Tree before you begin the session.*
- *Point to the image of the tree hanging on the wall. Tell them that this is the Question Tree. The Question Tree is where participants will place questions they have about contraception after pregnancy. Tell participants that they will answer the questions on the Question Tree together at the end of the session.*
- *Distribute the small pieces of paper so that everyone has at least two pieces.*
- *Ask participants to write down one or two questions they have about contraception after pregnancy. They do not need to write their names on the paper. They should use a new piece of paper for each question. When they are finished, they should pin or tape their questions to the Question Tree.*
- *Give participants enough time to finish writing and hanging their questions.*
- *Explain that they will return to the Question Tree later to see if the session helped answer their questions.* ■

Slide 2



Topics to Be Covered

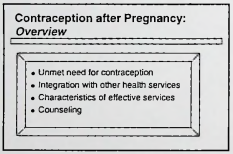
This module consists of three sections.

The first section contains general introductory information about contraception after pregnancy.

The second section describes contraceptive options after childbirth for women, both breastfeeding and nonbreastfeeding, and the timing of initiation of various methods for both situations.

The third section discusses contraceptive options for women who have had a spontaneous or induced abortion. ■

Slide 3



Contraception after Pregnancy: *Overview*

In this first section, we will:

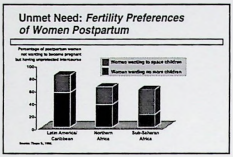
• Consider the unmet need for contraception after pregnancy and the advantages that meeting this need provides.

• Discuss how integrating family planning services with other health services gives providers more opportunity to reach women during and after pregnancy. During both of these periods, providers can offer information about contraception and help improve women's access to contraceptive methods.

• Describe some characteristics of effective contraceptive services for women after pregnancy.

• Discuss key messages for counseling after pregnancy. ■

Slide 4



Unmet Need: *Fertility Preferences of Women Postpartum*

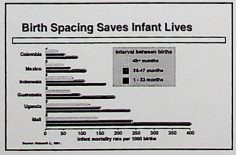
After childbirth, many women do not want more children or do not want them soon, yet are at risk for pregnancy and are not using contraception.

Some of this contraceptive need can be met through abstinence, which is a common practice for several months after pregnancy in some cultures, or through the temporary reduced fertility associated with breastfeeding, which will be discussed later.

However, this slide shows the results of a study of married women having unprotected intercourse interviewed seven to nine months after giving birth. The number of women who reported that they either wanted to delay pregnancy for at least two years or wanted no more children was highest in Latin American and the Caribbean, reaching 95 percent in Colombia. The number in Sub-Saharan Africa was lowest but still substantial.

Women who have had an induced abortion have demonstrated, by terminating their pregnancy, that the pregnancy was problematic, unwanted or mistimed. Many are likely to be motivated to prevent another pregnancy. However, they seldom leave medical facilities where abortions are performed or where abortion-related complications are treated with the knowledge and means to prevent pregnancy. ■

Slide 5

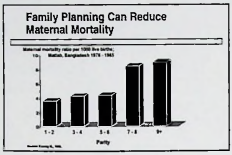


Birth Spacing Saves Infant Lives

One advantage of meeting the need for contraception after pregnancy is that it can help save infant lives. Numerous studies have shown that children born after an interval of at least two years from the preceding birth are more likely to survive. As this slide shows, infant deaths are dramatically reduced when births occur two or more years apart. This pattern of →

reduced infant deaths is evident regardless of the country's overall infant mortality rate. ■

Slide 6

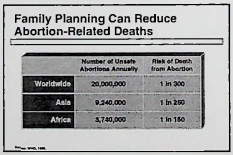


Family Planning Can Reduce Maternal Mortality

Family planning can also reduce maternal mortality by reducing the total number of pregnancies and births, both of which are risky. As the number of a woman's pregnancies and births increases, so does her lifetime risk of maternal death.

This slide shows the maternal mortality ratio for women 15 to 44 years old per thousand live births in rural Bangladesh. Notice that when parity increases to seven or more, the mortality ratio dramatically increases. Although not displayed in this chart, the risk is even greater for older women of high parity whose bodies may be less capable of meeting the demands of repeated pregnancy and childbirth. Access to family planning services and subsequent use of contraception may help reduce these higher-risk births. ■

Slide 7



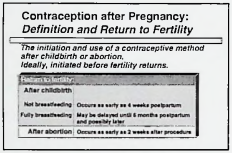
Family Planning Can Reduce Abortion-Related Deaths

Family planning can save the lives of women who have had an induced abortion by helping them avoid another unwanted pregnancy and the possibility of an unsafe abortion that can end either in injury or death. Based on estimates by the World Health Organization (or WHO), one of every 300 women worldwide undergoing an unsafe abortion dies. The danger posed by unsafe abortion is even greater in certain regions of the world. One of every 250 women undergoing unsafe abortion in Asia and one of every 150 in Africa dies as a result of the procedure. ■

Slide 8 Activity

- *Divide the participants into small groups and have each group answer the following:*
  - *What is contraception after pregnancy?*
  - *How does contraception after pregnancy differ from contraception at other times?*
- *Lead a discussion about the answers that are given and correct any misconceptions.* ■

Slide 8



Contraception after Pregnancy: *Definition and Return to Fertility*

Contraception after pregnancy refers to the initiation and use of a contraceptive method after childbirth or abortion. Ideally, contraception should be initiated before fertility returns.

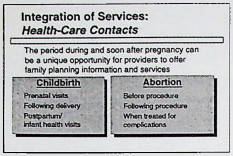
The timing of return to fertility varies:

- For nonbreastfeeding women postpartum, fertility can return as early as four weeks after childbirth. These women need effective contraception starting at this time, although contraceptive methods can be initiated sooner.

- For breastfeeding women, return to fertility may be delayed six months (or sometimes longer), depending upon the intensity of breastfeeding. This will be further discussed later in this presentation.

- Women are fertile as early as two weeks after an abortion. Therefore, a contraceptive method should be started as soon as possible. ■

Slide 9



Integration of Services: *Health-Care Contacts*

Providers have a unique opportunity to meet women's contraceptive needs during the prenatal period and after pregnancy. Not only are women more likely to be in contact with the health-care system then, but also they are often highly motivated to initiate contraception immediately after pregnancy. For these reasons, integrating family planning information and services with maternal and child health services is important.

Family planning information can be naturally integrated into prenatal visits during which nutrition, breastfeeding and other issues that enhance the health of both the mother and baby are commonly discussed.

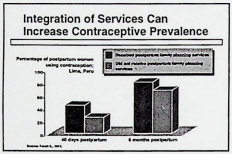
If the woman does not receive prenatal care, her baby's birth is another – and perhaps the only – opportunity providers have to offer contraceptive information. This information should be provided only after a woman has recuperated from the immediate stress of labor and delivery.

Finally, family planning services for new mothers can be integrated with infant health care, such as baby checkups and immunizations.

Women who have had an abortion sometimes return to a medical facility for follow-up. But, unlike women who have given birth, they will not be returning for postpartum and infant checkups. Thus, providers of abortions or those who treat abortion complications have a responsibility to offer family planning counseling before an abortion is performed, following the procedure, or when the woman is treated for complications. Such services are essential in order to help women who wish to avoid another unwanted pregnancy do so. At the very least, women should be informed after the procedure or after treatment for complications about their return to →

fertility and options for safe, effective contraception. If the woman wants to use contraception but is unable to choose a method at the time of the abortion or treatment, she should at least be offered a method such as condoms during the interim. A referral for family planning services can also be made. ■

Slide 10



Integration of Services Can Increase Contraceptive Prevalence

One of the many advantages of coordination and full integration of services is increased efficiency. Improved access to family planning services after pregnancy can also be very convenient for the client and can increase contraceptive prevalence.

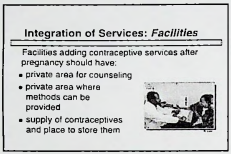
The Peruvian Social Security Institute conducted a study at one of that country's largest hospitals to examine the effectiveness of providing postpartum family planning services. In the study, women on one maternity ward were offered family planning counseling and contraceptive methods during their hospital stay. Women on a second maternity ward were discharged without receiving similar counseling or services.

The research demonstrated that the total contraceptive prevalence at 40 days postpartum was higher for the group of women receiving family planning services. At six months postpartum, contraceptive prevalence was even higher: 82 percent for women receiving family planning services versus 69 percent for those who did not receive similar services. In addition, costs of offering the services at the hospital were significantly lower than the costs of providing these services on an outpatient basis. Finally, use of hospital resources to provide family planning services relieved overcrowding at outpatient facilities, thus allowing more women to be served. ■

Slide 11-12 Activity

• Divide the participants into small groups and give each group a piece of flip chart paper and a marker.
• Tell each group to list on the paper the characteristics that programs should have to offer effective services for contraception after pregnancy.
• Have a representative from each group present their list to the larger group. ■

Slide 11



Integration of Services: *Facilities*

Integration of services may not be easy to accomplish. But many hospitals, doctors' offices, and maternal and child health facilities can add to existing services some family planning services for women after pregnancy. To provide these services, a facility should ideally have:

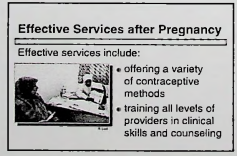
• a private area for counseling women about contraceptive needs,

• a private area where contraceptive methods can be provided, and

• a supply of contraceptives and a place to store them.

Facilities lacking supplies of contraceptive methods can make referrals to facilities that do provide them but should at least be able to offer methods such as condoms and, possibly, contraceptive pills. ■

Slide 12



Effective Services after Pregnancy

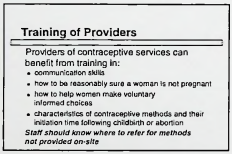
Policy-makers and providers should consider the following factors as they develop or modify their programs to provide effective family planning services after pregnancy.

Services should offer a variety of contraceptive methods to clients. Research shows that clients who have a variety of methods from which to choose are more likely to find one they like and to begin using it. Offering a mix of methods results in higher →

continuation rates because clients are more likely to obtain a method that meets their needs.

To be effective, health-care providers at all levels should be trained. This includes training to develop new clinical skills, such as IUD insertion or sterilization techniques after pregnancy. It also includes training in counseling techniques and in the special issues of postpartum contraception, such as the effects some contraceptives have on breastfeeding. Periodic refresher training should be offered to emphasize important facts and share new information. ■

Slide 13



Training of Providers

Programs that integrate family planning services into other health services provided after pregnancy can offer staff additional training in:

• communication skills,

• how to be reasonably sure a woman is not pregnant,

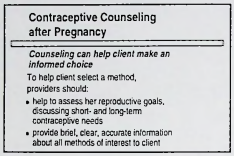
• how to help women make voluntary, informed choices about contraception, and

• characteristics of contraceptive methods and when methods can be initiated following childbirth or abortion.

If certain contraceptive methods cannot be offered on-site, providers should know where in the community to refer women for these methods and for ongoing family planning care.

Note to presenter: For more information about how to be reasonably sure a woman is not pregnant, see the pregnancy checklist in the reprints section of this module. ■

Slide 14



Contraceptive Counseling after Pregnancy

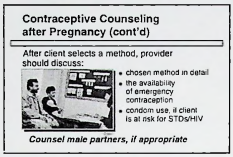
Counseling is one of the most important elements of contraceptive services provided after pregnancy. By offering clients up-to-date information on available contraceptives and providing an opportunity to discuss concerns about reproductive health, providers can help clients make an informed choice about contraceptive use.

First, providers should ask clients about their reproductive goals. Women who have had induced abortions or have given birth recently may want to avoid or postpone future pregnancies. Women who have experienced spontaneous abortions, or miscarriages, may want to become pregnant again soon.

Clients should be encouraged to consider both their short- and long-term contraceptive needs and options. Proper counseling can help the woman postpartum determine the method that is best for the short term, both while she may be breastfeeding and after her infant is weaned. Providers should also address particular concerns that clients may have following childbirth or abortion, such as the effects of contraceptives on breastfeeding, infant development, and the resumption of sexual relations.

Once reproductive goals have been discussed, a woman wishing to postpone pregnancy should receive brief, clear, accurate information about all appropriate methods of interest to her, taking into consideration whether she has given birth, had an induced abortion or experienced a spontaneous abortion. This information should include safety, effectiveness, mechanisms of action, side effects, protection from sexually transmitted diseases (or STDs), and other characteristics of the methods. ■

Slide 15



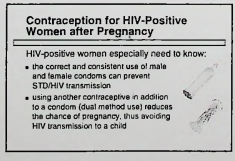
Contraceptive Counseling after Pregnancy (continued)

After a client makes an informed choice, the provider should discuss the chosen method in detail, ensuring that the client understands its risks, benefits, side effects and correct use. It is particularly important that clients choosing female or male sterilization understand that these methods are permanent, although – as with all methods – there is a small risk of contraceptive failure.

Clients should be counseled about the availability of emergency contraception in case unprotected intercourse occurs. Those at risk of STDs, including human immunodeficiency virus (HIV), should be encouraged to use male or female condoms alone or in combination with other contraceptive methods.

If appropriate, both partners should be offered counseling. In general, a male partner's awareness of the need for family planning and of available contraceptive methods can increase contraceptive use and continuation. It is particularly important that a woman's male partner be offered counseling if she is at high risk for STDs. Some couples may choose to rely on male methods, such as condoms or male sterilization. When sterilization is chosen, the male partner must receive careful counseling. ■

Slide 16



Contraception for HIV-Positive Women after Pregnancy

After pregnancy, clients who are HIV-positive need specific information, counseling and services, or appropriate referrals.

At the very least, these clients need to know that, aside from abstinence, condom use offers the best protection against STDs. Male or female condoms should be used every time intercourse occurs to →

avoid HIV transmission to partners and to protect the woman herself from other STDs, including other strains of HIV. An HIV-positive woman should be taught how to use condoms correctly and how to negotiate condom use with her partner.

HIV-positive women also need to know that children born to them may become infected with the virus during birth or breastfeeding. If they do not wish to become pregnant, they should consider "dual method" use; that is, using a condom for disease prevention and another, more effective method for contraception.

This concludes the first section of the module, which contained general introductory information about contraception after pregnancy.

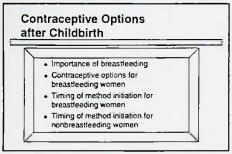
Note to presenter: A breastfeeding mother who is HIV-positive risks transmitting the infection to her infant through her breastmilk. In Section II, we will discuss this risk and ways to reduce it. ■

Summary Activity

At this point, essential information from Section I can be summarized. The presenter can remind participants of the unmet need for contraception after pregnancy, discuss integration of family planning services with maternal and child health services, describe some characteristics of effective contraceptive services for women after pregnancy, and discuss key messages for counseling after pregnancy. ■

Section II.
Contraceptive Options after Childbirth

Slide 17

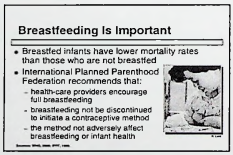


Contraceptive Options after Childbirth

In this section, we will discuss postpartum contraceptive options. We will review:

- the importance of breastfeeding,
- contraceptive options for breastfeeding women,
- the timing of method initiation for breastfeeding women, and
- the timing of method initiation for nonbreastfeeding women. ■

Slide 18



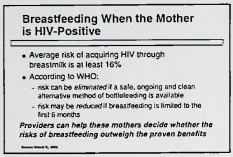
Breastfeeding Is Important

The importance of breastfeeding has been demonstrated in various studies, including a WHO-coordinated international study. WHO found that breastfed infants were six times less likely to die of infectious diseases in the first few months of life and had a lower mortality rate through the second year of life compared to those who were not breastfed.

The International Planned Parenthood Federation recommends that:

- health-care providers encourage full breastfeeding,
- breastfeeding not be discontinued to start the use of a contraceptive method, and
- the chosen method not adversely affect breastfeeding or the infant's health. ■

Slide 19

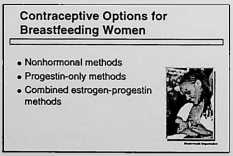


Breastfeeding When the Mother is HIV-Positive

Special consideration must be given to the decision to breastfeed if a mother is HIV-positive, since the virus may pass to the infant during breastfeeding in some cases. The average risk of acquiring HIV infection through breastmilk is at least 16 percent.

According to WHO, an HIV-positive mother can eliminate the risk of HIV transmission through breastmilk by using infant formula, modified animal milks or boiled expressed breastmilk. However, she must have access to a sufficient, ongoing and clean supply of this alternative form of milk. If there is no safe alternative form of milk, an HIV-positive mother should *only* give her infant breastmilk. She should not mix breastfeeding with use of other foods or milk replacements that are not safe. According to WHO, limiting breastfeeding to the first six months may also reduce the risk of HIV transmission. Health-care providers should counsel HIV-positive mothers and help them decide whether the risks of breastfeeding outweigh the proven benefits. ■

Slide 20



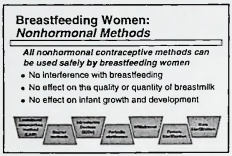
Contraceptive Options for Breastfeeding Women

About 90 percent of all mothers breastfeed their infants for some period of time, so the impact of contraceptive methods on breastfeeding, breastmilk and infant health is a very important consideration.

We will now discuss contraceptive options for breastfeeding women. These options include nonhormonal methods, progestin-only methods, and combined estrogen-progestin methods. Some of these methods are more appropriate than others for use during breastfeeding. →

Keep in mind that the following discussion applies only to breastfeeding women. ■

Slide 21



Breastfeeding Women: *Nonhormonal Methods*

All nonhormonal methods can be used safely by breastfeeding women.

They do not:

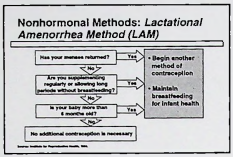
- interfere with a woman's ability to breastfeed,
- affect the quality or quantity of breastmilk, or
- affect infant growth and development.

Now, let us discuss types of nonhormonal contraceptive methods: lactational amenorrhea method (or LAM), barrier methods, intrauterine devices (or IUDs), periodic abstinence, withdrawal and female and male sterilization. ■

Slide 22 Activity

- *By way of review, divide the participants into seven groups and give them each a piece of flip chart paper and a marker. Have each group discuss one of the nonhormonal methods (the lactational amenorrhea method, barrier methods, IUDs, periodic abstinence, withdrawal and female and male sterilization) in terms of:*
  - *How the method works*
  - *Advantages and disadvantages of the method*
  - *Effectiveness of the method*
  - *Protection the method offers against STDs/HIV*
- *Have a representative from each group present their list to the larger group and correct any misconceptions.* ■

Slide 22



Nonhormonal Methods: *Lactational Amenorrhea Method (LAM)*

The Lactational Amenorrhea Method, also known as LAM, is a temporary contraceptive option used for up to six months postpartum by women who are fully or nearly fully breastfeeding and remain amenorrheic. Fully or nearly fully breastfeeding means that there are no intervals greater than four to six hours between breastfeeds and no regular dietary supplements have been introduced. When a woman fully or nearly fully breastfeeds, the baby's frequent suckling causes several biological changes that inhibit ovulation, resulting in a state of temporarily reduced fertility.

LAM provides more than 98 percent protection from pregnancy until one of three conditions occurs:

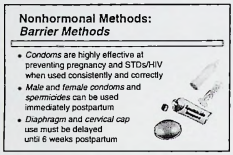
- menses returns, or
- the woman is no longer fully – or nearly fully – breastfeeding, or
- the baby reaches six months of age.

When one of these conditions occurs, another contraceptive method should be started for continued protection from pregnancy. A woman should continue breastfeeding for as long as she wishes, since breastfeeding is good for her infant's health. Providers should anticipate the period when LAM will cease in order to provide protection from pregnancy and counsel women well in advance about the use of other methods.

Recent studies suggest that if a woman remains amenorrheic and continues breastfeeding, LAM may be effective for some women for up to 12 months. Research into the duration of LAM's effectiveness continues. →

Note to presenter: For more detailed information about this method, see the "Lactational Amenorrhea Method (LAM)" module in the Contraceptive Technology Update Series. ■

Slide 23



Nonhormonal Methods: *Barrier Methods*

Barrier methods are another type of nonhormonal contraception. These methods include male and female condoms, spermicides, diaphragms and cervical caps. Barrier methods offer various degrees of protection against pregnancy. Some barrier methods also protect against STDs. Condoms are highly effective at preventing pregnancy and provide good protection against all STDs, except human papilloma virus (HPV), when used consistently and correctly. Spermicides provide modest protection against some bacterial STDs, and are much less effective than condoms in preventing pregnancy.

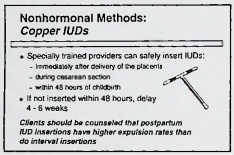
The effectiveness of barrier methods – as is true of some other methods – depends largely on consistent and correct use. Thus, it is important to explain to clients that barrier methods must be used correctly with each and every act of intercourse to be most effective. In addition, clients need to know where and how to obtain supplies of barrier methods.

Typically, male and female condoms and spermicides can be used immediately postpartum and can be obtained without a visit to a health-care provider. A variety of types are usually available. Condoms should be strongly encouraged for women at risk for STDs.

Use of a diaphragm or cervical cap must be delayed until six weeks postpartum. This is because the effectiveness of diaphragms and cervical caps depends on proper anatomical fit over the cervix, which does not return to its normal size until about six weeks postpartum. →

Note to presenter: For more detailed information about barrier contraception, see the "Barrier Methods" module in the Contraceptive Technology Update Series. For more detailed information about STDs, see the "Sexually Transmitted Diseases" module in the Reproductive Health Series. ■

Slide 24



Nonhormonal Methods: *Copper IUDs*

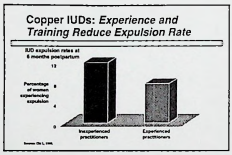
The copper IUD is a long-acting and reversible method that can be safely inserted postpartum if providers have proper training. Postpartum insertion is convenient for the woman and may be her only opportunity to obtain an IUD. However, like all women, women postpartum should be carefully screened to determine if they are at risk of STDs. The device can be inserted if laboratory testing rules out the presence of an STD. If women are at risk for STDs and laboratory testing is not possible, IUD use is not recommended.

Insertion can be safely performed vaginally immediately after the delivery of the placenta or during a cesarean section (through the uterine incision) as long as the woman has been counseled and has chosen the method well in advance of childbirth. If not done immediately, insertion can be performed safely within 48 hours after childbirth.

Postpartum insertion of copper IUDs poses no greater risk of infection, bleeding or perforation than insertion at other times. However, IUD expulsion rates are higher for postpartum insertions (especially those taking place after the first 10 minutes after placental delivery) than for interval insertions (those taking place any time after six weeks postpartum). Clients who have IUDs inserted within the 48 hours postpartum should be told that the risk of expulsion is greater and taught how to check IUD strings to ensure that the device is still in place. →

If an IUD insertion is not performed within 48 hours after delivery, WHO recommends that insertion be delayed at least four to six weeks. This recommendation is based on earlier observations that the risk of perforation is greater for postpartum insertions of older IUDs, such as Lippes Loop. With copper IUDs, it has been shown that there is no increased risk of perforation when inserted during the first 48 hours postpartum or after four weeks postpartum. However, there are no data on the risk of perforation between 48 hours and four weeks. ■

Slide 25

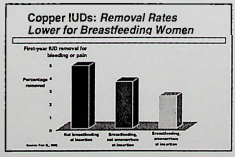


Copper IUDs: *Experience and Training Reduce Expulsion Rate*

Appropriate training of providers in postpartum IUD insertion techniques can reduce the risk of IUD expulsion. Training should emphasize placement of the device high in the uterus.

This slide shows the results of a large study comparing postpartum expulsion rates of insertions performed by experienced and inexperienced health-care providers. As you can see, expulsion rates at six months were significantly lower when the insertion was performed by an experienced provider trained in immediate postpartum insertion technique. These results have been corroborated in another large study conducted in Belgium. ■

Slide 26



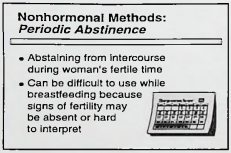
Copper IUDs: *Removal Rates Lower for Breastfeeding Women*

IUD insertion after childbirth offers certain benefits. Research shows that breastfeeding women report less pain during postpartum IUD insertion than women who are not breastfeeding. Also, breastfeeding women experience fewer side effects, specifically bleeding and pain, related to IUD use than nonbreastfeeding women. →

As this slide shows, breastfeeding women who are not amenorrheic at the time of IUD insertion have significantly higher one-year removal rates for bleeding or pain than breastfeeding women who are amenorrheic at the time of insertion. Removal rates are even higher for women who are not breastfeeding at the time of insertion.

Note to presenter: For more detailed information about IUDs, see the "Intrauterine Devices (IUDs)" module in the Contraceptive Technology Update Series. ■

Slide 27

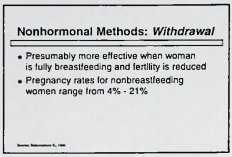


Nonhormonal Methods: *Periodic Abstinence*

Periodic abstinence is another nonhormonal contraceptive option. To use periodic abstinence, a woman must learn about the different stages of her menstrual cycle. She must learn to predict when she will ovulate and to identify her fertile period, during which pregnancy is likely to occur. She must avoid sexual intercourse around the time of expected ovulation – on what are called "unsafe" or "fertile" days.

However, this method can be difficult to use after pregnancy when a woman is breastfeeding because her signs of fertility may be absent or hard to interpret. For example, one method of periodic abstinence involves monitoring morning changes in basal body temperature. But these changes will not occur until ovulation has resumed. Even when ovulation has resumed, these changes may not occur if the woman gets up several times during the night to breastfeed her infant. Another method of periodic abstinence requires watching for patterns in cervical mucus. However, reduced ovarian function during breastfeeding may make the cervical mucus pattern more difficult to interpret. Women who are fully breastfeeding and amenorrheic may not have signs of fertility for up to six months after childbirth. ■

Slide 28

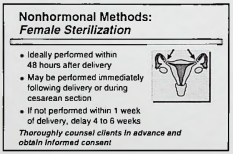


Nonhormonal Methods: *Withdrawal*

Withdrawal is not a very effective contraceptive method, but it may be more reliable when a woman is breastfeeding and her fertility is reduced.

For nonbreastfeeding women, pregnancy rates associated with withdrawal range from four percent to 21 percent during the first year. Even when this method is used correctly, pregnancy may still be possible because pre-ejaculatory fluid may contain sperm. ■

Slide 29



Nonhormonal Methods: *Female Sterilization*

For women who do not want more children, female sterilization is a safe and effective nonhormonal postpartum contraceptive option. Ideally, the procedure is performed not immediately but within the first 48 hours postpartum, after the woman has recovered from delivery, and the health and survival of the newborn is more certain than immediately after delivery.

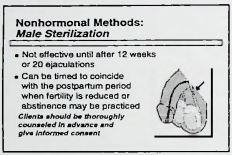
However, surgical sterilization can also be performed immediately following a vaginal delivery if the woman has selected this method in advance. Scheduling sterilization to coincide with delivery may be appropriate if the woman has limited contact with the health-care system. Sterilization can also be performed at the time of cesarean section.

If sterilization is not performed within a week postpartum, it should be delayed until four to six weeks postpartum when the uterus returns to its normal size and the fallopian tubes are easier to locate.

If sterilization is to be performed at the time of delivery or during cesarean section, providers should counsel the client thoroughly and obtain informed consent during the prenatal period – well before →

the woman gives birth. Counseling should never be conducted during the stress of labor or delivery. Providers must be sure that clients realize that female sterilization is permanent in order to help avoid regret. However, they should also inform clients that – as with all methods – there is a small risk of contraceptive failure. ■

Slide 30



Nonhormonal Methods: *Male Sterilization*

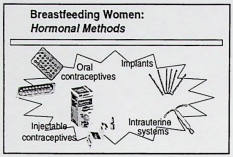
Male sterilization or vasectomy also should be considered as a postpartum contraceptive option for couples who have reached their desired family size.

Vasectomy is highly effective, causes few side effects, and is safer and typically less expensive than female sterilization. It is a relatively simple procedure that can be performed at any time by properly trained clinicians. Following the procedure, it usually takes 12 weeks or 20 ejaculations until sperm is cleared from the man's tubes for the sterilization to become fully effective. Thus, the postpartum period – when a breastfeeding woman's fertility is reduced and abstinence may be practiced – may be an ideal time for a man to undergo vasectomy. However, if a woman's fertility returns before the vasectomy becomes effective, another form of contraception should be used in the interim.

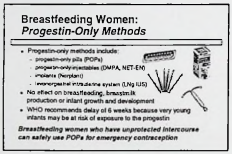
Providers must counsel men that vasectomy, like female sterilization, is permanent, although – as with all methods – there is a small risk of contraceptive failure. Careful counseling and informed consent before the procedure is performed are essential to help avoid regret.

Note to presenter: For more detailed information about sterilization, see the "Female and Male Sterilization" module in the Contraceptive Technology Update Series. ■

Slide 31



Slide 32



Breastfeeding Women: *Hormonal Methods*

Now that we have discussed nonhormonal method options for breastfeeding women, let us move on to hormonal methods, beginning with progestin-only methods and continuing with combined estrogen-progestin methods. ■

Breastfeeding Women: *Progestin-Only Methods*

Progestin-only methods include progestin-only contraceptive pills (or POPs), injectables such as DMPA and NET-EN, subdermal implants such as NORPLANT, and the levonorgestrel intrauterine system (LNg IUS).

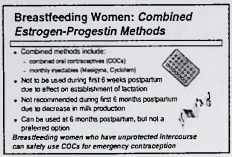
Studies indicate that the use of progestin-only contraceptives does not affect breastfeeding, breastmilk production, or infant growth and development. Regardless of the progestin-only method used, studies suggest that only a very small amount of the progestin reaches the infant through breastmilk. Long-term follow-up of children exposed to progestin-only contraceptives through breastmilk has not shown any adverse effects from this exposure.

However, WHO recommends that breastfeeding women delay use of progestin-only methods until six weeks postpartum due to theoretical concerns that steroid hormones may pose some risk to young infants.

If a breastfeeding woman has unprotected intercourse, she can safely use progestin-only emergency contraceptive pills, although many breastfeeding women are protected by, and choose to rely on, LAM.

Note to presenter: For more detailed information about emergency contraceptive pills, see the "Emergency Contraceptive Pills" module in the Contraceptive Technology Update Series. ■

Slide 33



Breastfeeding Women: *Combined Estrogen-Progestin Methods*

Combined estrogen-progestin contraceptives include combined oral contraceptives (or COCs) and monthly injectable methods such as Mesigyna and Cyclofem.

Combined contraceptives have been shown to interfere with the establishment of lactation. For this reason, they should not be used by breastfeeding women during the first six weeks postpartum because lactation is not fully established during this period.

Combined estrogen-progestin contraceptives have also been shown to decrease milk production. For this reason, their use is not recommended for breastfeeding women from six weeks to six months postpartum.

At six months postpartum, breastfeeding women can use a combined estrogen-progestin method, but it is still not a preferred option for women who want to continue breastfeeding.

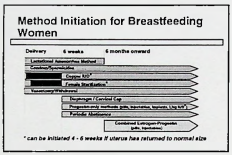
If a breastfeeding woman has unprotected intercourse, she can use combined estrogen-progestin emergency contraceptive pills, although many breastfeeding women are protected by, and choose to rely on, LAM. This short-term exposure to estrogen is thought to have no effect on milk production.

Note to presenter: For more detailed information about hormonal contraceptives, see the "Oral Contraceptives," "Injectable Contraceptives," "Introduction to Contraceptive Methods" and "Emergency Contraceptive Pills" modules in the Contraceptive Technology Update Series. ■

Slide 34-35 Activity

- *Divide the participants into small groups.*
- *Distribute a blank copy of the charts on slides 34 and 35 (available in the Audience Handouts section of this module) to each group.*
- *Tell each group to fill in the charts, determining which methods go in each category.*
- *Have a representative from each group present their charts to the larger group. Lead a discussion and correct any misconceptions.* ■

Slide 34



Method Initiation for Breastfeeding Women

Now we will review contraceptive options for breastfeeding women according to the timing of initiation.

Women who are fully breastfeeding and want to use LAM can begin doing so immediately after childbirth. LAM is considered to be effective for up to six months. No additional contraceptive method is needed. However, women who cannot or choose not to rely on LAM have the following contraceptive options.

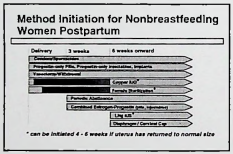
Condoms and spermicides can be initiated at any time postpartum. IUD insertion can be performed within the first 48 hours after birth, and female sterilization can be performed within the first week of birth (although preferably within 48 hours). Otherwise, these two procedures should be postponed until four to six weeks postpartum. Male sterilization, or vasectomy, can be performed anytime during this period and withdrawal can be used anytime as well.

At six weeks postpartum, all of the methods mentioned above can be used. In addition, diaphragms, cervical caps and progestin-only methods can be initiated. Periodic abstinence may be difficult to use because breastfeeding women may not have signs of fertility or, if they do, the signs may be →

difficult to interpret. However, women who choose to use periodic abstinence should begin keeping track of their menstrual cycles and watching for signs of fertility at six weeks postpartum.

LAM can be effective for up to 12 months for some women who are fully breastfeeding; however, it is generally considered ineffective after six months postpartum. At this time, any of the other methods mentioned above may be initiated. In addition, combined hormonal contraceptives can be initiated at this time, although they are still not a preferred option for breastfeeding women. ■

Slide 35



Method Initiation for Nonbreastfeeding Women Postpartum

Providers need to offer nonbreastfeeding women contraceptive options early in the postpartum period since these women will not benefit from the protection that LAM offers. Contraceptive use is most effective if started by three weeks postpartum. For nonbreastfeeding women postpartum, all contraceptive methods except LAM are options. However, the timing of initiation varies according to the method.

As shown in the top three horizontal bars, use of condoms, spermicides, progestin-only pills, progestin-only injectables, subdermal implants, vasectomy and withdrawal may be initiated immediately postpartum.

IUD insertion can be performed within the first 48 hours after birth or delayed four to six weeks postpartum. Female sterilization can be performed within the first week after giving birth (although preferably within 48 hours). Otherwise, it should be delayed until four to six weeks postpartum.

Women who wish to use periodic abstinence should begin looking for signs of fertility about three weeks postpartum. →

Combined estrogen-progestin contraceptives should be delayed until three weeks postpartum due to the increased risk of blood clotting problems during this period.

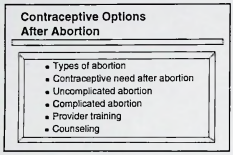
LNg IUS insertion should be delayed until the uterus returns to normal size at six weeks postpartum.

As is true for breastfeeding women, initiation of the use of a diaphragm or cervical cap must be delayed until six weeks postpartum when the woman's uterus has returned to normal size, at which time the devices can be fitted by a trained provider.

This concludes the section about contraceptive options for women postpartum. ■

SECTION III.
Contraceptive Options after Abortion

Slide 36

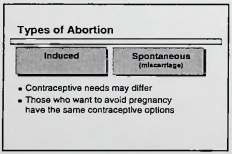


Contraceptive Options after Abortion

In this section, we will discuss contraceptive options after abortion. We will review:

- types of abortion,
- contraceptive need after abortion,
- contraception after uncomplicated abortion,
- contraception after complicated abortion,
- training of providers working with clients after abortion, and
- counseling of clients who have had an abortion. ■

Slide 37



Types of Abortion

There are two types of abortion: induced and spontaneous. The contraceptive needs of women may differ, depending upon which type of abortion they have had.

Women who have had an induced abortion – of which there are some 26 to 53 million worldwide each year – are likely to want to use family planning services to avoid another pregnancy. Often, unwanted pregnancy can be prevented with adequate information about, and access to, a range of contraceptive methods.

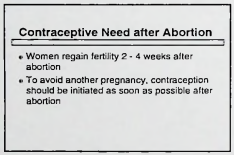
Helping such women avoid another unwanted pregnancy and possibly another induced abortion is important. A woman's reproductive health – and perhaps her life – could be at risk if the abortion is performed by an untrained individual in unhygienic conditions. Unsafe abortions are estimated to →

cause the death of between 50,000 and 100,000 women each year.

In contrast to women who have undergone an induced abortion, women who have experienced a spontaneous abortion, or miscarriage, may want to become pregnant again soon.

Women who want to avoid pregnancy after induced or spontaneous abortion have the same contraceptive method options. ■

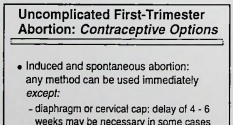
Slide 38



Contraceptive Need after Abortion

The contraceptive needs of women who have had abortions are even more immediate than those of women who have given birth. This is because women can conceive soon after undergoing an abortion, with ovulation typically occurring within two to four weeks. Therefore, if a woman wants to avoid pregnancy, she should begin using contraception as soon as possible after the abortion has occurred. ■

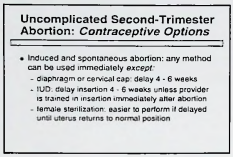
Slide 39



Uncomplicated First-Trimester Abortion: *Contraceptive Options*

Women who have an uncomplicated first-trimester abortion, either induced or spontaneous, can begin using any method immediately afterwards, except possibly diaphragms and cervical caps. Fitting these devices may need to be delayed four to six weeks in the cases when cervical dilation has occurred. ■

Slide 40



Uncomplicated Second-Trimester Abortion: *Contraceptive Options*

Women who have an uncomplicated second-trimester induced or spontaneous abortion can – like nonbreastfeeding women who have given birth – use most methods immediately.

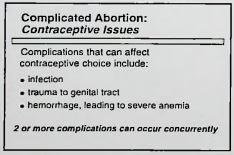
There are a few exceptions:

• As with an uncomplicated first-trimester abortion, delay fitting or use of a diaphragm or cervical cap for four to six weeks after abortion to allow the uterus to return to its normal size. Otherwise, an improper anatomical fit may reduce the effectiveness of these barrier methods.

• In addition, delay IUD insertion for four to six weeks when the uterus returns to normal size, unless the provider has the skill and experience to insert the device immediately after abortion.

• Also, be aware that female sterilization may be easier to perform if delayed until the uterus has returned to its pre-pregnancy position and size. ■

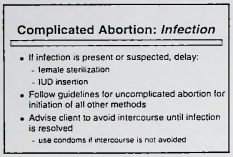
Slide 41



Complicated Abortion: *Contraceptive Issues*

Complications can occur after abortion – especially unsafe abortion – that may affect contraceptive method options. Complications include infection, trauma to the genital tract and hemorrhage that results in severe anemia. We will now review these complications individually. However, it is important to note that a woman may experience more than one complication concurrently, in which case the provider would need to consider the recommendations for all existing complications. ■

Slide 42



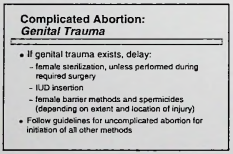
Complicated Abortion: *Infection*

If an infection is present or suspected, WHO recommends delaying female sterilization and insertion of an IUD or levonorgestrel intrauterine system (LNg IUS) until the infection is either fully resolved or ruled out. If a woman chooses one of these methods, a provider should offer an interim contraceptive method, such as condoms, and make a follow-up appointment or referral.

All other contraceptive methods can be used as they would be in the case of an uncomplicated first or second trimester abortion.

However, until the infection is resolved, the provider should advise the patient to avoid intercourse. If intercourse cannot be avoided, the infected woman and her partner should use a condom as protection against other infectious agents. ■

Slide 43



Complicated Abortion: *Genital Trauma*

Genital trauma includes burns, perforations, cervical tears or lacerations. If a woman has suffered genital trauma as the result of an abortion, WHO recommends delaying sterilization until the trauma is healed. However, if abdominal surgery is required, sterilization can be done concurrently. This is appropriate only if a woman was counseled and gave her informed consent for sterilization before the abortion was performed.

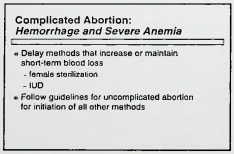
WHO also recommends delaying IUD and LNg IUS insertion until uterine perforation or other serious trauma has healed. Meanwhile, the client should be provided with a short-term method that she can use while awaiting IUD insertion and make a follow-up appointment or referral. →

Finally, according to WHO, use of female barrier methods should be delayed, depending on the extent and location of the injury. These methods should not be used, for example, if they will come in contact with a significant cervical or vaginal injury. At the least, diaphragms and cervical caps should not be fitted until four to six weeks after abortion, when the woman's dilated cervix has returned to its normal size.

All other contraceptive methods can be used as they would be in the case of an uncomplicated first or second trimester abortion.

In cases of lower genital tract injury, the provider may want to advise the woman to avoid intercourse until the injury has healed. ■

Slide 44



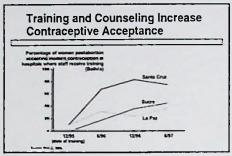
Complicated Abortion: *Hemorrhage and Severe Anemia*

Some women undergoing unsafe abortions suffer hemorrhage. Many women in developing countries are anemic and hemorrhage may worsen their anemia, making it severe.

Until severe anemia is resolved, any method that might increase or maintain short-term blood loss should be avoided. Thus, female sterilization and insertion of IUDs should be delayed. Meanwhile, the provider should offer a short-term method and make a follow-up appointment or referral.

All other contraceptive methods can be used as they would be in the case of an uncomplicated first or second trimester abortion. ■

Slide 45



Training and Counseling Increase Contraceptive Acceptance

Having discussed contraceptive options for women who have experienced abortion, we will now describe how enhanced training of providers can increase contraceptive use after abortion.

In a study in three Bolivian hospitals, training hospital staff about the provision of services following abortion resulted in marked increases in contraceptive use by women after abortion. The training emphasized prevention of future abortions and how to implement a counseling program.

Physicians and counselors at these hospitals attended a training course on care and contraception following abortion. Particular emphasis was placed on training providers to give compassionate care and to improve their communication skills. Later, the hospitals implemented a counseling program that provided women with three separate opportunities to decide to use contraception and to choose a method. Those who were discharged prior to reaching a decision about contraception had an additional opportunity to discuss their options during a follow-up visit scheduled one month after discharge.

Contraceptive counseling was almost nonexistent before the study. Contraceptive acceptance before the training of personnel was low. But acceptance in the three hospitals increased soon after the training and implementation of the counseling program.

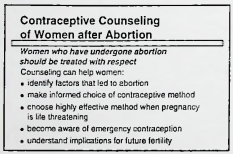
This slide illustrates the rise in acceptance of modern contraception (IUDs and hormonal methods) in the three hospitals during the periods evaluated.

A similar intervention program conducted in a large public hospital in Mexico also resulted in a statistically significant increase in the percentage of women who accepted a contraceptive method →

following abortion (from 30 percent to 60 percent), and in the percentage of women who received the method at the hospital before discharge (from 34 percent to 56 percent).

Finally, a Kenyan study looked at the provision of postabortion family planning services on a hospital gynecological ward. The study found that provision of these services by trained ward staff was easier, more effective and more acceptable to clients than provision by maternal and child health/family planning staff either on the ward or in the family planning clinic. ■

Slide 46



Contraceptive Counseling of Women after Abortion

It is important that staff working with women who have had an abortion treat these clients with respect and not allow any negative attitudes about abortion to affect the interaction.

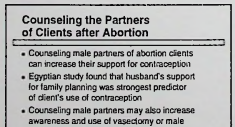
Pregnancies resulting in abortion have many causes. If an abortion was induced, counseling after the abortion can help women identify the factors that led to the pregnancy and, in some cases, prevent a recurrence.

Among the reasons for an unwanted pregnancy is failure to use contraception. A woman may fail to use contraception because she lacks access to family planning services, contraceptive methods are unavailable, unpleasant side effects prompt her to discontinue use of a method, or family planning providers fail to help her find a method that is acceptable to her. Other unwanted pregnancies occur when a woman has not used a method consistently and correctly. Occasionally, an unwanted pregnancy may occur if the contraceptive method itself fails. Finally, an unwanted pregnancy may be the result of coerced, nonconsensual sex. →

A woman who has had either an induced or spontaneous abortion and does not wish to become pregnant again soon should make an informed choice of a contraceptive method based on information about method options, method characteristics, and how to use the methods correctly. If a woman who had an induced abortion was using a contraceptive method when the unwanted pregnancy occurred, the provider can help her choose another method that may be more effective for her. Or, if the woman wants to continue using the same method, the provider can ensure that she knows how to use it correctly and has ready access to it. The availability and appropriate use of emergency contraception should also be discussed.

A woman who has had an induced abortion because pregnancy was life-threatening needs to be counseled about the use of highly effective methods of contraception that will protect her from another pregnancy and its associated health risks. Also, women treated for abortion complications need to understand the implications for their future fertility. Infection resulting from an unsafe, improperly performed induced abortion, for example, can cause infertility. ■

Slide 47



Counseling the Partners of Clients after Abortion

If a woman agrees, her male partner should be included in counseling when possible. Counseling male partners of clients can help make these men more supportive of clients' family planning decisions, increasing their subsequent use of contraception. A study conducted in six Egyptian hospitals, for example, has shown the importance of counseling the husbands of women following abortion.

In the study, counseling of husbands was part of an initiative to improve clinical services for women →

following abortion. The results showed that the husbands' support of family planning was the strongest predictor of family planning use by clients. Other studies have shown an association between husbands' support of family planning and the initiation and continuation of contraception.

Also, counseling of male partners may increase their awareness and use of male contraceptive methods, such as vasectomy and condoms. ■

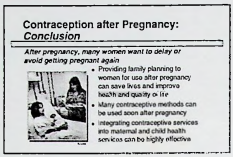
Slide 48 Activity: Patient Scenarios

◦ *Before you begin: Prepare copies of the patient scenarios located in the Audience Handouts section of this module. Write a list of all methods on a flip chart.*

• *Tell participants that they will now consider some common patient scenarios related to contraception after pregnancy. Each scenario describes the specific situation of a woman either postpartum or following abortion. The participants' task is to develop a list of contraceptive methods appropriate for each woman to use. It should be assumed that all of these women are healthy and have no medical conditions (aside from those mentioned in the scenario) that would affect their use of contraception. At this point, it is not necessary for them to cover counseling points.*
• *Divide participants into small groups. (There are enough scenarios for seven groups.)*
• *Give each group a patient scenario.*
• *Ask participants to list the contraceptive methods appropriate for the patient in the scenario, based on the information they received during this session. Point to the flip chart containing the list of methods and explain that they should consider all of these methods.*
• *Allow five to 10 minutes to discuss.*
• *Each group should then present their scenario and their list of appropriate methods to the entire group.*
• *Discuss the lists and correct any misinformation presented.*

You may want to develop your own scenarios and include situations not discussed in this module. Your scenarios might take into account, for example, advantages or disadvantages of various contraceptive methods, or specific client preferences. ■

Slide 48



Contraception after Pregnancy: *Conclusion*

After pregnancy, many women want to delay or avoid getting pregnant again. Providing family planning information and services to women after pregnancy can improve the health and quality of life of women and children. It can even save their lives.

Effective contraceptive services provided after pregnancy help women who want to delay or prevent subsequent pregnancies choose contraceptive methods that are safe, effective, convenient, and best meet their short- and long-term family planning needs.

Many contraceptives can be used successfully soon after pregnancy. Providers must learn which methods are appropriate for each woman during this period, the timing for initiating these methods, and how to counsel clients accordingly. This is especially important for clients who are breastfeeding. Because some contraceptive methods can be initiated immediately after delivery or abortion, providers ideally should discuss family planning before labor and birth, or abortion.

Meeting the contraceptive needs of women following pregnancy is an important component of maternal and child health services and services that provide abortion or treatment for abortion complications. Integrating family planning services with other health services can be a highly effective way to reach these women. Providers, program managers and policy-makers who look for ways to integrate services can benefit both clients and their health-care systems. ■

Concluding Activity

Have two or three participants go to the Question Tree that was posted on the wall during the Opening Activity.

- *Ask them to pull questions off the tree and read them to the group. Ask members of the group to volunteer the answers if they know them. If they do not know the answers you can answer the questions for them. Be certain to correct false statements.*
- *Congratulate the group on their new knowledge.* ■

Contraceptive Technology

Contraception after Pregnancy

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Introduction

This training module is part of a series of slide presentations entitled *Contraceptive Technology Update Series* (CTU). The CTU series, as well as the *Reproductive Health Series* (RH), are developed and produced by Family Health International (FHI) with funding from the U.S. Agency for International Development (USAID) and assistance from other agencies concerned with international family planning.

Other currently available topics are:

- Barrier Methods
- Client-Provider Interaction
- Emergency Contraceptive Pills
- Female and Male Sterilization
- Injectable Contraceptives
- Intrauterine Devices (IUDs)
- Introduction to Contraceptive Methods
- Lactational Amenorrhea Method
- Oral Contraceptives (OCs)
- Reproductive Health of Young Adults
- Sexually Transmitted Diseases

All modules are available in English, French and Spanish.

The purpose of these training modules is to meet the continuing educational needs of family planning practitioners and policy-makers in developing countries by providing the most current information available about contraceptive technology and reproductive health. The information in the modules is intended to be used at workshops or seminars for physicians, nurses, pharmacists, family planning counselors, midwives, or other trained health-care personnel. The information is appropriate for those with a basic knowledge of and familiarity with family planning programs, methods of contraception and reproductive health, but can also be used in preservice training settings for medical and nursing students.

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Olivia McDonald, MD, FRCOG, MPH, and selected health providers in Kingston, Jamaica; and Maureen Kuyoh and selected health providers in Nairobi, Kenya.

This publication is based on the earlier FHI module, *Postpartum Contraception.*

Module Contents

Narrative

This is a carefully researched and reviewed script designed to accompany the slides. It is only a suggested narrative. You are strongly encouraged to use this information to develop your own presentation. As written, the narration lasts 1 1/2 to 2 hours. If you do elect to read all or part of the suggested narrative, it is best not to read the topic headings printed in bold type. Suggestions on how to adapt this presentation are included later in this section.

Activities and Discussion Questions

The activities and discussion questions, found in shaded boxes throughout the narrative, allow facilitators to create an interactive workshop rather than give a lecture presentation. Facilitators may use some or all of the activities, as appropriate. The more activities a facilitator includes, the more likely participants will retain the information. This is because most people learn better and have a greater chance of achieving behavior change when actively thinking about, rather than just receiving, information. As with your selection of slides, conducting such training activities requires advance preparation.

Slides

Forty-eight 35mm color slides are numbered and labeled for your use. You are encouraged to consider the usefulness of each slide when preparing a presentation for your audience. Slides can be deleted, added from another source, or rearranged to highlight certain information. The slides are followed by black and white paper copies of the information that appears on the slides. These may be used as a tabletop flip chart if no slide projector is available. Or, the paper copies can be used to create overhead transparencies for projection.

Audience Handouts

This section contains handouts that can be copied and distributed to the audience. The summary fact sheet can help audience members remember key learning points. There are also pages that the audience can use for note-taking during the presentation.

Pretest and Posttest

There is an evaluation questionnaire that can be used as a pretest and posttest. It can be given before the session to ascertain the knowledge level of the audience. This same instrument can also be given afterwards to assess how much the audience learned and whether the information presented resulted in changed attitudes. A questionnaire with the answers marked correctly is also included.

Participant Evaluation

There is an evaluation form to be given to each participant in the audience. Please make copies and have the audience members complete the form after each training session. You may find that the comments from the audience are useful in planning future presentations. We would also appreciate your sending to us any suggestions for improving the module based on your experience as a presenter. Please return completed forms to FHI to help us revise current modules and improve future ones.

References and Resources

A list of important readings about contraceptives is provided for persons wanting to learn more about this topic. The information in this presentation was drawn from these sources.

Reprints of Scientific Articles

Key journal articles and book chapters are included in this section to provide more detailed scientific information about contraception. You should read these materials before giving your presentation. If feasible, they may be shared with audience members.

How to Use This Module

The following are two ways this module can be presented:

1. Presentation using slides and narrative only (requires approximately 1 1/2 to 2 hours).
2. Presentation using slides, narrative, activities and discussion questions in an interactive session (requires approximately 2 to 2 1/2 hours).

The needs of the participants, as well as the time available and the size of the group, are factors to consider when determining which presentation approach to use. For groups of fewer than 25-30 participants, the interactive approach works well. For larger groups, a simple slide presentation may be more appropriate. However, it is important to remember that retention of information and the impact on participant behavior and attitude will increase with interactive approaches to learning. Regardless of which presentation method you choose, the following steps are recommended when preparing for and conducting a presentation or interactive training session.

Preparing for Your Session

- Review the suggested narrative and slides several times to become familiar with the information.
- When choosing an interactive approach, review and rehearse the activities and discussion questions. Anticipate possible questions and further discussion topics that may arise.
- Read the materials in the "Reprints of Scientific Articles" section and, if possible, review some of the materials listed in the "References and Resources" section.
- Become familiar with relevant policies and procedures regarding contraception after pregnancy in the country where you are making the presentation or training.
- Adapt slides, narrative, activities and discussion questions to meet the needs of your specific audience, considering their level of education, training and experience. Also, consider the amount of time available for the presentation. Add or remove slides, information, activities or discussion questions where appropriate.
- Use language that you are comfortable with and that will be easily understood by the audience. Speaking from your own notes is more effective than reading directly from the narrative, even if not including participatory activities. Actively engaging the audience with a combination of slides, activities and discussion questions is optimal.
- Rehearse your session, preferably using the same room and equipment that you plan to use during your presentation.

Preparing Materials for Your Session

- Make photocopies of the pretests, fact sheet, note-taking handouts, evaluations and World Health Organization (WHO) eligibility criteria for your audience.
- If including the activities, obtain a flip chart and prepare pages for the activities being used.
- Assess which, if any, of the reprints of scientific articles would be appropriate for your audience. Prepare summaries if necessary.
- Reserve a room large enough for your audience that can be darkened for slide viewing.
- Obtain a 35mm slide projector. Select a place to project the image, either a screen, white sheet or blank wall. If a slide projector is not available, use the paper copies of the slides to make overhead transparencies or use the pages as a tabletop flip chart.

Presentation Checklist

__ Before the presentation, give participants the pretest.

__ After the presentation, lead a group discussion. Explore the ideas presented and examine ways in which each participant thinks he or she can improve information about and access to contraception after pregnancy. Identify issues that are especially important for additional training or research.

__ Give participants the posttest.

__ Ask participants to complete an evaluation form.

__ Return the evaluation forms, and any other suggestions for improving the module, to Family Health International, CTU/RH Modules Project Administrator.

__ Follow up with participants, if appropriate.

Ideas for Adapting the Module for Different Audiences

This training module provides basic information about contraception after pregnancy. Presentations can be made more interesting and valuable by adding information about local experiences and practices, especially those that apply to your audience. In addition, some adaptation of the text or slides may be needed to meet the specific needs, priorities, scope, resources and constraints of different programs. If method-specific FHI modules are available, the presentation can be customized and extended by including the more detailed information contained in these volumes.

The amount of clinical information that is appropriate to present will depend on the medical background and knowledge of your audience. As designed, all slides and scripted material are appropriate for clinicians with at least a basic familiarity with family planning. The best way to select slides for your audience is to ask yourself: "What information does this audience need to enable them to provide their clients with information and counseling on contraception after pregnancy? Is the information provided too basic or too advanced for this audience?" Answering these questions will help you prepare a presentation appropriate for your audience.

Learning Goals and Objectives

Contraceptive technology is an evolving, dynamic and ever-changing subject. To offer high-quality services and care, policy-makers, administrators and providers of contraceptive services need to remain abreast of current information and practices. The purpose of this module is to provide information about contraception after pregnancy to policy-makers, managers, health-care providers and students. The module provides a core of information that can be adapted as needed for various audiences.

After the presentation, audience members will be able to:

- discuss contraception after pregnancy, which contraceptive methods are appropriate and the timing of their initiation;
- discuss the main counseling points for contraception after pregnancy;
- discuss the importance of offering contraception after pregnancy.

POPULATION FOUNDATION OF INDIA

IT MATTERS TO EVERYONE

INVEST IN FAMILY PLANNING

POPULATION FOUNDATION OF INDIA

FAMILY PLANNING SAVES WOMEN'S LIVES

FAMILY PLANNING PREVENTS

272,000

MATERNAL DEATHS WORLDWIDE

CONTRACEPTIVE USE

CAN AVERT MORE THAN HALF OF

MATERNAL DEATHS

Family Planning Directly Reduces the Number of Maternal Deaths because it Reduces the Chance of Pregnancy and Associated Complications

- LOWERS RISK OF UNSAFE ABORTION
- DELAYS FIRST PREGNANCY IN YOUNG WOMEN
- REDUCES HAZARDS OF CLOSELY SPACED PREGNANCIES

INDIA ACCOUNTED FOR 15% (45,000) OF ALL MATERNAL DEATHS (303,000) WORLDWIDE IN 2015 (ESTIMATED)*

MATERNAL MORTALITY IS

167*

*Per 100000 Live Births

PROPORTION OF MATERNAL DEATHS AVERTED BY CONTRACEPTIVE USE[1]

57.3%

FOR EACH WOMAN WHO DIES DURING CHILDBIRTH

20

MORE SUFFER FROM INFECTION, INJURY AND DISABILITY CONNECTED TO PREGNANCY OR CHILDBIRTH

86,000 MATERNAL DEATHS AVERTED BY CONTRACEPTIVE USE

FAMILY PLANNING IS THE PRIMARY INTERVENTION TO PREVENT MATERNAL MORTALITY

[1] Data from: Ahmed, Saifuddin, Qingfeng Li, Lale Liu, Amy O Tsui. "Maternal deaths averted by contraceptive use: An analysis of 172 countries." Lancet, Family Planning, July 2012.
Sushela Singh et al., *Barriers to Safe Motherhood in India*, New York, Guttmacher Institute, 2009.
Sample Registration System, 2013, Registrar General of India, Maternal Mortality in India, MDG analysis provided by USAID, Health Policy Initiative Project.
* Source: Trends in Maternal Mortality: 1990 to 2015 (estimates by WHO, UNICEF, UNFPA, World Bank group and the United Nations Population Division.

ICPD SHAPING FAMILY PLANNING POLICIES BASED ON RIGHTS, DIGNITY AND HEALTH

POPULATION FOUNDATION OF INDIA

ICPD Commitments – 1994

Provide universal access to family planning and sexual and reproductive health services and reproductive rights.

Deliver gender equality, empowerment of women and equal access to education for girls.

Address the individual, social and economic impact of urbanization and migration.

Support sustainable development and address environmental issues associated with population changes.

ICPD Impact on Policies and Programmes in India

National Population Policy, 2000- rights based approach and a target free approach.

National Health Mission - for improved health care delivery in urban and rural areas.

Reproductive and Child Health Programme (phase 1 & 2) 1997, 2005 - multiple stakeholders; lifecycle approach; quality of care; informed choice.

National Health Policy (2002) - equitable access to healthcare; funding for women's health.

STRENGTHENING FAMILY PLANNING ESSENTIAL TO ACHIEVE LARGER DEVELOPMENT GOALS

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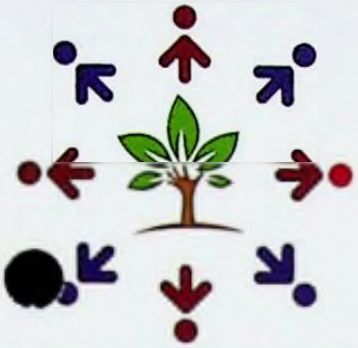

Family planning is a critical element of social, human, economic and environmental development.

Linkages

Access to family planning- supports women's social and economic well-being; enables them to choose the number and spacing of their children.

Better birth spacing - reduces the incidence of low birth weight and poor maternal nutrition. Family planning results in more wealth and less hunger.

Delay Childbearing - Women who are able to delay childbearing are more likely to meet their educational goals, obtain productive employment, increase household income, and thus help reduce extreme poverty.

Using family planning empowers women - When women are empowered and are decision-makers in their families, they spend more resources on their children's nutrition, healthcare and education.

STRENGTHENING FAMILY PLANNING ESSENTIAL TO ACHIEVE LARGER DEVELOPMENT GOALS

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Linkages

Birth spacing through family planning - Reduces child mortality. Children born three to five years apart are 2.5 times more likely to survive than children born two years apart.

Family planning saves lives - Family planning allows spacing of pregnancies and avoids unwanted pregnancies. It can delay pregnancies in young women at increased risk of health problems and death from early childbearing.

Family planning and reproductive health services - are essential to preventing the spread of HIV/AIDS.

- Improving access to condoms can reduce the number of infections acquired through sexual intercourse.
- Increasing contraception use among HIV-positive women through voluntary family planning services can avert almost 30% more cases of mother-to-child-transmission than anti-retrovirals alone.

THE PATH AHEAD POST 2015

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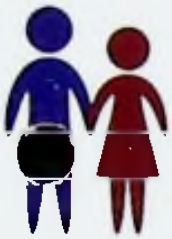
Priorities



1. Expanding contraceptive choices for delaying and spacing births

2. Quality of care in reproductive health services

Focus Areas

FAMILY PLANNING – Currently unmet need for family planning in India is 21%; unmet need for spacing methods is highest (26%) among the youngest age group (15-19 years)*.

QUALITY OF CARE – Emphasis on informed choice and counselling.

ADOLESCENT HEALTH – Delaying age at marriage and age at first pregnancy are critical in India – 46% of all women are married before the legal age of marriage, one in six women aged 15-19 have begun childbearing and 50% of maternal deaths among girls in the same age group are due to unsafe abortions.

STUDIES show that a large number of risk factors for poor reproductive and child health are rooted in adolescence and yet only 15% of youth receive any education on sex or family planning.

COMMUNITY INVOLVEMENT to be strengthened for accountability of services.

Promoting a **MULTI STAKEHOLDER INVOLVEMENT** and better interaction between Central and State Govt.

*Source - DLHS-3 2007-08

EVIDENCE ON CONTRACEPTIVE METHOD MIX IN DEVELOPING COUNTRIES: SOUTH/SOUTH-EAST ASIA

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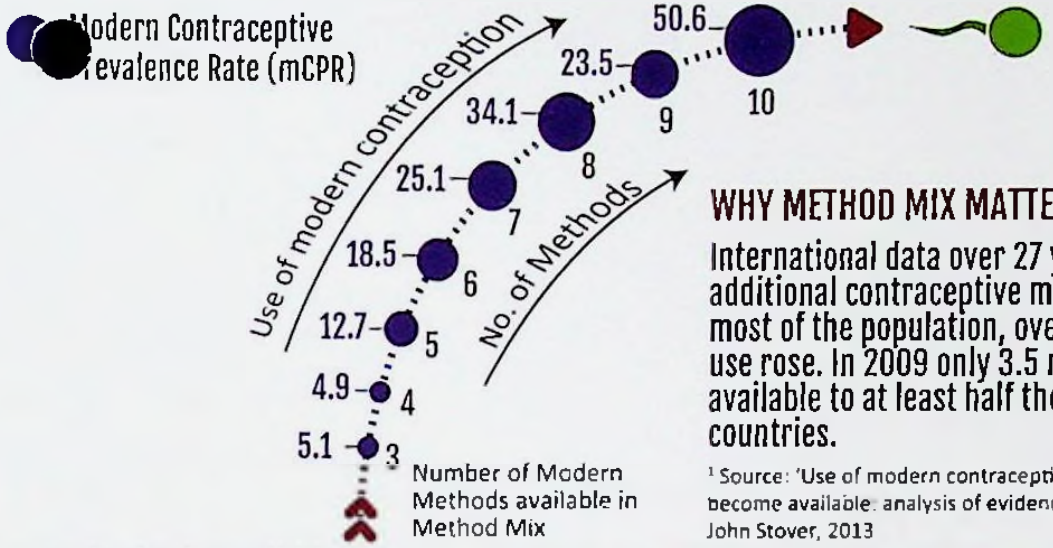
The addition of 1 method available to at least half the population correlates with an increase of 4-8 percentage points in total use of the 6 modern methods, for example, from 40% to 44% or 48%.[1]

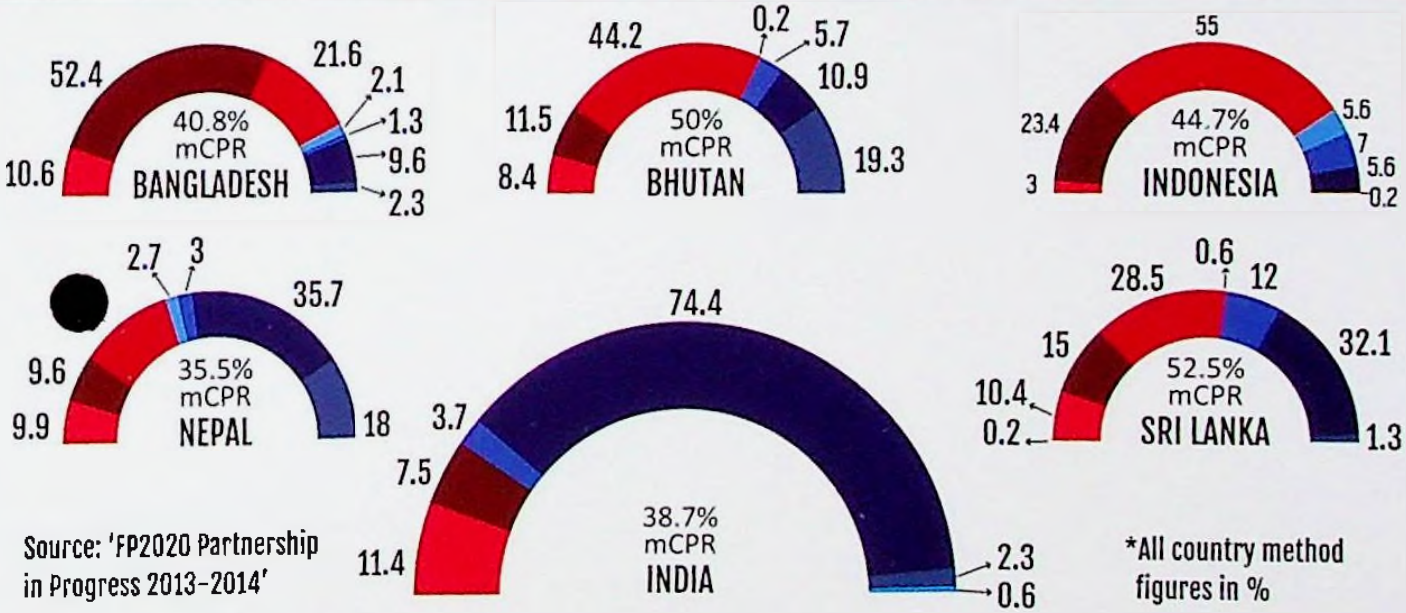


WHY METHOD MIX MATTERS

International data over 27 years shows that as each additional contraceptive method became available to most of the population, overall modern contraceptive use rose. In 2009 only 3.5 methods, on average, were available to at least half the population in surveyed countries.

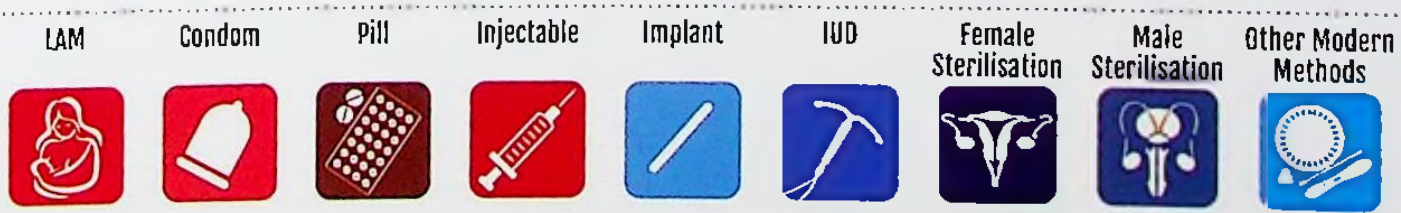
[1] Source: 'Use of modern contraception increases when more methods become available: analysis of evidence from 1982-2009', John Ross and John Stover, 2013

METHOD MIX SCENARIO



Source: 'FP2020 Partnership in Progress 2013-2014'

*All country method figures in %



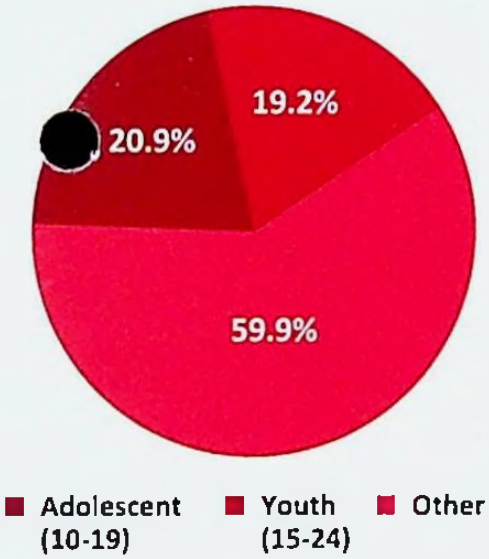
INVESTING IN YOUTH

THE YOUTH DIVIDEND

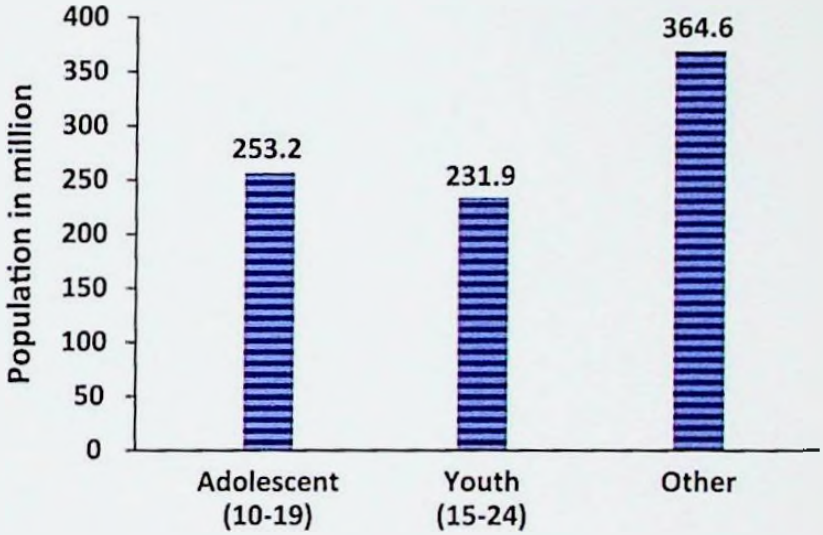
ADOLESCENT AND YOUTH POPULATION - INDIA*

POPULATION FOUNDATION OF INDIA

PERCENTAGE OF POPULATION

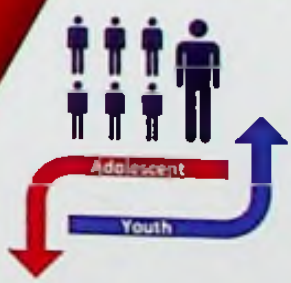


AGE GROUP



In India, as per Census 2011 ADOLESCENT population (10-19) is 253.2 MILLION and that of the YOUTH (15-24) is 231.9 MILLION constituting 20.9% and 19.2% of the total population respectively.

There has been a decline in the proportion of adolescent population and an increase of youth population compared to Census 2001.



*Source - Census 2011

YOUTH FAMILY PLANNING & UNMET NEED

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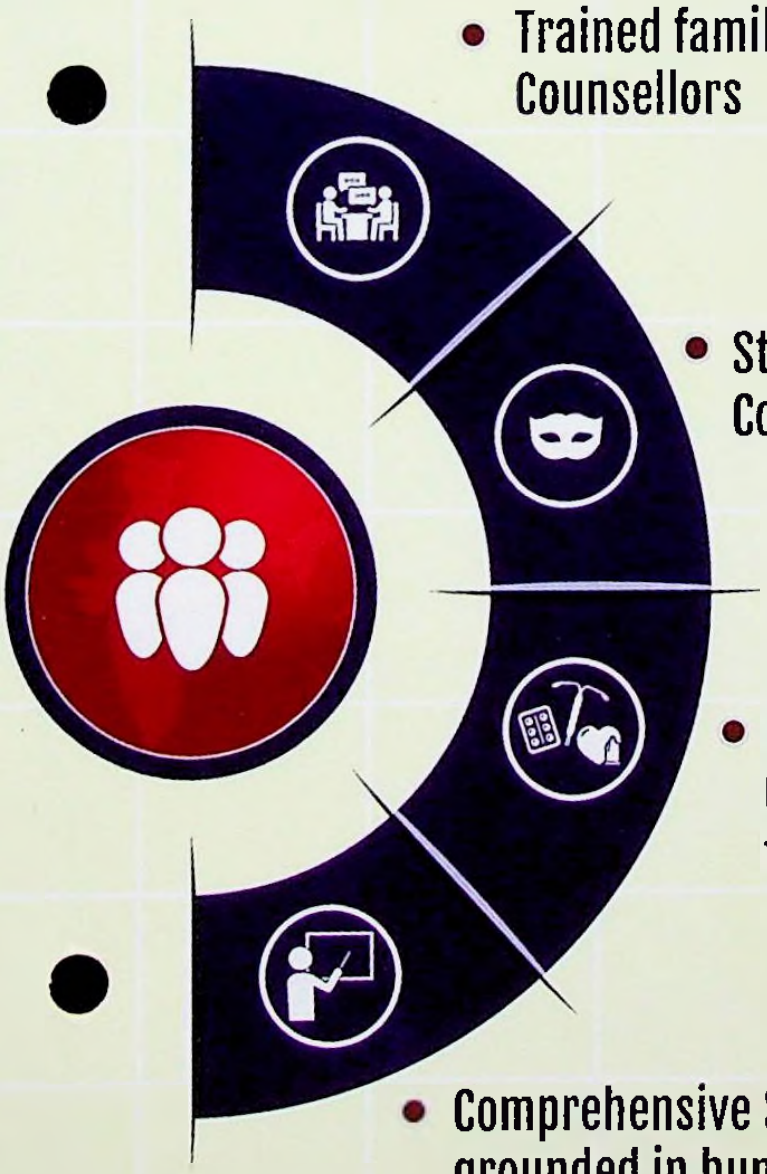
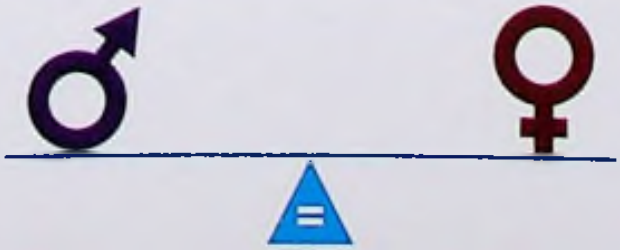
Addressing their needs will require



- Trained family planning Counsellors
- Statutes on Privacy and Confidentiality
- Emphasis on Youth-Friendly Contraceptive Services for Informed Choice
- Comprehensive Sexuality Education which is grounded in human rights and gender equality



Venous thromboembolic disease and combined oral contraceptives: results of international multicentre case-control study

*World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception**

Summary

The composition and use of oral contraceptives (OCs) have changed since their cardiovascular side-effects were established 20 years ago. This report describes the risk of idiopathic venous thromboembolic (VTE) events (deep vein thrombosis [DVT] and/or pulmonary embolism [PE]) in association with current use of combined OCs among 1143 cases aged 20–44 and 2998 age-matched controls, as evaluated in a hospital-based, case-control study in 21 centres in Africa, Asia, Europe, and Latin America.

OC use was associated with an increased risk of VTE in Europe (odds ratio 4·15 [95% CI 3·09–5·57]) and in non-European ("developing") countries (3·25 [2·59–4·08]). Risk estimates were generally higher for DVT than for PE but no consistent trend by certainty of diagnosis (definite, probable, possible) was found. Increased risk was apparent within 4 months of starting OCs, was unaffected by duration of current episode of OC use, and had disappeared within 3 months of stopping OCs. Relative risk estimates of VTE associated with OC use were unaffected by age of user, by history of hypertension (excluding hypertension in pregnancy), or in any consistent way by smoking. However, in both groups of countries increased body mass index (BMI) was an independent risk factor for VTE, and OC-associated odds ratios were higher among those with a BMI above 25 kg/m² than among those with smaller BMIs. OC-associated risk estimates were high among women in Europe with a history of hypertension in pregnancy.

Odds ratios associated with the use of OCs containing a third-generation progestagen were higher than those observed with progestagens of the first (norethindrone type) and second (norgestrel group) generation. Odds ratios associated with first and second generation progestagens tended to be lower, though not significantly, when used in combination with low (<50 μg oestrogen) rather than higher oestrogen doses. This study confirms an association between OC use and VTE in Europe and the developing countries, although overall risk estimates associated with use were lower than demonstrated in most previous studies of non-fatal idiopathic VTE.

Lancet 1995; **346**: 1575–82
See Editorial page 1569 and Commentary page 1570

*Writing committee, study organisation, and participants listed at end of article

Correspondence to: Dr N R Poulter, Department of Epidemiology and Public Health, University College London Medical School, 1–19 Torrington Place, London WC1E 6BT, UK; and Dr O Meirik, Task Force on Epidemiological Research in Reproductive Health, UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, 1211 Geneva 27, Switzerland

Introduction

Following the introduction, in 1960, of oral contraceptives (OCs) into clinical practice, the first published suggestion of an association with increased risk of cardiovascular disease was a case-report of a 40-year-old woman who developed a pulmonary embolism (PE) after taking Enovid.[1] Subsequently, a series[2–13] of case control studies have evaluated the risk of venous thromboembolism (VTE) associated with OCs. These studies differed in the events included—fatal or non-fatal, idiopathic or secondary to operations, trauma, or infection, and PE or deep-vein thrombosis (DVT) or a mixture of both. Relative risk (RR) estimates varied between 2 and 11 and tended to be higher when only idiopathic cases were included. Despite being limited in size, the few cohort studies to have investigated the risks of VTE associated with OC use[14–18] found RRs compatible with those estimated in case-control studies.

The association between OC use and VTE requires further evaluation for several reasons. First, almost all previous studies took place in the 1960s and 1970s, when OCs contained higher doses of oestrogen and progestagen than they do today, and before prescribing practice had changed towards the preferential use of OCs by younger women who do not have other risk factors for cardiovascular disease.[19] Some studies[17,20] but not others[12] have suggested that such changes in dose and composition might reduce the risk of VTE. Second, most studies have been done in northern Europe and the USA, and it may not be appropriate to extrapolate the results to populations with different incidence rates of VTE disease and prevalence of associated risk factors. Third, part of the apparent variability in OC-associated risk estimates reported was due to the difficulties in diagnosing DVT and PE accurately,[21,22] particularly when the diagnosis was based mainly on clinical grounds. Finally, only one study included more than 100 cases[5] and previous attempts to see if the risk of VTE was modified by or interacted with other risk factors such as smoking lacked power and produced inconsistent results.

This paper reports on the relation between idiopathic VTE and use of combined OCs from a multicentre, hospital-based, case-control study of stroke, acute myocardial infarction, and VTE in Africa, Asia, Europe, and Latin America (including the Caribbean). Findings on stroke and myocardial infarction will be reported elsewhere. The principal aim of the VTE component was to evaluate whether current OC use was associated with increased risk of a first DVT, PE, or both in women from Europe and from the other three regions combined. Secondary aims were to evaluate the risk in each of the four regions and whether risks differed among subgroups of women, such as smokers or those overweight, and according to type, duration, and past use of OCs.

Certainty	Europe (n=470)	Developing countries				Combined (n=1217)
		All (n=747)	Africa (n=159)	Asia (n=84)	L Am (n=504)	
DVT	76·4	87·3	91·8	82·2	86·7	83·1
Definite	50·8	25·0	13·2	48·8	24·8	35·0
Probable	15·3	43·6	42·1	31·0	46·2	32·7
Possible	4·9	14·5	32·7	1·2	10·9	10·8
Other	5·3	4·2	3·8	1·2	4·8	4·6
PE	23·6	12·7	8·2	17·8	13·3	16·9
Definite	7·2	2·4	0·0	10·7	1·8	4·3
Probable	12·4	8·7	6·9	7·1	9·5	10·1
Possible	1·7	1·1	1·3	0·0	1·2	1·3
Other	2·3	0·5	0·0	0·0	0·8	1·2

Table 1: **Percentage distribution of types of VTE cases by region**

Patients and methods

A more detailed description of study methods will be published elsewhere.[23] This hospital-based case-control study was undertaken in 21 centres in 17 countries subdivided into four regions. Each centre recruited cases and controls from a variable number of collaborating hospitals. Women were eligible as cases if they were aged 20–44 years (15–49 in three centres), had been admitted to a collaborating hospital between Feb 1, 1989 and Jan 31, 1993, and had a discharge diagnosis of DVT and/or PE. Those who died within 24 h of admission, who had a history of stroke, DVT, PE, acute myocardial infarction, or natural or surgical menopause, or who had a recent history (within 6 weeks) of pregnancy, major illness causing prolonged bed rest, or surgery were excluded.

Case definitions

A monitoring system was set up in each centre to identify all eligible cases. A review of the medical history, examination, and investigations allowed classification of these cases as definite, probable, possible, or other in respect of DVT or PE. These four categories, based on signs and symptoms and the results of investigations, were developed using published data[24,25] and the opinions of four senior clinicians with a special interest in thrombotic disease during a pilot review of a sample of cases. This allowed a standardised classification of DVT and PE diagnosed with varying degrees of certainty. All cases considered by their physician to have had a DVT or PE were categorised as:

Definite DVT when confirmed by venography, duplex scanning, or radioisotope studies.

Probable DVT in the absence of any other likely cause for the presenting signs and symptoms, when swelling and induration extended above the knee, and when any two of the following four indicators were present: increased superficial temperature of affected limb, tenderness on palpation, superficial venous engorgement, compatible doppler ultrasound investigation. In the absence of any other likely cause for the presenting signs or symptoms, when swelling and induration were only apparent in the calf, and when three of the four indicators were present, a case was also accepted as "probable DVT".

Possible DVT in the absence of any other likely cause for the presenting signs and symptoms and when swelling occurred below the knee together with any two of the four clinical indicators listed under "probable DVT"—or, in the absence of any other likely cause for the presenting signs and symptoms, when marked swelling and induration extended above the knee.

Other DVT for all remaining DVT cases.

Definite PE if either ventilation/perfusion (V/Q) scan, angiography or necropsy findings were so reported.

Probable PE if no good evidence of an alternative diagnosis was reported and any three of the following signs, symptoms, or investigations were reported: haemoptysis, pleuritic chest pain of sudden onset, breathlessness of sudden onset, ECG pattern of right heart strain, chest X-ray changes compatible with the diagnosis, arterial gas concentrations compatible with the diagnosis, syncope with tachypnoea, other compatible clinical signs (eg, pleural rub, raised jugular venous pressure, added heart sounds), compatible ventilation (V) or perfusion (Q) scan.

Possible PE if no good evidence of an alternative diagnosis was reported and any two of the nine signs, symptoms or investigations above were reported, or where evidence of an alternative diagnosis was reported and three of the nine were reported.

Other PE for the remaining PE cases.

Those cases diagnosed as having both DVT and PE were treated in the analyses under the event diagnosed with more certainty. When diagnostic certainty was the same the case was classified as DVT on the basis that PE is usually preceded by DVT.

Characteristic*	Europe					Developing countries				
	Cases (n=433)	Controls, by OC use				Cases (n=710)	Controls, by OC use			
		All (n=1044)	Current (n=356)	Past (n=484)	Never (n=204)		All (n=1954)	Current (n=239)	Past (n=647)	Never (n=1068)
Age (yr) (mean and SD)	32·5	32·2	29·1	34·0	33·1	32·7	32·4	30·0	34·2	31·8
	7·0	7·0	6·5	6·6	6·9	7·3	7·3	6·3	6·6	7·7
BMI (kg/m²) (mean and SD)	25·1†	23·9†	23·4	24·0	24·4	25·2‡	23·8‡	23·6	24·3	23·5
	4·8	4·5	4·0	4·7	5·0	5·1	5·0	5·4	4·5	5·1
Number of live births										
0	26·3	29·5	40·2	21·3	30·4	19·3	24·5	18·4	5·3	37·5
1–2	59·6	56·9	51·7	59·3	60·3	39·4	37·1	49·4	38·0	33·7
≥3	14·1	13·6	8·2	19·4	9·3	41·3	38·5	32·2	56·7	28·8
Married/stable union	76·7	73·6	71·9	76·7	69·1	61·1	60·5	65·7	68·8	52·4
Education beyond secondary	28·6	35·8	48·0	33·7	19·6	20·3	20·2	20·5	15·9	22·8
Current smoker	40·7	37·1	36·8	41·1	27·9	15·9	16·7	20·9	15·5	16·6
At least 1 unit of alcohol/wk	30·7	30·8	35·7	29·7	25·0	3·4	4·6	5·9	7·3	2·7
Self-reported history of										
Hypertension (HBP)	4·6	5·2	2·0	6·6	7·4	6·9	4·0	0·8	6·2	3·5
Hypertension (HIP)	17·0	10·6	5·9	14·5	9·8	12·5	11·2	11·3	16·2	8·1
Diabetes mellitus	1·4	1·2	0·6	1·7	1·0	2·8	1·9	1·7	2·0	1·9
Rheumatic heart disease	1·2	0·6	0·3	0·4	1·5	1·6	0·1	0·0	0·2	0·0
Family history of CVD	4·4	4·5	2·5	6·0	4·4	5·4	4·0	3·8	4·6	3·7

*Notes: current smoker=at least 1 cigarette in 3 months before illness which caused hospital admission (cases) or before admission (controls); hypertension (HBP)=that diagnosed before current OC use and excluding hypertension in pregnancy; hypertension (HIP)=blood pressure problems in pregnancy including pre-eclampsia and eclampsia; CVD=stroke and/or AMI in either parent before age 60 and 50, respectively.
†3 cases and 6 controls (2 never, 3 past, 1 current users) with unknown BMI.
‡236 cases and 678 controls (346 never, 238 past, 94 current users) with unknown BMI.

Table 2: **Characteristics of VTE cases and controls (% unless otherwise shown)**

Region	Type of user	Cases	Controls	Crude OR (95% CI)
Relative to non-users				
Europe	Non-user	168	688	1·00
	User	265	356	3·95 (2·96–5·28)*
Developing countries	Non-user	505	1715	1·00
	User	205	239	3·25 (2·59–4·08)
Africa	Non-user	107	338	1·00
	User	46	69	2·14 (1·37–3·36)
Asia	Non-user	56	228	1·00
	User	26	16	7·30 (3·39–15·72)
Latin America	Non-user	342	1149	1·00
	User	133	154	3·37 (2·53–4·48)
Relative to never users				
Europe	Never	53	204	1·00
	Past	115	484	0·84 (0·58–1·24)
	Current	265	356	3·53 (2·39–5·21)
Developing countries	Never	320	1068	1·00
	Past	185	647	1·00 (0·80–1·24)†
	Current	205	239	3·25 (2·54–4·14)‡

Adjusted ORs *4·15 (3·09–5·57) adjusted for hypertension in pregnancy (HIP) excluding 3 cases (users) and 1 control (non-user) with unknown HIP; †0·93 (0·74–1·17) and ‡3·08 (2·40–3·96) adjusted for number of live births (0, 1–2, 3 or more).

Table 3: **Odds ratios of VTE in relation to combined OC use by region, with non-user or never user as reference group**

Controls

For each case, an attempt was made to recruit 3 female controls matched by 5 year age band (20–24, 25–29, and so on). Controls were subject to the same exclusion criteria as cases and their date of admission to hospital had to be between 2 weeks before and 4 months after that of the case. Controls had to be admitted to the same hospital as the case, with one of 27 diagnoses considered to have no association with OC use.[11] The procedure for control selection was defined in a field protocol produced by each collaborating centre. Methods were adapted to local conditions but were similar. Controls were recruited by paying regular visits, in a predefined random order to those wards which accepted women with any of the control diagnoses.

Interviews

All cases and controls were interviewed in a standard way using the same questionnaire, which established eligibility and included self reported details of medical and reproductive history, estimated height and weight, past and present contraceptive use, use of other medications, family history of stroke and/or myocardial infarction (in either parent before age 60 and 50, respectively), details of smoking habit, use of alcohol and coffee, level of education and social class (assessed locally on the basis of housing, income, education and/or occupation). A current smoker was defined as a woman who had smoked at least 1 cigarette in the 3 months before the illness which had caused her to be admitted to hospital and a moderate smoker was one who smoked at least 10 cigarettes per day. Information about hypertension was obtained from responses to three questions—had the respondent ever (excluding pregnancy) had high blood pressure; had she had a blood pressure problem, including pre-eclampsia or eclampsia, during but not necessarily confined to pregnancy (hypertension in pregnancy); or had medication to control blood pressure been used in the 3 months before the illness which had caused hospital admission. Identification of OC type was assisted by showing the women samples or pictures of locally available OC packets. Details of cases' diagnostic information were recorded.

This report assesses risk of DVT and PE associated with the current use of combined OCs compared with those not currently using OCs (non-users). Women who currently used progestagen-only contraceptives (oral, 24 cases and 68 controls; injectable, 14 cases and 38 control) and women who used combined injectable contraceptives (7 cases and 12 controls) were not considered to be current OC users but were classified as never or past OC users on the basis of any previous use of combined OCs. Current OC use was defined as having taken an OC at any time during the 3 months before the event (cases) or before hospital admission (controls). Women who were current OC users but who did not know the type (3 cases, 4 controls) were considered to be current users of combined OCs and were included in all analyses, except those referring to type of preparation. In the analyses non-users (past and never users combined) were preferred to never users as the reference group because VTE risk is associated with current rather than ever use of OCs, and never users, particularly in Europe, represent a small and possibly atypical subset of non-users.

11 women (1·0%) eligible as VTE cases were not interviewed because they were too ill or had died before the questionnaire could be completed. For them, the closest available relative or friend was interviewed as a proxy.[8] Complete participation of eligible cases and controls was reported by 13 or the 21 collaborating centres and in the remaining 8 centres only 26 cases of stroke, myocardial infarction, or VTE, and 53 controls refused participation.

Statistics

Conditional logistic regression analyses were done with EGRET software.[28] Adjusted models included confounding variables, selected in a sequential manner, which resulted in at least a 5% change in the estimate of the risk associated with OC use.[11] The patterns of OC use, risk factors for VTE, and confounding differed in Europe from those in the developing regions and it was decided a priori to examine patterns of OC-associated risk separately in these two groups of countries. Consequently, separate models were fitted for Europe and for the developing regions combined. Trends of odds ratios (OR) in stratified analyses were assessed by a test for linear trend in the log odds ratios.[28] 95% confidence intervals were calculated and are shown after ORs in parentheses.

Results

Of the 1011 cases of DVT and 206 cases of PE recruited, 42% and 25%, respectively, had their diagnoses confirmed by definitive investigations. The proportion of VTE cases which were diagnosed as DVTs ranged from 92% in Africa to 76% in Europe. Over 80% of both case types were classified as definite or probable, and the data were insufficient to allow classification as definite, probable, or possible VTE on 71 women (table 1). The data presented in all subsequent tables (except table 8) and the analyses exclude these 71 ("other") cases and their controls. 1 additional case whose OC status was not known was also excluded from all subsequent analyses, as were 2 further cases because no matched controls had been recruited.

To the remaining 1143 cases a total of 2998 matched controls were recruited with an average of 2·4 controls per case in Europe and 2·8 in the developing countries. 56·9% and 56·0% of controls in Europe and the developing countries, respectively, had a diagnosis of

Age (yr)	Europe*				Developing countries			
	Non-user	<50 µg	≥50 µg	All users	Non-user	<50 µg	≥50 µg	All users
<35	1·00 (64/333)†	4·32 (2·88–6·49) (132/198)	3·29 (1·95–5·54) (44/75)	4·00 (2·74–5·83) (176/273)	1·00 (253/942)	3·23 (2·32–4·49) (93/117)	3·55 (2·36–5·34) (56/63)	3·35 (2·54–4·41) (149/180)
≥35	1·00 (104/354)	3·93 (2·30–6·73) (42/37)	5·19 (2·78–9·67) (42/43)	4·39 (2·75–7·00) (84/80)	1·00 (252/773)	2·50 (1·46–4·28) (28/35)	3·88 (2·14–7·05) (28/24)	3·05 (2·02–4·59) (56/59)

*Adjusted for HIP and excluding 2 cases and 3 controls with unknown OC type, and 3 cases (users) and 1 control (non-user) with unknown HIP. †No of cases/no of controls.

Table 4: **Odds ratios of VTE in relation to combined OC use by age group (non-user as reference) and oestrogen dose**

OC use	Europe		Developing countries	
	Non-HIP	HIP	Non-HIP	HIP
Non-users	1·00 (128/597)	1·83 (1·20–2·81) (40/90)	1·00 (431/1513)	1·23 (0·91–1·67) (68/191)
Users	4·04 (2·97–5·49) (229/335)	9·24 (4·93–17·31) (33/21)	3·34 (2·63–4·26) (183/211)	3·11 (1·72–5·63) (21/27)
	BMI ≤25 kg/m²	BMI >25 kg/m²	BMI ≤25 kg/m²	BMI >25 kg/m²
Non-users	1·00 (88/445)	1·52 (1·06–2·19) (80/237)	1·00 (186/780)	1·63 (1·21–2·19) (149/351)
Users	3·91 (2·76–5·54) (157/257)	7·01 (4·65–10·59) (103/98)	3·33 (2·33–4·75) (85/112)	9·44 (5·30–16·82) (54/33)
	Non-smokers	≥10 cigarettes per day*	Non-smokers	≥10 cigarettes per day*
Non-users	1·00 (100/431)	1·21 (0·82–1·78) (52/185)	1·00 (424/1438)	1·08 (0·66–1·76) (24/76)
Users	4·05 (2·83–5·78) (155/225)	5·53 (3·58–8·54) (76/83)	3·46 (2·69–4·44) (173/189)	2·23 (0·98–5·06) (10/19)

Exclusions: HIP analyses in Europe 3 cases (users) and 1 control (non-user) and in developing countries 7 cases (6 non-users, 1 user) and 12 controls (11 non-users, 1 user) with unknown HIP; BMI analysis in Europe adjusted for HIP, excluding unknown HIP and 2 cases (users) and 6 controls (5 non-users, 1 user) with unknown BMI; BMI analysis in developing countries excluding 236 cases (170 non-users, 66 users) and 678 controls (584 non-users, 94 users) with unknown BMI; smoking analysis adjusted for HIP in Europe. risk estimates among smokers of <10 cigarettes/day not shown.

Table 5: **Odds ratios of VTE in relation to combined OC use by history of hypertension in pregnancy, BMI, and smoking**

trauma, acute infection, appendicitis, or bone or joint disorders.

Characteristics of cases and controls in Europe and the developing countries are shown in table 2. Whilst mean body mass index (BMI) was greater among cases than controls in both groups of countries, cases and controls had similar mean age, number of live births and marital status, and reported similar rates of cigarette and alcohol consumption. In Europe, but not the developing countries, cases were less likely than controls to have gone beyond secondary education and were more likely to have reported hypertension in pregnancy. Cases in the developing countries but not in Europe were more likely than controls to have had at least 1 live birth, to give a history of high blood pressure (detected before the current episode of OC use and not during pregnancy), and rheumatic heart disease and to report a family history of premature cardiovascular disease. Rates of cigarette smoking and alcohol intake were higher and mean number of live births was lower in Europe than in the developing countries.

In Europe and the developing countries the crude ORs of having a VTE were 2·32 (0·71–7·63) and 33·0 (4·26–255·6), respectively, for a history of rheumatic heart disease; 2·70 (1·68–4·34) and 4·61 (2·77–7·68) for a BMI over 30 kg/m² compared with ≤20 kg/m²; 2·65 (1·73–4·05) and 3·81 (2·75–5·27) for a history of varicose veins; 2·59 (0·46–14·55) and 1·22 (0·11–13·53) for moderate smoking (≥10 cigarettes per day) compared with non-smokers; 1·66 (1·20–2·29) and 1·16 (0·89–1·52) for hypertension in pregnancy; and 0·95 (0·56–1·62) and 1·82 (1·25–2·65) for a history of high blood pressure.

Table 2 also includes the characteristics of controls who were current users, past users, or had never used OCs. Never users were less likely than current and past users to be regular alcohol drinkers. In Europe, never users were less likely than current and past users to be regular alcohol drinkers. In Europe, never users were less likely to be current smokers and to have reached secondary education than current or past users (the converse trend was apparent in the developing countries), and were more likely to have a history of rheumatic heart disease and/or high blood pressure (outside pregnancy).

The prevalence of current OC use among cases and controls in Europe (61·2% and 34·1%, respectively) was higher than in the developing countries (28·9% and 12·2%). The overall ORs of having a VTE associated with current OC use compared with non-users (never and past-users combined) and with never users were significantly raised in all four regions (table 3). In Europe, HIP confounded the relation whereas in the developing countries combined no confounders were identified. ORs among past users compared with never users were less than unity. Consequently, risk estimates associated with current OC use were smaller when compared with never rather than non-users.

No consistent patterns of risk estimates among OC users were apparent according to age or oestrogen dose (table 4). No consistent or important effect of a history of high blood pressure (excluding pregnancy) on OC-associated risk was apparent either. However, compared with non-users of OCs with no history of hypertension in pregnancy, risk estimates associated with OC use in Europe but not the developing countries were higher among those who also reported hypertension in pregnancy (table 5). This effect was similar in younger and older women and was also apparent among women whose blood pressure problems were confined to

Months	Europe†	Developing countries
Duration of episode of use of current OC		
Non-users	1·00 (168/687)	1·00 (505/1715)
Users		
<4	4·39 (2·50–7·71) (29/35)	4·77 (2·96–7·84) (40/33)
4–12	5·63 (3·58–8·84) (61/62)	3·75 (2·54–5·53) (57/58)
13–24	4·20 (2·41–7·33) (32/52)	2·23 (1·31–3·79) (23/40)
25–48	3·51 (2·28–5·41) (54/88)	3·31 (2·08–5·25) (38/47)
49–72	3·68 (2·26–6·64) (33/45)	2·31 (1·26–4·25) (18/29)
73–96	3·56 (1·78–6·34) (20/32)	1·61 (0·67–3·84) (8/18)
>96	4·04 (2·32–7·04) (33/41)	6·23 (2·78–13·96) (19/9)
(Trend)	(p=0·25)	(p=0·26)
Time since last use of combined OCs		
Never user	1·00 (53/204)	1·00 (320/1068)
Past user		
>144	0·77 (0·46–1·28) (33/129)	1·17 (0·82–1·65) (63/162)
109–144	0·81 (0·42–1·57) (15/59)	0·66 (0·38–1·12) (18/87)
73–108	0·72 (0·37–1·42) (14/75)	0·76 (0·45–1·28) (21/85)
37–72	1·28 (0·72–2·27) (25/82)	0·96 (0·62–1·50) (31/108)
25–36	1·07 (0·43–2·65) (8/32)	0·81 (0·38–1·72) (9/40)
13–24	0·71 (0·28–1·82) (6/37)	0·64 (0·33–1·24) (11/60)
>3–12	0·70 (0·29–1·67) (7/45)	1·21 (0·72–2·03) (22/69)
Current user		
>2–3	0·65 (0·07–5·79) (1/9)	2·67 (1·05–6·81) (8/11)
>1–2	1·37 (0·57–3·29) (8/25)	1·73 (0·77–3·85) (10/20)
≤1*	4·05 (2·70–6·07) (256/322)	3·28 (2·53–4·26) (187/208)
(Trend)	(p=0·65)	(p=0·52)

ORs adjusted for HIP for Europe, duration of use, and for live-birth categories (0, 1–2, 3 or more) for developing countries, time since last use. Exclusions: duration of use, unknown HIP and 1 control with unknown duration of current episode of OC use, Europe, and 2 cases and 5 controls with unknown duration of current episode of OC use. developing countries: time since last use unknown. 7 cases, and 25 controls. Europe, and 10 cases and 36 controls, developing countries.

*Including cases and controls taking OCs at time of even and at time of hospital admission respectively.

Table 6: **Odds ratios of VTE in relation to duration and recency of combined OC use**

Progestagen	Europe†				Developing countries			
	<50 μg		≥50 μg		<50 μg		≥50 μg	
First	3·37 (1·44–7·93)	(10/18)	4·05 (1·92–8·54)	(19/27)	0·00	(0/8)	3·62 (2·04–6·44)	(26/31)
Second	3·61 (2·53–5·13)	(102/163)	3·83 (2·44–6·02)	(54/73)	2·79 (2·08–3·75)	(103/137)	3·79 (2·47–5·82)	(50/47)
Third	7·36 (4·20–12·90)	(53/51)	..	(0/0)	12·23 (4·76–31·43)	(18/7)	..	(0/0)
Other	15·70 (3·90–63·15)	(9/3)	3·83 (1·74–8·45)	(13/18)	..	(0/0)	3·44 (1·25–9·46)	(8/9)
Total	4·24 (3·07–5·87)	(174/235)	3·96 (2·66–5·90)	(86/118)	3·02 (2·28–4·00)	(121/152)	3·64 (2·60–5·09)	(84/87)

OR relative to 168/687 and 505/1715 non-users in Europe and the developing countries, respectively.
*First generation, ethynodiol diacetate, lynoestrenol, norethisterone, norethisterone acetate, and norethynodrel; Second generation, norgestrel, levonorgestrel, and norgestrienone; Third generation, desogestrel, gestodene, and norgestimate; Others, chlormadinone acetate and cyproterone acetate.
†Excluding 2 cases and 3 controls with unknown OC type, and 3 cases (users) and 1 control (non-user) with unknown HIP, and adjusted for HIP.

Table 7: **Adjusted odds ratios of VTE in relation to current use of combined OCs by progestagen type and oestrogen dose**

Certainty	Europe*			Developing countries		
	VTE	DVT	PE	VTE	DVT	PE
Definite	3·88 (2·70–5·57)	4·13 (2·79–6·10)	2·54 (0·95–6·77)	4·75 (3·11–7·26)	4·60 (2·97–7·14)	7·11 (1·38–36·75)
Probable	4·90 (2·79–8·61)	5·61 (2·69–11·69)	4·02 (1·69–9·54)	3·11 (2·26–4·28)	3·47 (2·42–4·99)	2·09 (1·06–4·15)
Possible	3·96 (1·17–13·34)	4·32 (1·09–17·15)	2·82 (0·21–38·14)	1·95 (1·14–3·31)	1·95 (1·14–3·36)	1·73 (0·10–30·76)
Other	2·22 (0·90–5·47)	2·39 (0·79–7·19)	1·91 (0·40–9·02)	6·04 (1·89–19·30)	..†	..†

*Adjusted for HIP. †Cannot be calculated due to zero in one cell.

Table 8: **Odds ratios (95% CI) of VTE, DVT and PE by certainty of diagnosis in relation to combined OC use**

pregnancy. A significant trend of increasing risk of VTE was apparent with increasing BMI ($p<0·001$).

In univariate analyses smoking less than 10 cigarettes per day was not associated with an increased risk of VTE compared with non-smokers, whereas those smoking at least 10 cigarettes per day had ORs of 2·59 (0·46–14·55) in Europe and 1·22 (0·11–13·53) in the developing countries.

Duration of current episode of use (table 6) and lifetime duration of use (data not shown) did not affect the risk estimates of VTE. Increased ORs were fully realised within 4 months of starting OCs and had resolved within 3 months of stopping (table 6). However, risk estimates among those who, although classified by study definition as current users, had stopped OC use between 1 and 3 months before the event precipitating admission (cases) or hospital admission (controls) were only marginally increased in Europe 1 month after stopping, whereas in the developing countries they remained significantly increased up to 3 months after stopping OCs. However, in both groups of countries ORs were highest among those current users who had continued OC use at least until 1 month before the event (cases) or admission (controls).

No appreciable difference in risk estimates was apparent between users of OCs containing low or higher oestrogen doses (table 7). However, risk estimates among users of first and second generation progestagens were slightly larger when used in combination with a higher rather than with a low oestrogen dose. Risk estimates among users of OCs containing third-generation progestagens, which are only used in combination with lower dose oestrogen, were higher than for users of first and second generation progestagens, and the highest OR was observed among users of other progestagens combined with a low oestrogen dose in Europe.

Table 8 shows OC-associated risks by certainty of diagnosis. ORs tended to be higher for DVT than PE and in the developing countries, but not in Europe, tended to fall with decreasing certainty.

Discussion

In this study, the largest so far to have investigated VTE and OC use, current use of combined OCs was associated with a significantly increased risk of a first event of VTE, with ORs of about 4·2 in Europe and 3·3 in the developing countries. These estimates are at the lower end of the range of ORs previously reported for idiopathic VTE associated with OCs.

Risk factors

The only identifiable confounder was a history of hypertension in pregnancy, in Europe; there was no confounding in the developing countries. The only other risk factors for VTE identified were a history of varicose veins, a BMI of over 25 kg/m², and a history of rheumatic heart disease.

The finding that ORs associated with current OC use were unaffected by age accords with previous studies.[5,8] Similarly, as reported in most[4,29] but not all studies,[10] no striking association between smoking and risk of VTE emerged.

In univariate analyses, a history of high blood pressure detected outside pregnancy and before OC use (so not in any causal pathway linking OCs and VTE) was a significant risk factor for VTE in the developing countries only; hypertension in pregnancy was significantly associated with VTE in Europe. In Europe OC users who had a history of hypertension in pregnancy had high ORs compared with non-OC users without such a history (table 5). OCs induce adverse effects on platelets and the coagulation and fibrinolytic systems,[30] including antithrombin III activity,[31] which are similar to the changes seen in pregnancy-induced hypertension. Perhaps women with a history of pregnancy-induced hypertension are prone to OC-induced VTE, and these two problems may share some pathophysiological characteristics.

BMI was calculated from self-reported height and weight, not routine measurements on admission to hospital. Nevertheless, compared with lighter women who did not use OCs, those with a BMI over 25 kg/m² consistently had higher risk estimates associated with OC use than those with lower BMIs, a finding which has not been observed in most previous studies.[5,10] An increasing risk of VTE associated with increasing levels of BMI over 20 kg/m² was demonstrated in univariate analyses. Women with higher BMIs who wish to use OCs should be made aware of these increased risks. Because BMIs were reported during the hospital stay this study could not differentiate women whose BMI was high before OC use from those whose BMI rose while they were using an OC, and these data may have implications for those whose

body weight rises significantly whilst they are on an OC.

The rapid onset of OC-induced risk, the lack of effect of duration of OC use, and the rapid reduction of risk after stopping OCs are in keeping with previous reports.[12,32,33] Table 6 suggests that while there was no increased risk after stopping OCs for 3 months, very little, if any, increase in risk of VTE was maintained among those women in Europe who had stopped OCs for between 1 and 3 months, whilst in the developing countries some increase was apparent for up to 3 months after stopping. These levels of risk were, however, less than among those who continued OC use at least until 1 month before their illness or admission to hospital. Risk estimates associated with current OC use, as defined in this study, therefore tend to be smaller than those among women who used OCs in the month before the event or admission.

The lack of any significant oestrogen dose effect on risk estimates is in keeping with the results of some[17] but not all[20,34,35] studies. Whilst risk estimates among users of OCs containing first and second generation progestagens tended to be lower when used in combination with low rather than higher oestrogen doses, the overall impact of low-dose OCs was affected by the higher risk estimates associated with third-generation progestagens, which were always used in combination with low dose oestrogens. Third-generation progestagens are reported to have less adverse metabolic effects than with first and second generation compounds[36-38] so, despite controversial pharmacokinetic data[39,40] (which have not been confirmed),[41,42] the high ORs observed with OCs containing these progestagens were unexpected. These differences are further evaluated in the accompanying paper.[43]

Possible sources of bias

One review[44] has questioned all previously published data on OC use and VTE, pointing to difficulties in accurate diagnosis[21,22] and the potential for bias. In the WHO study the proportion of DVT cases definitively investigated was greater among OC users than non-users in Europe (60% and 48%, respectively) and in the developing countries (45% and 34%). This difference may have resulted from investigation bias; and hence led to an overestimate of risk. Alternatively, such differences would result if OC use is associated with more severe cases[3,4] and if such cases are more likely to be investigated. This difference in investigation rate between OC users and non-users was not apparent for PE.

Angiography was rarely used at the time of the study in routine clinical practice to diagnose PE, and V/Q scanning was the most frequently used "definitive" diagnostic tool in this study. V/Q scanning has been shown to be an insensitive test for detecting angiographically proven PE[45] but the conclusion was that combining a V/Q scan with a strong clinical suspicion of PE (as in the present study) was a "sound diagnostic strategy".[45] Furthermore, the relative stability of the ORs in various categories of diagnostic certainty of both DVT and PE in Europe suggests that differing diagnostic accuracy could not account for the observed association between VTE and OC use. The pattern of reducing ORs with decreasing certainty of case diagnosis seen in the developing countries might be expected because the association between OC use and risk of VTE was diluted by the inclusion of more non-VTE case. The ratio of DVT to PE cases recruited varied in the four regions, with a very high ratio in Africa. Limited diagnostic facilities in the African centres may have made PE more difficult to confirm than DVT.

Hospital-based controls have advantages and disadvantages.[46] Hospital controls with one of a range of permissible diagnoses were preferred to community controls because of the potential for bias due to differential use of hospital services by cases and community controls. In most collaborating centres it was not feasible to recruit community controls. In the 5 centres where both types of control were recruited ORs for VTE associated with OC use were similar with neighbourhood controls (4·07 [2·74–6·04]) and with hospital controls (3·71 [2·41–5·72]).

The possibility of bias introduced by proxy respondents for cases has been evaluated. Information from proxies proved reliable for recent or current events, and specifically for current OC use. Less than 1% of VTE cases required a proxy, and the impact on risk estimates for VTE due to misclassification of OC use by these repondents is less than 0·1%.[25]

Cases were restricted to those who survived for at least 24 hours after hospital admission and, because of the difficulties of accurate diagnoses, other cases may not have been included. In addition, subclinical or less obvious VTE were almost certainly underrepresented in this study, although one study suggested that OCs may be associated with more severe VTE events.[3,4] Thus, a potential limitation of this study is that the cases may not have been representative of all cases of VTE.

One strength of the study was the detailed information on OC exposure. Cases and controls were interviewed under similar conditions in hospital and they were not aware of the main objective of the study. The use of samples and pictures of locally available OCs and the comprehensive history of OC use permitted detailed evaluation of all types and patterns of OC use. Biased recall of OC exposure could have occurred as a result of the relative severity of DVT and PE compared with some of the control diagnoses and the knowledge of cardiovascular risk associated with OCs. This potential bias cannot be explored because contraceptive history was not validated against medical records or prescriptions. An exaggerated estimate of risk associated with OC use could also have occurred if controls stopped taking OCs in anticipation of hospital admission so that they were classified as past and not current OC users. However, only 0·6% and 0·2% of non-user controls from Europe and the developing countries, respectively, had stopped OC use more than 3 months before hospital admission for this reason, and were thus classified as past rather than current users.

Balancing risks

The risk estimates associated with OC use in this study, whilst high, are lower than those reported in most previous studies of idiopathic VTE. In assessing the public and individual health importance of different adverse cardiovascular events associated with the use of OCs, age-specific incidence and morbidity and mortality need to be taken into account. In the European centres, VTE was the most common adverse cardiovascular event associated with OC use while in the developing countries stroke predominated. However, the case-fatality rate for VTE events, which occurred in this study with similar

incidence throughout the reproductive years, is only 1–2% whereas 5-10% of strokes and up to 50% of acute myocardial infarctions, which occur predominantly in older women, are fatal.[11]

Information on these risks of cardiovascular disease associated with OC use should be made available to and be considered by women choosing a contraceptive method. In addition, the estimated risks of VTE in association with current use of OCs should be considered in the context of both the risks and benefits of alternative forms of contraception and the effects of OCs on quality of life, on protection against certain forms of neoplasia,[42] and ultimately on overall morbidity and mortality.

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8.

Effect of different progestagens in low oestrogen oral contraceptives on venous thromboembolic disease

*World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception**

Summary

A multinational hospital-based case-control study of the risk of venous thromboembolic disease associated with combined oral contraceptives (OCs) done in 1989–93 prompted a separate inquiry comparing the risk of venous thromboembolism (VTE) associated with low oestrogen (<35 µg ethinyloestradiol) OCs containing levonorgestrel with risks in low oestrogen preparations containing the third-generation progestagens desogestrel or gestodene. This analysis of data from 9 countries, involved 769 cases and 1979 age matched hospital controls and, in one centre, 246 community controls matched on age and general practice.

137 cases and 203 controls were current users of levonorgestrel (odds ratio [OR with 95% confidence interval] 3·5 [2·6–4·7]), with non-users as the reference; 35 cases and 28 controls were current users of desogestrel (9·1 [4·9–17·0]), and 36 cases and 28 controls were current users of gestodene (9·1 [4·9–16·7]). The ratios of these risks, compared with levonorgestrel, were 2·6 (1·4–4·8) for both products separately. Risk estimates adjusted for body mass index (BMI) were 3·4, 7·3, and 10·2 for levonorgestrel, desogestrel, and gestodene, respectively, compared with non-users, and 2·2 and 3·0 for desogestrel and gestodene, respectively, compared with levonorgestrel. 48 (68%) cases and 48 (86%) controls exposed to desogestrel or gestodene were from the UK (Oxford region). In this centre risk estimates compared with non-users, adjusted for BMI, were 2·6, 5·3, and 5·7 for levonorgestrel, desogestrel, and gestodene, respectively.

Current users of low oestrogen dose combined OCs containing desogestrel or gestodene appear to be at higher risk of VTE than users of combined OCs containing levonorgestrel. The possibility that these unexpected results on a secondary study objective are due to chance, bias, or residual confounding cannot be excluded entirely and the results need to be confirmed by independent studies. They are at variance with the apparently more favourable metabolic effects of the newer progestagens. Whether the new progestagens are associated with lower risk of arterial disease (stroke and myocardial infarction) must be evaluated further.

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See Editorial page 1569 and Commentary page 1570

Introduction

The WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception investigated the risks of venous thromboembolic disease, myocardial infarction, and stroke associated with use of combined oral contraceptives (OCs). The first report to be published covered venous thromboembolism (VTE).[1] This analysis, following a predefined plan, revealed a 3–4-fold increased risk among OC users compared with non-users and a further doubling or tripling of this risk among users of third-generation OCs. This unexpected observation, based on 71 exposed cases, prompted a detailed analysis of risk of VTE associated with the use of low oestrogen (<35 µg ethinyloestradiol) OCs containing levonorgestrel or two of the newer third-generation progestagens, desogestrel and gestodene. The study also showed that users of low oestrogen OCs containing

*Participants and study organisation listed in companion paper (*Lancet* 1995; **346**: 1575–82); writing committee listed at end of this article

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Country	Cases							Controls						
	Total	Non-users	Users	Type of OC*				Total	Non-users	Users	Type of OC*			
				De	Ge	Lng	Other				De	Ge	Lng	Other
Brazil	25	12	13 (52%)	2	2	5	4	74	56	18 (24%)	2	1	10	5
Chile	28	17	11 (39%)	0	2	9	0	84	73	11 (13%)	0	1	9	1
Colombia	215	156	59 (27%)	0	8	16	35	584	519	65 (11%)	0	3	25	37
Germany	127	20	106 (84%)	3	2	40	61	251	115	136 (54%)	0	1	53	82
Hong Kong	19	12	7 (37%)	1	1	3	2	57	52	5 (9%)	0	0	2	3
Hungary	52	24	28 (54%)	0	0	10	18	155	127	28 (18%)	0	0	11	17
Jamaica	133	93	40 (30%)	0	1	11	28	375	326	49 (13%)	0	0	17	32
Thailand	13	6	7 (54%)	1	0	3	3	39	37	2 (5%)	0	0	0	2
UK (Oxford region)	158	57	101 (64%)	28	20	40	13	360	214	146 (41%)	26	22	76	22
Total	769 (100%)	397 (52%)	372 (48%)	35 (5%)	36 (5%)	137 (18%)	164 (21%)	1979 (100%)	1519 (77%)	460 (23%)	28 (1%)	28 (1%)	203 (10%)	201 (10%)

*De=desogestrel, Ge=gestodene, Lng=levonorgestrel, Other=other combined OCs.

Table 1: **OC use among VTE cases and hospital controls**

progestagens other than first, second, or third generation had more than 4 times higher risk than users of low oestrogen dose OCs containing levonorgestrel, though this observation was based on small numbers. An assessment of the risk associated with the use of such products is also presented here.

Patients and methods

This analysis is limited to those participating centres where there were any cases or controls who were current users of OCs containing third-generation progestagens. This subset of 10 of the 21 centres in nine countries provided 829 VTE cases, 2135 age and hospital matched controls, and 506 community controls. Details of the study methods, case definitions, and selection of hospital controls and the characteristics of cases and controls are described elsewhere.[1,2]

Community controls

In four centres where this was feasible community controls were identified in addition to hospital controls. In the Oxford centre (hospitals in the Oxford region, UK), up to 2 community controls were selected for each case by referring to the records of the general practice (GP) with which the case was registered. 6 age-matched women not related to the case were identified as potential controls by random selection from the practice's age and sex register or from the alphabetical list of registered patients. After the practitioner's consent had been obtained the first 2 women selected were contacted by letter, seeking agreement to an interview. The letter was followed by a telephone call. If no contact could be made, or there was no response to a follow-up letter, the next woman identified from the practice records was contacted in the same way. These controls were interviewed at home within 4 months of the date of the case's admission to hospital and by the same people who did the case and hospital control interviews. Permission to select controls from the register was not granted by the general practitioner for 6 cases (4%), and permission to contact selected women was not granted for 8 of 924 potential controls (1%). Of 491 women sent letters requesting an interview, 32 had moved, 69 refused, and no reply was received from 110 (non-response rate 39%). The non-response rates among potential controls matched to cases aged 20–24, 25–29, 30–34, or 35–44 years were 52%, 44%, 31%, and 27%, respectively. No GP-based controls were interviewed for 18 cases (11%), representing 8%, 20%, 15%, and 6% of cases in the four age strata, respectively.

Community controls were also interviewed in Colombia, Hungary, and Jamaica but the identification and interviewing of such women proved difficult and expensive and not all subcentres recruited community controls. In Hungary recruitment of such controls was stopped after the first year. In Hungary and Jamaica no community control or matched case used desogestrel or gestodene. In Colombia community controls were recruited for 98 cases, 65 did not use OCs, and 1, 10 and 22 used gestodene, levonorgestrel, or other OCs, respectively. The corresponding figures among the community controls were 162 and 0, 9, and 25. Thus these community controls contributed little information on risks associated with desogestrel or gestodene and they were not included in further analyses.

Classification of OC types and referent groups

Current users of third-generation progestagens were subdivided according to product (desogestrel, gestodene, and norgestimate) and desogestrel users were further classified by ethinyloestradiol dose (20 µg or 30 µg). Non-users (past and never users combined) were the primary referent group, but risks associated with use of third-generation OCs were also compared with those among current users of levonorgestrel OCs in combination with <35 µg ethinyloestradiol. This type of OC was the most commonly used by cases (36%) and hospital (44%) and community (45%) controls, and is the most common combined OC world wide.[3] Users of levonorgestrel in combination with more than 35 µg ethinyloestradiol and users of combined OCs containing other progestagens were classified as a separate group. 1 case and 2 controls used norgestimate (250 µg, with 30 µg ethinyloestradiol) and these were reclassified with the levonorgestrel group. Norgestimate is rapidly metabolised to levonorgestrel or its metabolites.[4,5] Also the number of users was too small to provide useful estimates of risk.

Modelling risks and adjustment for confounding

Conditional logistic regression models were fitted using LogXact-Turbo (Cytel Software Corp, Cambridge, MA) that performs both asymptotic[6] and exact inference.[7] Risk estimates are presented with 95% confidence intervals in parentheses. Variables considered a priori as potential confounders were body mass index (BMI), live births, alcohol consumption, smoking, and history of hypertension (detected before current episode of OC use and not during pregnancy), hypertension in pregnancy, diabetes, and varicose veins. These variables were included sequentially in the models if they changed the estimate of the odds ratio associated with the use of levonorgestrel, desogestrel, or gestodene by more than 5%.[8]

Results

Distribution of cases by centre

829 VTE cases were identified in 10 collaborating centres from nine countries, almost half being either in Colombia (28%) or the UK (21%). 42% were classified as definite VTE, 42% probable, and 9% possible. In the other 54 (7%) cases the information was insufficient for classification, and they were excluded from further analyses. Also excluded were 1 case in the non-Oxford centres and 2 in the Oxford region whose type of OC was not known and 3 cases in the non-Oxford centres for whom no controls were identified. The remaining 769 cases were matched with 1979 hospital controls and 246 GP-based controls with known OC type. Among cases

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regulatory agencies and prominent discussion in the medical and lay press. The project incorporated three matched case-control studies with virtually identical methods [2] for which the exposure factor of particular interest was use of third generation oral contraceptives. The outcomes for the three studies were venous thromboembolism, myocardial infarction, and ischaemic (thrombotic) stroke. Results of the study testing an association between the third generation products and venous thromboembolism are reported in the accompanying article.[3] We report here the initial results of the case-control study assessing and contrasting the relation between second and third generation oral contraceptives and myocardial infarction in young women. Case recruitment continues. Identification and quantification of publicity bias will be incorporated in an amended protocol if extended field work proves feasible in the United Kingdom.

Subjects and methods

The subjects were women aged 16-45 who were recruited in 16 centres in five countries (Austria, France, Germany, Switzerland, and the United Kingdom). In this paper we include results for all five countries as well as for the United Kingdom and Germany alone to permit concurrent evaluation of our results on venous thromboembolism and myocardial infarction. An average of three controls was matched to each case; at least one control was from a hospital and at least one from the community. We matched for age in five year age bands. The cases of myocardial infarction (*International Classification of Diseases* code 410) met the criteria of the World Health Organisation.[4] Controls were identified and interviewed within four months of the myocardial infarction of the index case. Current use of oral contraceptives was defined as use within three months before the event for a case, the date of admission for a hospital control, and the date of interview for a community control. The field work, beginning with feasibility and pilot projects, started in July 1991, and case recruitment continued until November 1995. Recruitment of controls for this report continued until 15 November 1995.

We assessed current use of third generation oral contraceptives containing low doses of ethinyl oestradiol (usually 30 μg or 20 μg) and one of two progestogens, gestodene or desogestrel. Second generation oral contraceptives (the main reference group) are other low dose ethinyl oestradiol preparations (under 50 μg) with progestogens introduced to the market earlier. We report unmatched odds ratios with 95% confidence intervals and their P values. We combined community controls and hospital controls as our main reference group. Odds ratios were calculated by unconditional logistic regression to adjust for the potential confounders listed in the footnote to the table, of which current smoking was deemed to be the most important. We estimated the effect of smoking adjusted for use of oral contraceptives. Matched analyses were done as a sensitivity check and to determine whether overmatching may have occurred. Further details on methods have been published[1,2] or are available from us. We used a general plan and operational procedures virtually identical with those of the WHO's study group[4] on oral contraceptives to facilitate comparison of the results of that project with those of the transnational project.

We have outlined the method we used to calculate the number of lives "saved" by switching from second to third generation oral contraceptives in the accompanying paper.[3]

Results

We enrolled 153 cases of myocardial infarction (11 of them fatal) and 498 controls. Eighty two cases were identified in the United Kingdom, 47 in Germany, five in Switzerland, six in Austria, and 13 in France. When we compared current use of third generation with current use of second generation products as risk factors for myocardial infarction in all 651 women the odds ratio was 0·36 (0·1 to 1·2) (P=0·1; table 1). When current use of third generation products was compared with no previous use of oral contraceptives the odds ratio was 0·3 (0·1 to 1·0) (P=0·06). When we excluded the three countries with small sample sizes (Austria, Switzerland, and France) the estimates and confidence intervals became 0·45 (0·1 to 1·8) (P=0·26) for use of third generation *v* second generation products; 1·0 (0·3 to 3·5) (P=0·96) for current use of third generation products *v* no current use of oral contraception; and 2·2 (1·0 to 5·0) (P=0·07) for current use of second generation products *v* no current use.

When we compared women who currently used third generation oral contraceptives with those who currently used second generation products we considered the controls as two groups matched for hospital or community. The odds ratio was 0·91 (0·2 to 4·7) (P=0·9) for cases and hospital controls and 0·25 (0·06 to 1·0) (P=0·05) for cases and community controls.

In matched analyses the odds ratio was 0·40 (0·1 to 1·6) (P=0·19) in the comparison of third *v* second generation oral contraceptives. The odds ratio for second generation products *v* no use, was 3·1 (1·4 to 6·8) (P=0·01) and for third generation products *v* no current use 1·2 (0·34 to 4·4) (P=0·76). When current smoking was adjusted for use of oral contraceptives the odds ratio for the risk of myocardial infarction was 10·1 (5·7 to 17·9) (P<0·001) among our study subjects. Among women who used third generation products the crude odds ratio for current smoking was 3·1 (0·5 to 19·8) (P=0·23). Among those who used second generation products it was 11·1 (3·0 to 40·2) (P<0·001), and for women who were not current users of oral contraceptives the equivalent risk estimate was 7·7 (4·0 to 14·7) (P<0·001).

Given the prevalence of use of third and second generation preparations in the controls of this study, the observed odds ratio of 0·36 (0·1 to 1·2) for third compared with second generation products is consistent with a switch from second to third generation oral contraceptives, resulting in 12 fewer deaths from acute myocardial infarction per year in England and Wales. The confidence interval for the number of

Table 1—*Odds ratios* for risk of myocardial infarction for current use of different types of oral contraceptives: principal results of transnational study*

Comparison	Odds ratio (95% confidence interval)	P value	No exposed cases; No exposed controls
All cases (n=153)			
All controls (n=498)			
Third generation *v* second generation products	0·36 (0·1 to 1·2)	0·1	6; 34
Third generation products *v* no current use	1·1 (0·4 to 3·4)	0·9	6; 34
Second generation products *v* no current use	3·1 (1·5 to 6·3)	0·003	23; 45
Hospital controls (n=210)			
Third generation *v* second generation products	0·91 (0·2 to 4·6)	0·9	6; 11
Third generation products *v* no current use	1·8 (0·4 to 8·7)	0·4	6; 11
Second generation products *v* no current use	2·0 (0·8 to 4·9)	0·1	23; 26
Community controls (n=288)			
Third generation *v* second generation products	0·25 (0·1 to 1·0)	0·05	6; 23
Third generation products *v* no current use	0·9 (0·3 to 3·0)	0·8	6; 23
Second generation products *v* no current use	3·5 (1·5 to 8·6)	0·005	23; 19

*Adjusted for centre, age, body mass index, smoking, alcohol intake, and duration of exposure to oral contraceptives before current contraceptive.

	Non-Oxford centres		Oxford region		
	Cases	Controls	Cases	Hospital controls	GP-based controls
No	611	1619	158	360	246
Age (yr) (mean [SD])	33·2 (7·1)	32·8 (7·1)	30·7 (7·1)	30·0 (7·1)	31·6 (7·0)
BMI (kg/m) (mean [SD])	25·1 (4·9)	23·7 (4·7)	25·2 (5·0)	23·6 (4·8)	23·1 (3·9)
Live births					
0	20·1	24·3	42·4	47·8	37·8
1 or 2	48·3	44·7	39·2	38·9	45·5
3 or more	31·6	31·1	18·4	13·3	16·7
Medical history					
Hypertension	6·1	4·6	5·7	1·9	2·0
Hypertension in pregnancy	14·4	11·4	17·1	10·3	17·5
Varicose veins	17·3	4·9	5·7	5·3	6·5
Rheumatic heart disease	1·6	0·1	0	0	0
Smoking					
Non-smoker	75·2	75·3	55·7	60·3	76·4
<10 cigarettes/day	13·6	4·0	8·2	11·1	8·1
≥10 cigarettes/day	11·1	10·7	36·1	28·6	15·4
Alcohol consumption					
Never	23·3	24·9	9·5	11·2	8·1
Occasionally	69·3	67·9	48·1	41·7	44·3
Regular, ≤13 units/wk	6·6	5·9	34·8	37·5	38·2
Regular, >13 units/wk	0·8	1·3	7·6	9·5	9·3
Family history of premature CVD	6·4	4·7	1·9	3·6	3·7

BMI unknown for 76 cases (12%) and 241 controls (15%) in the non-Oxford centres and 1 case, 1 hospital, and 1 GP-based control in the Oxford region; hypertension in pregnancy not stated for 1 case and 1 control in the non-Oxford centres and 1 case in the Oxford region; rheumatic heart disease unknown for 1 control in the non-Oxford centres; smoking unknown for 1 case in the non-Oxford centres; alcohol consumption unknown for 1 case and 4 controls in the non-Oxford centres and 3 hospital controls in the Oxford region; family history of stroke and/or AMI unknown for 6 cases and 18 controls in the non-Oxford centres and 3 hospital and 4 GP-based controls in the Oxford region.

Table 2: **Characteristics of cases and controls**

and hospital and GP-based controls the proportions of OC users were 48·4%, 23·2%, and 32·5%, respectively.

Patterns of OC use among cases and hospital controls are shown in table 1. The proportion of women who used desogestrel or gestodene was greater among cases than controls in all nine countries except Hungary where the only user of a third-generation OC was a case taking norgestimate (included with levonorgestrel in table 1). Among women using levonorgestrel OCs, the distributions of OC type were similar in cases and controls; 10%, 49%, and 2% of controls used levonorgestrel 125, 150, and 250 µg, respectively, with 30 µg ethinyloestradiol, and 39% used phasic preparations. Among users of other OC types, 50% used levonorgestrel with 50 µg ethinyloestradiol (including phasic preparations), 37% norethisterone OCs with ethinyloestradiol or mestranol, and 13% other OC combinations.

Most cases and controls using desogestrel or gestodene were from the Oxford region and risk estimates were computed separately for this centre.

Characteristics of cases and controls (table 2)

In both the non-Oxford centres and the Oxford region, cases had higher BMI and more live births and were more likely to have reported a history of hypertension outside or during pregnancy than hospital controls. In the Oxford region, cases were more likely to be smokers and less likely to have a family history of premature cardiovascular disease. GP-based controls in the Oxford region were older than hospital controls, were less likely to have extreme BMI values, had more live births, reported more hypertension in pregnancy, and were less likely to smoke. In the non-Oxford centres cases were more likely than controls to have a history of varicose veins and rheumatic heart disease.

77% of GP-based controls were married or in stable union compared with 68% of hospital controls in the Oxford region (p=0·018), with a particular excess of married women in the 25–29 year age group (90% *vs* 68%). The prevalence of OC use among GP-based controls was lower (33%) than among hospital controls (41%), but among users, 33% of hospital and 38% of GP-based controls used desogestrel or gestodene.

Risks of VTE according to progestagen

Hospital controls (table 3)—In all centres risks among users of desogestrel and gestodene were 2·6 times higher than those for levonorgestrel users, and adjustment for the main confounder (BMI) did not change risk estimates substantially; nor did the omission of women with unknown BMI. Additional adjustment for alcohol consumption had only a small impact. Among users of desogestrel in combination with 30 µg ethinyloestradiol unadjusted risk estimates relative to non-users were 7·6 (3·9–14·7) based on 27 cases and 27 controls, and 38·2 (4·5–325) based on 8 cases and 1 control in combination with 20 µg ethinyloestradiol. In the non-Oxford centres risk estimates for desogestrel and gestodene users compared with non-users were higher than they were in the Oxford region. After adjustment for BMI and a history of varicose veins, the risk estimates for desogestrel and gestodene were similar. In the Oxford region, adjustment for BMI decreased the risks for both desogestrel and gestodene, with little change in risk for levonorgestrel users. Further adjustment for alcohol and hypertension in pregnancy increased the risk estimates for all three products, with little impact on the ratio of risk estimates.

GP-based controls—Risk estimates associated with OC use for the 140 VTE cases with GP-based controls were higher than the corresponding risks with hospital controls for all OC types. Due to lack of controls there were proportionately more cases omitted from the analysis for gestodene users (20%) than for levonorgestrel (10%) or desogestrel (4%) users. After adjustment for BMI and

Type of user	Cases	Controls	Unadjusted		Adjusted for BMI*		Adjusted for BMI and additional factors†	
			OR	p	OR	p	OR	p
All centres compared with non-users								
Non-user	397	1519	1		1		1	
Desogestrel	35	28	9·1 (4·9–17·0)		7·3 (3·9–13·8)		8·3 (4·3–15·9)	
Gestodene	36	28	9·1 (4·9–16·7)		10·2 (5·4–19·2)		10·5 (5·5–20·0)	
Desogestrel or gestodene	71	56	9·1 (5·6–14·7)		8·6 (5·3–14·2)		9·4 (5·6–15·6)	
Levonorgestrel	137	203	3·5 (2·6–4·7)		3·4 (2·5–4·6)		3·4 (2·5–4·7)	
Other	164	201	4·0 (3·0–5·2)		3·7 (2·8–5·0)		3·8 (2·8–5·2)	
All OC users	372	460	4·1 (3·3–5·1)		4·0 (3·1–5·0)		4·1 (3·2–5·2)	
Compared with levonorgestrel users								
Desogestrel			2·6 (1·4–4·8)	0·003	2·2 (1·2–4·1)	0·015	2·4 (1·3–4·6)	0·007
Gestodene			2·6 (1·4–4·8)	0·003	3·0 (1·6–5·8)	0·001	3·1 (1·6–5·9)	0·001
Desogestrel or gestodene			2·6 (1·6–4·2)	<0·001	2·6 (1·6–4·3)	<0·001	2·7 (1·6–4·8)	<0·001
Levonorgestrel			1		1		1	
Non-Oxford centres compared with non-users								
Non-user	340	1305	1		1		1	
Desogestrel	7	2	31·1 (3·7–262)		25·1 (2·9–215)		19·1 (2·1–173)	
Gestodene	16	6	12·5 (4·8–32·9)		18·9 (6·6–54·5)		21·0 (7·3–60·2)	
Desogestrel or gestodene	23	8	15·2 (6·3–36·4)		20·1 (7·8–51·9)		20·7 (7·9–53·7)	
Levonorgestrel	97	127	3·8 (2·7–5·3)		3·7 (2·5–5·3)		4·0 (2·7–5·8)	
Other	151	179	4·1 (3·1–5·5)		3·9 (2·8–5·4)		4·0 (2·9–5·6)	
All OC users	271	314	4·2 (3·3–5·4)		4·1 (3·1–5·5)		4·4 (3·3–5·8)	
Compared with levonorgestrel users								
Desogestrel			8·2 (1·0–68·8)	0·054	6·8 (0·8–58·5)	0·079	4·8 (0·5–43·4)	0·16
Gestodene			3·3 (1·2–8·8)	0·018	5·2 (1·8–15·1)	0·003	5·3 (1·8–15·5)	0·002
Desogestrel or gestodene			4·0 (1·6–9·7)	0·002	5·5 (2·1–14·4)	0·001	5·2 (2·0–13·7)	0·001
Levonorgestrel			1		1		1	
Oxford region (hospital controls) compared with non-users								
Non-user	57	214	1		1		1	
Desogestrel	28	26	6·4 (3·1–13·0)		5·3 (2·5–10·9)		7·3 (3·3–16·0)	
Gestodene	20	22	5·1 (2·7–13·9)		5·7 (2·5–13·2)		6·2 (2·7–14·7)	
Desogestrel or gestodene	48	48	6·3 (3·4–11·6)		5·4 (2·9–10·2)		6·8 (3·5–13·4)	
Levonorgestrel	40	76	2·7 (1·6–4·7)		2·6 (1·5–4·6)		3·1 (1·7–5·5)	
Other	13	22	3·1 (1·3–7·3)		3·1 (1·3–7·5)		4·0 (1·6–9·7)	
All OC users	101	146	3·7 (2·3–5·9)		3·5 (2·1–5·6)		4·1 (2·5–6·9)	
Compared with levonorgestrel users								
Desogestrel			2·4 (1·2–4·8)	0·017	2·0 (1·0–4·1)	0·057	2·3 (1·1–4·9)	0·027
Gestodene			2·3 (1·0–5·2)	0·055	2·2 (0·9–5·1)	0·075	2·0 (0·8–4·7)	0·12
Desogestrel or gestodene			2·3 (1·2–4·3)	0·008	2·1 (1·1–3·9)	0·024	2·2 (1·1–4·2)	0·018
Levonorgestrel			1		1		1	
Oxford region (GP based controls)‡ compared with non-users								
Non-user	49	166	1		1		1	
Desogestrel	27	17	13·0 (5·0–33·5)		12·2 (4·6–32·3)		15·0 (5·2–43·6)	
Gestodene	16	13	10·7 (3·6–32·0)		9·1 (3·0–27·2)		7·8 (2·4–25·1)	
Desogestrel or gestodene	43	30	12·1 (5·2–28·2)		10·9 (4·7–25·4)		11·5 (4·6–28·8)	
Levonorgestrel	36	40	6·4 (2·9–14·0)		7·4 (3·3–17·0)		8·5 (3·5–20·3)	
Other	12	10	8·6 (2·7–26·7)		8·7 (2·6–28·9)		13·0 (3·5–47·9)	
All OC users	91	80	8·4 (4·1–17·0)		8·9 (4·3–18·5)		10·0 (4·6–21·9)	
Compared with levonorgestrel users								
Desogestrel			2·0 (0·9–4·8)	0·10	1·6 (0·7–4·0)	0·27	1·8 (0·7–4·8)	0·25
Gestodene			1·7 (0·6–4·6)	0·31	1·2 (0·4–3·4)	0·70	0·9 (0·3–2·6)	0·89
Desogestrel or gestodene			1·9 (0·9–4·0)	0·088	1·5 (0·7–3·1)	0·32	1·4 (0·6–3·1)	0·46
Levonorgestrel			1		1		1	

*BMI categorised as ≤20, >20 but ≤25, and >25 kg/m². Excluding 76 cases (54 non-users, 7 levonorgestrel, and 15 other OC users) and 241 controls (217 non-users, 1 gestodene, 7 levonorgestrel, and 16 other OC users) in the non-Oxford centres, and 1 case (gestodene user), 1 hospital control (gestodene user) and 1 GP-based control (non-user) in the Oxford region with unknown BMI.

†Additional factors were: alcohol consumption (never, occasional, regular light, regular heavy) for all centres comparisons, and Oxford region (hospital controls); varicose veins (no/yes) for non-Oxford centres; hypertension in pregnancy (nulliparous, none or not stated, yes) for Oxford region (hospital controls); and smoking (non-smoker, <10 cigarettes/day, >10 cigarettes/day) for Oxford region (GP-based controls).

‡Excluding 18 cases with no matched controls (8 non-users and 1 desogestrel, 4 gestodene, 4 levonorgestrel, and 1 other OC user).

Table 3: **ORs (95% CI) of VTE by type of current OC used (matched risk estimates)**

smoking, the risk estimate for gestodene was similar to that for levonorgestrel users, though the risk for desogestrel remained high.

Risks according to age, smoking, BMI, and duration of use

There was no clear pattern of risk estimates in all centres combined compared with hospital controls for levonorgestrel, desogestrel, or gestodene users according to age group or smoking status. Risks did increase with increasing BMI among non-users (1·0, 2·2, and 3·1 for BMI ≤20 [referent category], >20 but ≤25, and >25 kg/m², respectively) and among levonorgestrel users (4·8, 6·0, and 8·7), though risks among desogestrel and gestodene users combined did not follow this pattern (32·6, 13·7, and 29·0). There was a slight decline in risk estimates relative to non-users for users of desogestrel, gestodene, and levonorgestrel OCs in the first 3 years of use. However, the ratio of risks for desogestrel and gestodene relative to levonorgestrel users were higher in

the second and third years of use (3·4 and 4·4, respectively) than in the first year (2·1). The ratio was higher for women who had not used OCs before the current episode of use (5·2) than for other current users (2·1).

Type and certainty of VTE diagnosis

The matched, unadjusted risk estimates for deep-vein thrombosis (DVT) were higher than for pulmonary embolus (PE) among all OC users (4·3 and 3·4, respectively), among levonorgestrel users (3·8 and 2·7), and among users of desogestrel or gestodene (11·6 and 5·5). These patterns of risk remained substantially unchanged after adjustment for BMI or alcohol consumption.

Risk estimates for all OC users compared with non-users increased with certainty of diagnosis (4·1 among definite, probable and possible, 4·4 among definite and probable, and 6·0 for definite VTE cases) with a similar pattern of increasing risk estimates among levonorgestrel, desogestrel, or gestodene users. The ratio of risk estimates for desogestrel or gestodene compared with levonorgestrel users remained constant (between 2·6 and 2·8 according to certainty of diagnosis).

Risk of VTE for users of other progestagens

The 9 cases and 3 controls using combined OCs with progestagens other than first, second, or third-generation types in combination with <50 µg ethinyloestradiol all used a single product (2 mg cyproterone acetate with 35 µg ethinyloestradiol [CPA/35]). 9 cases and 9 controls who used the same progestagen in combination with 50 µg ethinyloestradiol (CPA/50) were classified with users of other progestagens and high oestrogen dose. Compared with non-users, matched, unadjusted risk estimates were 14·9 (3·7–59·4) and 3·8 (1·4–10·7) for CPA/35 and CPA/50, respectively. The ratios of risks compared with levonorgestrel users were 5·1 (1·3–20·3) and 1·3 (0·5–3·8), respectively.

Discussion

The WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception[1] demonstrated that combined OCs were associated with an increased risk of VTE, although risk estimates were at the lower end of the range found in earlier case-control studies of non-fatal idiopathic VTE.[4] The analyses reported here indicate that while users of low oestrogen combined OCs containing levonorgestrel had 3·5 times the risk of VTE of non-users, OCs containing the third-generation progestagens desogestrel or gestodene were both associated with significantly higher risks (9·1 compared with non-users). This substantiates the unexpected observation in the main report, though the discrepancy between the results using hospital and GP-based controls in the Oxford region qualifies the interpretation of the data.

Hospital controls were the preferred comparison group because they provide information in a similar way and have similar usage of hospital services as the cases. Community controls were also recruited where feasible. In areas where there is homogeneous coverage of health services such controls may be more representative of the population from which the cases arise. When GP-based controls in the Oxford region were used for comparison the risk estimates for all OC types were higher than when hospital controls were used, and the risks associated with the use of desogestrel and gestodene were greater than those for levonorgestrel. However, the ratio of risks for gestodene compared with levonorgestrel users (1·7) was less than that observed with the hospital controls (2·3), and was reduced to 0·9 after adjustment for BMI and smoking. The risk estimates for desogestrel users remained high (1·8). The varying results from analyses of cases compared with hospital and GP-based controls highlight the importance of appropriate selection and recruitment of controls and the biases that can occur with incomplete case or control series. The high non-response rate, in part a consequence of local ethics committee restrictions, among women approached as potential GP-based controls, particularly in the younger age groups, may have resulted in a biased sample of women.

The 18 cases for whom no GP-based controls could be identified had different patterns of OC use from the remaining cases, and their exclusion attenuated the higher risk associated with gestodene compared with levonorgestrel. An analysis of the risks compared with hospital controls restricted to those cases for whom GP-based controls had been identified resulted in a similar attenuation of the risk for gestodene users, with little change in the risk for desogestrel compared with levonorgestrel. In an unmatched analysis, using all cases and GP-based controls in the Oxford region, risk estimates for desogestrel and gestodene were similar and higher than those for levonorgestrel, both before and after adjustment for age, BMI and smoking.

Analysis of the prevalence of OC use according to admission diagnosis for all hospital controls[5] showed no systematic differences between groups of admission diagnoses, other than those expected from the age distributions of the groups of controls. A detailed investigation of OC prevalence and distribution of OC type among hospital controls in the Oxford region showed no differences within age strata between women admitted for the two largest groups of diagnoses (ear, nose, and throat conditions and emergency admissions for trauma or appendicitis) or other diagnoses. Moreover, hospital controls were more similar to cases in terms of marital status, educational level, and social class than were GP-based controls. Thus, in this study, the former sample of controls in whom the non-response rate was low appears better to represent the population from which the cases arose.

Interpretations

The difference in risk estimates in low oestrogen OCs according to progestagen type might be due to chance, subgroup analysis, confounding, or bias, or a combination of these—or result from a true difference in the effect of low-dose OCs on the incidence of VTE.

Chance—The p values for the ratio of risk estimates for desogestrel and gestodene compared with levonorgestrel were 0·007 and 0·001, respectively, in all centres, even after adjustment for confounding factors (table 3). Although the magnitude of the risk differed in the two main subgroups the p values for both products combined were 0·001 (non-Oxford centres) and 0·018 (Oxford region). Similarly, the crude ratios of cases and controls exposed to desogestrel or gestodene compared with those exposed to levonorgestrel in each individual centre were all in the same direction (table 1).

Subgroup analysis—The detailed analyses in this report were prompted by the observation of an increased risk in

a subgroup of OC users.[1] Although not prespecified in the study protocol, a secondary objective was to determine whether the risk of VTE (and also acute myocardial infarction and stroke) varied with OC composition or duration of use.[2] The layout of the table of risk estimates by progestagen content and oestrogen dose was defined in the plan for analysis, prior to the results being computed. Nevertheless, the estimates reported here may be exaggerated because the analyses were prompted by extreme values noted in two of many cells in a table of ORs. If these results are due to chance, other research will fail to replicate them. If they represent a true effect, the magnitude can be expected to be less than that reported here—an example of regression to the mean, as suggested for the unexpected observation of an increased risk of prostate cancer after vasectomy.[10,11]

Confounding—Although there was evidence of different prevalence of OC use, as well as brand specific patterns of use, according to cardiovascular disease risk factors, these did not appreciably confound the risk estimates for VTE associated with OC use. The major risk factors for VTE (trauma, surgery, immobilisation, and pregnancy[12]) were excluded since the study was designed to investigate idiopathic VTE. Since differential prescription of OC types is most likely to be based on known risk factors for myocardial infarction and stroke, the effect of such prescription bias on VTE will be limited to risk factors common to the three conditions, such as increased BMI. Although controlling for BMI in this study may have been incomplete because height and weight were self-reported, adjustment for BMI did not alter risk estimates sufficiently to suggest that they would change substantially if exact measurements had been available on all women. The possibility of other important, unmeasured confounding factors affecting the risk estimates is slight, but cannot be excluded.

Bias—Bias due to differential health care seeking behaviour of cases and controls, or according to exposure status cannot be excluded. Diagnostic bias in the study of OC use and VTE is a clear possibility, as is recall and reporting of contraceptive method. However, such biases would have to have occurred differentially according to OC type for them to affect the results presented here. Exposure to the different types of OCs may have been related to educational level or social class, as may the likelihood of being admitted to hospital for VTE, though adjustment for such variables in the models had no impact above that of the confounding variables previously identified. The disparate results with hospital and with GP-based controls could be accounted for by biased sampling, directly or indirectly related to the exposures of interest.

Biological plausibility

The association between OC use and risk of VTE has been found to be related to dose of oestrogen by some,[13-15] although not all,[16] groups. The relation between VTE and dose and type of progestagen in combined OCs is uncertain, and evidence for an independent effect of the progestagen has not been convincing.[17] Although it has not been clearly shown that the progestagen component for combined OCs affects the incidence of VTE, some information is available from studies of the influence of progestagen-only contraceptives on haemostasis. A 3-year study of the levonorgestrel subdermal implant Norplant concluded that changes in haemostatic variables might increase the risk of thrombosis,[18] although this was not found in a similar 6-month study in Egypt.[19] Changes in haemostatic indices induced by low-dose OCs and Norplant are minor, few of the alterations are outside the normal range, and their clinical significance remains uncertain.[20] Recent reviews have concluded that OCs containing third-generation progestagens do not differ from earlier low-dose combinations in their impact on haemostatic variables.[20-22] These reviews stressed the need for additional clinical and epidemiological studies. Low-dose OCs containing desogestrel and gestodene seem to be less androgenic than other low-dose preparations and have less adverse impact on carbohydrate and lipoprotein metabolism.[21] Lowering the dosages of desogestrel and gestodene may reduce the possible excess of venous thromboembolic side-effects. Such dose reductions may be achievable without compromising efficacy and cycle control[23] since there is evidence that low oestrogen dose OCs containing these progestagens result in stronger suppression of ovarian activity.[24]

CPA is similar to gestodene and desogestrel in being less androgenic than levonorgestrel,[21,24] and is often prescribed for the management of acne in young women.[22] While the results for CPA-containing OCs are based on small numbers, the similarity of the observations with the third-generation progestagens, including the higher risk associated with use of lower oestrogen dose, as observed with desogestrel, requires further explanation. It has been noted from a study of different combined injectable preparations[25] that both the ratio and absolute levels of progestagen and oestrogen influence their pharmacodynamics. However, the observations of increased risk with lower oestrogen dose with these two progestagens are both compatible with chance.

Attributable risk and risk of other cardiovascular endpoints

Any increase in the risk of VTE associated with the use of different OCs needs to be seen in the context of the absolute risk of disease, the mortality rates, and the risks of other cardiovascular endpoints. Cases in the Oxford region were identified from all hospitals that admitted acute cases and covered a defined geographical area. From estimated population size,[29] total number of VTE cases identified in the study, patterns of OC use among the hospital controls by age, and estimated risks from the Oxford region compared with the hospital controls, the incidence of idiopathic VTE was estimated[30] to be 3·9 for non-users, 10·3 for levonorgestrel users, 21·3 for users of desogestrel or gestodene, and 12·3 for users of other OCs per 100 000 woman-years. The excess for users of desogestrel or gestodene over levonorgestrel OCs was 11·0 per 100 000 woman-years (CI 1·2–22·7). The case fatality for VTE is low (1–2%)[12] and needs to be considered in the context of the incidence of other cardiovascular diseases in women of reproductive age.[31] Provisional results from the WHO case-control study show no clear evidence of any difference in the risk of stroke according to type of progestagen within the class of low-oestrogen OCs. The cases of acute myocardial infarction occurred predominantly among older women within the reproductive age range where the prevalence of current OC use was low and the number exposed to third-generation OCs was too small to provide useful estimates of risk.

Conclusion

This WHO case-control study, only part of which has been reported so far, was designed to investigate possible risk of cardiovascular disease associated with current patterns of OC use. It is to our knowledge the first epidemiological study to report specifically on OCs containing desogestrel and gestodene. These two products were found to be associated with a similar level of increased risk of VTE above those for second-generation combined OCs with less than 35 μg ethinyloestradiol. These observations are based on an analysis of a secondary study objective, and the possibility that they are due to chance, confounding, or bias or a combination of these cannot be excluded entirely. They must be confirmed by independent epidemiological studies, and the impact of these new OC preparations on the risk of stroke and myocardial infarction must be further assessed.

Study organisation

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Centres and Principal Investigators, Study Design and Monitoring, Study and Data Co-ordination, and Publications Advisory Committee as in companion paper (*Lancet* 1995; **346:** 1575–82).

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