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PRELIMINARY REPORT TO THE U.S.A.I.D. MISSION IN ISLAMABAD, PAKISTAN

"A Study of Breastfeeding and the Return of Menses
and Conception in Karachi, Pakistan"

Family Health International
November 4, 1988

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INTRODUCTION

This report of preliminary findings from a longitudinal study of breastfeeding and the return of menses is submitted at the request of USAID/Islamabad. The figures within have not been discussed with the principal investigators from the National Research Institute for Fertility Control in Karachi, (Dr. (Mrs.) Afroze Kazi and Dr. (Mrs.) Talat Khan). Therefore, these findings are open to re-interpretation by the Pakistani investigators. A final report of this study should be available in the second quarter of calendar year 1989 if the Pakistani investigators are able to complete a trip to Family Health International for data analysis early in the year, as currently planned.

This project was intended to be the fourth in a series of four longitudinal studies on the recovery of **ovulation** during breastfeeding. The other study sites were located in Mexico, Egypt and Thailand. A paper published on the Mexican data is included as Appendix A, and includes details of the protocol followed in the Karachi study as well. (Papers on the studies in Thailand and Egypt have been submitted for publication.) An apparent systematic break in the cold chain that was needed to preserve the weekly urine samples has caused the entire hormone assay protocol to be abandoned. As a result, the time of first postpartum ovulation is not available as an outcome variable. The relatively small N in this study is the result of the great cost of performing dozens of hormone assays per woman. Had it been originally intended to use menses as the main outcome variable, a much larger

sample would have been drawn. Nevertheless, the data collected in this study, without the hormone values, stand alone and appear to confirm the findings in other research.

METHOD

The study methodology has been previously reported, as in Appendix A. Briefly, women who were attended at the Jinnah Postgraduate Medical College Clinic and the Khokra Par Clinic in Karachi were recruited into the study shortly after delivery of a term pregnancy. Normal, healthy women who planned to breastfeed were recruited if they agreed to weekly follow-up visits in their homes and to giving weekly overnight urine samples and a monthly serum sample for the hormone protocol. They needed also to mark a pictorial chart everyday to record the number and type of feedings, including breastfeedings that they gave their babies. The pictorial chart is included as Appendix B. All women were asked to remain in follow-up for one year, unless they recovered fertility sooner.

HYPOTHESES

Early studies of breastfeeding and the recovery of ovulation were conducted in Western settings, and identified a basement value for the breastfeeding frequency associated with anovulation. The current series, as well as studies by other investigators in non-Western settings, have reported no association between breastfeeding frequency and the time until the recovery of fertility. The original hypothesis,

however, is that high numbers of breastfeeding episodes inhibit ovulation (or in the case of the Karachi study--menses, a proxy for ovulation). At low frequencies of breastfeeding then, fertility events such as menses or ovulation will appear.

A second hypothesis has been articulated most recently in the consensus statement of an interdisciplinary group of international researchers on lactational amenorrhea. The consensus (included as Appendix C) states that there is not more than a 2% chance of pregnancy during breastfeeding in the first six months postpartum in the absence of vaginal bleeding (bleeding before the 56th day is ignored) and in the absence of regular supplementation.

Both of these hypotheses are considered here.

SAMPLE

Twenty-eight breastfeeding mothers were recruited into the study at the two Karachi clinics. Four non-breastfeeding postpartum women were also recruited and originally intended as controls. These four non-breastfeeding women may be discussed in future documents. Of the 28 breastfeeding women, one discontinued the study on postpartum day 31 because she did not wish to give monthly blood samples (for the measurement of prolactin). She has been eliminated from consideration in this report.

General information about the 27 women studied is found in Table 1. On

average the women were 25.5 years of age with 2.4 years of education, (although two thirds reported no education). Seventy percent lived in urban or slum areas and 70% had partners who worked as skilled laborers, unskilled laborers or office workers. They averaged between 3 and 4 live births and 70% wanted more children. Two women used family planning prior to this pregnancy (IUDs).

At the time of admission to the study, the women were asked about the last child that was breastfed. Table 2 shows that the last breastfed child nursed for 17 months on average, and started to receive supplements at about 7 months postpartum. Postpartum amenorrhea lasted for 6 months on average. The babies' first foods were typically milk supplements. Most women had stopped breastfeeding because of the child's age, insufficient milk or pregnancy.

INTRODUCTION OF REGULAR SUPPLEMENTS

All mothers started regular (i.e. consistent) food supplementation to the babies' diets while in the study. Two mothers (including the one with the earliest pregnancy) totally weaned their children while in the study, between 5 and 6 months of age.

The mean time to the initiation of regular supplements was 3.5 months (107 days). The range of times when supplements began was from 2 to 6 months (61 to 184 days).

FIRST VAGINAL BLEEDING EPISODE

Four women completed a year of follow-up without experiencing any vaginal bleeding episodes. One woman moved out of Karachi and left the study at 5 months, still amenorrheic. One woman conceived at 3 1/2 months postpartum during amenorrhea, and this case is discussed later in greater detail.

The majority (21) experienced two or more vaginal bleeding episodes while in the study. Nine of the first bleeds occurred between 41 and 56 days postpartum. Each of these nine mothers had at least one additional vaginal bleeding episode after the eight week mark and before either conception or completing follow-up.

The median time until the first postpartum bleed was 102 days (164 days, mean), but further analysis excluding bleeds before the eighth week will increase this duration appreciably.

BREASTFEEDING FREQUENCY AT THE TIME MENSES RETURNED

Twenty-one women experienced vaginal bleeding (not lochia) while they were in the study. At the time of the first vaginal bleeding episode, these mothers were breastfeeding an average of 9 1/2 times per 24 hours (Table 3). When the mothers were separated according to the quarter year in which they bled, there was no meaningful difference in breastfeeding frequency at the time of first bleed.

Six women did not have any bleeding while they were in the study. Four of them terminated the study at one year still amenorrheic. These four were breastfeeding an average of 9 times per 24 hours. One mother left the study amenorrheic at 5 months postpartum, and she was breastfeeding 9 times per 24 hours when she left. The remaining mother was the one who conceived during amenorrhea at about 3 1/2 months postpartum.

BREASTFEEDING, SUPPLEMENTATION AND BLEEDING AT THE TIME OF CONCEPTION

Nine of the 27 mothers became pregnant while in the study. The earliest conception is discussed below. The number of days from delivery to the subsequent conception ranged from 109 to 252. It is important to remember, however, that only the pregnancies that occurred in the first year postpartum are known. Had all women been followed-up until a subsequent pregnancy occurred, the average time to conception would have been greater than a year.

In all nine cases, the mothers had introduced regular dietary supplements to their babies prior to conception. In eight cases, the mother also had between 2 and 5 vaginal bleeding episodes to herald the return of her fertility. (In all of these 8 cases, at least one bleeding episode occurred after postpartum day 56.) The one mother who did not have a herald bleed (although she had begun regular supplements) was the mother who conceived the earliest, at approximately 3 1/2 months postpartum.

EARLIEST CONCEPTION IN A BREASTFEEDING MOTHER

The earliest conception occurred at 3 1/2 months postpartum in a breastfeeding woman during amenorrhea. Very early in the postpartum period, the woman reported having sore nipples on several occasions. From postpartum weeks 4 to 11 the number of breastfeeding episodes per 24 hours decreased from 12 per day to 8 per day. At the twelfth week postpartum, the woman reduced her average daily frequency of breastfeeding from 8 to 6 and started giving the baby one feeding of semi-solid food (cerelac) per day. Within one week, her breastfeeding frequency further decreased to 5 per day and the number of semi-solid supplements increased to 3 per day (cerelac, rice and eggs). It is estimated that she conceived after one more week of 5 breastfeeding episodes and 3 supplements per day. The supplements appear to have been replacements for breastfeedings.

CONTRACEPTIVE USE DURING THE STUDY

Women who intended to use hormonal methods of family planning were excluded from recruitment into this study. This is because the original protocol required the determination of ovarian hormonel levels, and this information would have been invalid in women taking steroidal contraceptives.

All women in the study were sexually active. Twenty-one women used no family planning method for the duration of the study. Seven of these (33%) became pregnant. Six women reported condom use during the study.

All six women started using condoms after the first vaginal bleeding episode (usually very soon after). Two of these six women (33%) became pregnant during the period of condom use.

Two women responded at admission that they were "unsure" whether they wanted another child. Both became pregnant during the study. One was using condoms and the other was not.

The only woman who said she wanted no more children and who also conceived during the study was the mother with the earliest pregnancy. She used no family planning method during the study.

DISCUSSION

The data from this study about breastfeeding frequency at the time of the first vaginal bleeding episode are consistent with the findings from other studies where non-Western breastfeeding patterns are the norm. The frequency of breastfeeding appears to be a poor correlate of infertility. This finding goes against earlier hopes of finding a critical number of breastfeedings that would guarantee infertility. (Further analysis of the bleeding and breastfeeding data will exclude bleeds between 40 and 56 days postpartum as per the Bellagio guidelines, to see if this impression is upheld under those conditions.) **This does not mean that breastfeeding did not have a contraceptive effect.** These women did experience considerable protection from pregnancy due to lactation. The number of breastfeeding episodes is simply not a good variable for measuring the

degree of protection.

The conception data clearly verify the Bellagio Consensus since no woman conceived unless she was having menses or regularly supplementing her child's diet.

The family planning use data suggest that the women recognize the contraceptive effect of breastfeeding, since family planning was initiated upon the appearance of the first postpartum menses. The fact that equal proportions of condom users and non-users conceived during the study does not speak well of condom use effectiveness in this sample.

The breastfeeding mothers studied supplemented their babies earlier than expected. As few as half of the babies might have been expected to require supplements by six months, but all babies actually received regular supplements by this time. It has not yet been determined whether suboptimal rates of infant growth warranted supplementation, and for the time being, this must remain a possibility. These mothers reported that they breastfed their previous babies twice as long as the ones studied. There are many possible reasons for this finding: maternal depletion could have contributed to lower milk supplies and the need to supplement; earlier supplementation could have been an observation effect, with the mothers altering their usual behavior just because they were in the study; recall bias is a possibility since mothers were asked to remember a process that occurred at least one year previously; the mothers may not have considered their early

nonbreastmilk feedings as "supplements"; and finally there may have been environmental factors that resulted in changed breastfeeding behavior, such as the advertising and availability of breastmilk substitutes.

The fact that no woman worked outside the home made for a convenient opportunity for exclusive breastfeeding. Perhaps the urban setting with its infant feeding status quo was a stronger factor effecting the breastfeeding pattern.

The women in this study were not randomly selected and 70% wanted more children. Contraceptive use was low, but users of steroidal methods were excluded from the protocol. Nevertheless, early supplementation plus no contraception is a formula for infant illness and short birth intervals. Breastfeeding promotion efforts might concentrate on the benefits of proper spacing through optimal breastfeeding.

APPENDICES

Appendix A: Rivera R, Kennedy K, Ortiz E et al. "Breastfeeding and the return of ovulation in Durango, Mexico", Fertility and Sterility, 1988, 49(5):780-787.

Appendix B: pictorial infant feeding chart used in the Karachi breastfeeding study.

Appendix C: "Consensus Statement--Breastfeeding as a family planning method", Lancet, November 5, 1988.

Table 1: Characteristics of the Breastfeeding Women (N=27)

	Mean	(SD)	Percent	(n)
Age (years)	25.5	(4.4)		
Education (years)	2.4	(3.9)		
Live births	3.7	(1.9)		
Urban residence			70	(19)
Partner's occupation				
skilled laborer			41	(11)
unskilled laborer			15	(4)
office worker			15	(4)
all else			30	(8)
Want more children				
no			22	(6)
yes			70	(19)
undecided			7	(2)
FP used before this pregnancy				
none			93	(25)
IUD			7	(2)
Reason for termination from study				
one year follow-up completed			59	(16)
pregnant			33	(9)
moved			7	(2)

Table 2: Previous Breastfeeding Experience (N=24*)

	Mean	(SD)	Percent	(n)
Number of months last baby breastfed	17.2	(8.6)		
Age of baby when supplements started	6.9	(4.7)		
Month postpartum of first menses	5.9	(5.7)		
First food=milk supplement			62	(15)
Reason breastfeeding stopped				
maturity of child			38	(9)
insufficient milk			33	(8)
pregnant			17	(4)
other			13	(3)

*Excludes three women who never breastfed.

Table 3: Mean (range) Breastfeeding Frequency by Time of First Postpartum Bleed

Month of First Bleed	# BF DAY	# BF NIGHT	# BF 24 HRS	N
1-3	6.4 (4-8)	3.5 (2-5)	9.9 (6-13)	11
4-6	5.4 (3-7)	3.0 (2-4)	8.4 (6-11)	5
7-9	6.5 (4-8)	3.8 (3-5)	10.2 (7-13)	4
10-12	5.0 (5)	4.0 (4)	9.0 (9)	1
Total	6.1 (3-8)	3.5 (2-5)	9.6 (6-13)	21
No bleed at conception (3 1/2 months)	3.0 (3)	2.0 (2)	5.0 (5)	1
No bleed at termination (5 months)	6.0 (6)	3.0 (3)	9.0 (9)	1
No bleed at termination (2 years)	5.5 (3-8)	3.8 (2-5)	9.3 (5-13)	4

FERTILITY AND STERILITY
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Vol. 49, No. 5, May 1988
Printed in U.S.A.

Breast-feeding and the return to ovulation in Durango, Mexico*

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Twenty-nine breast-feeding mothers and 10 non-breast-feeding postpartum comparison mothers from a rural area of Mexico were followed longitudinally until ovulation resumed. A simple set of guidelines is described involving three obvious milestones for the breast-feeding mother to safely use the natural contraceptive benefit of breast-feeding. Those milestones are: the first vaginal bleeding episode, the initiation of supplementation, and the child's monthly birthday. In the absence of bleeding and supplementation, 100% of breast-feeding mothers remained anovular for 3 months postpartum, 96% for 4 months, 96% for 5 months, and 96% for 6 months. This suggests that, if a mother understands these three conditions, she can use breast-feeding alone as effectively as modern family planning methods for the prevention of pregnancy. Fertil Steril 49:780, 1988

Breast-feeding provides the best nutrition for infants and secures substantial protection against infection. It also plays an important role in fertility control by delaying the onset of postpartum ovulation, thus prolonging the interval between births. (For reviews, see Rolland, 1976,[1] and McNeilly, 1979.[2]) Researchers have measured the mean period of postpartum amenorrhea and results vary greatly, probably due in large part to variations in the duration of breast-feeding.[3] Importantly, the return of menses does not necessarily imply the return of ovulation or fertility. Some women may experience several anovulatory "cycles" postpartum, while others conceive before the onset of postpartum menstruation. Although breast-feeding is a reasonably effective method of family planning before the resumption of menses, ready predictors of ovulation are not yet available for the individual woman.

The focus of this study is to measure the time of the first postpartum ovulation and to assess the relationships of the onset of bleeding and infant food supplementation practices to this variable. A longitudinal study of a small number of women in a rural area of Durango, Mexico, was chosen to investigate these relationships. The aim is to develop simple guidelines that will help determine the optimum time for breast-feeding women to initiate other methods of regulating fertility, and that will take full advantage of the antifertility potential of breast-feeding.

MATERIALS AND METHODS

The study was conducted in a rural area of Durango, situated in north-central Mexico. Women were included in the study if they fulfilled the following criteria: (1) they lived in the selected rural

Received November 9, 1987; revised and accepted January 13, 1988.

* Supported in part by Family Health International with funds from the United States Agency for International Development.

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Reprinted from Fertility and Sterility Volume 49, Number 5, May 1988
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area, (2) they planned to breast-feed their infants, (3) they proposed to use no systemic method of contraception, (4) they had no taboo on intercourse during lactation, (5) they had delivered a healthy baby, (6) they had no previous history of infertility or major gynecologic problems, (7) they were accessible and agreeable to long-term follow-up on a weekly basis, and (8) they were informed, understood the implications of the study, and agreed to participate. A comparison group of women who were not breast-feeding their newborns also was studied.

Two nurses administered the study: one with previous experience in the local health center and one with experience in field research. The nurses conducted weekly home visits to all mothers throughout the study. Initial contact was made with the local midwives, to whom the study was explained. The midwives identified the women who ultimately participated. All of the volunteers were admitted within their first week postpartum.

During the study, data were collected on suckling frequency per day and night, type and frequency of supplementary foods given, pattern of vaginal bleeding, maternal and child health, weekly urinary pregnanediol levels, and sexual activity. Volunteers recorded each suckling episode on a picture chart.[4] The day that supplementary food was introduced into the baby's diet also was recorded on the chart, together with the number and nature of supplementary feedings. The initiation and frequency of sexual relations also was recorded. The women recorded every day of vaginal bleeding on a menstrual diary card. Additionally, at each weekly visit, the nurse asked the woman about the resumption of menses. Each week the nurse collected the charts at the home of the volunteer and any questions were answered at that time.

The occurrence of the first ovulation was determined by a sustained rise in the urinary excretion of pregnanediol to a level over 1.0 mg/l, followed by either vaginal bleeding or conception.[5] An overnight urine sample was collected once a week for the estimation of pregnanediol by the Goldzieher and Nakamura method.[6] The weekly measurements were continued until pregnancy or until two consecutive ovulations were detected. Conception was defined as three consecutive weeks of elevated pregnanediol confirmed by a pregnancy test. The women remained in the study until any one of the following circumstances occurred: (1) conception, (2) two consecutive ovulatory cycles, (3) initiation of hormonal contraception, (4) the passage of 1 year since admission, (5) loss to follow-up, or (6) the desire to withdraw from the study.

The Kaplan-Meier life-table method[7] was used where median times to events are calculated, and the Breslow statistic was used to compare the survival curves between the groups. Differences between means were calculated by *t*-test.

Patient Characteristics

Twenty-nine breast-feeding women and 10 non-breast-feeding postpartum volunteers were recruited into the study during 1981. The study setting, a rural area of Durango, was selected because breast-feeding was relatively prolonged and the incidence of family planning low. Non-breast-feeders were difficult to locate, and control subjects from the same geographic area had to be supplemented from a poor area on the outskirts of the city of Durango. All of the mothers delivered normal babies at term.

Information about the age, education, and employment of the volunteers is found in Table 1. The comparison group was somewhat younger and

Table 1 Characteristics of the Volunteers

	Cases (n = 29)	Controls (n = 10)
Residence		
Rural	100%	40%
Peri-urban	—	60%
Age at delivery		
Mean	28.9	25.8
Range	16–44	18–33
Number of live births		
Mean	5.6	3.9
Range	1–15	1–11
Years of education		
Mean	3.9	4.2
Range	1–7	1–8
Sex of infant		
Male	55%	40%
Female	45%	60%
Work outside home	7%	20%
Wants no more children	76%	60%
No family planning used before this pregnancy	66%	60%
Reason for termination from the study		
Followed for 1 year	52%	—
Pregnancy	10%	40%
Two or more ovulations	7%	30%
Started hormonal contraceptives	7%	20%
Moved, spouse objected, other personal reason	24%	10%

tended to desire more children. The women in both groups had about 4 years of education and most did not work outside the home.

About two thirds of the women from both groups used no family planning method before this pregnancy. Among those who previously used family planning, all of the controls and 70% of the cases had used oral contraceptive pills. Twenty-eight percent of the breast-feeding group reported that they had used family planning while breast-feeding the last child; of these women, half used pills, one quarter used "prolonged breast-feeding," and one quarter used condoms or rhythm to prevent or postpone subsequent pregnancy.

Fifty-nine percent of the breast-feeding mothers and 30% of the comparison group terminated from the study because they had completed 1 year of follow-up, or had experienced two or more ovulatory cycles. Forty percent of the comparison group terminated due to pregnancy, as did 10% of the breast-feeders. Only four women (two breast-feeders, two comparisons) terminated to use a hormonal family planning method.

At admission, information was collected from the breast-feeding mothers about previous breast-feeding experience, with specific reference to the last child breast-fed. Three women had no previous breast-feeding experience. Previous children were weaned, on average, at 14 months (Table 2), although there was some heaping of data at 6-month intervals. Supplements began at about 5 months, with some heaping at 3-month intervals. Most women (69%) stated that the first supplement they gave was a semi-solid food, such as soup or mashed bananas, and a milk supplement was the first weaning food for 31%. The women stopped breast-feeding the last child because they became pregnant again (35%), because the child was considered too old to continue breastfeeding (35%), because of insufficient milk supply (19%), or because of illness or some other reason (11%).

Table 2 Previous Breast-feeding Experience: Only the Last Child Breasted (n = 26) (Breast-feeding Cases Only)

	Months	
	Mean	Range
Age of child when weaned	14.0	1–36
Age of child at first supplement	5.2	1–15
Age of child at mother's first menses	9.5	1–25

RESULTS

Comparison of the Cohorts: Pregnancy

Pregnancies in the groups can be compared by using ratios of the number of pregnancies to the number of days of exposure in each group. The days of exposure to pregnancy were counted as the number of days from delivery until termination from the study, or until conception. Three breast-feeding women became pregnant during the study and the breast-feeding group was exposed for a total of 9054 days. Four non-breast-feeding women conceived over a total of 1698 days of exposure, producing a (Pearl) rate of conception for comparison women seven times greater than that for the breast-feeders.

Comparison of the Cohorts: Time until Bleeding and Ovulation

The median time until the first bleeding episode was 140 days for the breast-feeding group and 46 days for the non-breast-feeders. The difference between the distributions was significant ($P = 0.02$). Seven breast-feeders and one non-breast-feeder were censored in the "bleeding" life table at conception or termination from the study because they reported no bleeding throughout the observation period. (Data are included in the life tables until the time follow-up ended for those women who finished the study without an endpoint.)

The median time from delivery until the first ovulation was 259 days for the breast-feeders and 119 days for the comparison women. The difference in these distributions is also statistically significant ($P = 0.04$). Seven of the 10 non-breast-feeders (70%) ovulated during the observation period, compared with 15 of the 28 breast-feeders* (54%).

The First Post-Partum Ovulation

Twenty-four percent of the breast-feeding women and 10% of the non-breast-feeders ovulated before the first bleeding episode. (See Table 3, where the complements of these percentages are expressed.) By 3 months postpartum, 18% of the

* In one breast-feeding woman, the pregnanediol values were elevated throughout the entire study (she was not pregnant), so it was impossible to determine when she ovulated. Throughout this article, this case is excluded in calculations that require an estimate of the time of first ovulation.

Table 3 Predictors of Ovulation: Percent of Women in Whom the Event(s) Predicted (Preceded) Ovulation

	Cases			Controls		
	Percent	95% CI[a]	N[b]	Percent	95% CI[a]	N[b]
One event						
First vaginal bleeding episode	76	58, 94	21	90	71, 100	10
Initiation of supplements	78	62, 94	27		NA	
Cessation of night breast-feeding	13	0, 30	15		NA	
3-mo birthday	82	68, 96	28	60	30, 90	10
4-mo birthday	75	59, 91	28	38	4, 72	8
5-mo birthday	68	51, 85	28	13	0, 36	8
6-mo birthday	57	39, 75	28	13	0, 36	8
Two events						
Initiation of supplements or first bleeding episode	92	82, 100	27		NA	
Initiation of supplements or 3-mo birthday	93	84, 100	28		NA	
First bleeding episode or 3-mo birthday	93	84, 100	28	90	71, 100	10
Initiation of supplements or 4-mo birthday	89	77, 100	28		NA	
First bleeding episode or 4-mo birthday	89	77, 100	28	90	71, 100	10
Initiation of supplements or 5-mo birthday	86	73, 99	28		NA	
First bleeding episode or 5-mo birthday	89	77, 100	28	90	71, 100	10
Initiation of supplements or 6-mo birthday	82	68, 96	28		NA	
First bleeding episode or 6-mo birthday	86	73, 99	28	90	71, 100	10
Three events						
Initiation of supplements or first bleeding episode or 3-mo birthday	100	—	28		NA	
Initiation of supplements or first bleeding episode or 4-mo birthday	96	89, 100	28		NA	
Initiation of supplements or first bleeding episode or 5-mo birthday	96	89, 100	28		NA	
Initiation of supplements or first bleeding episode or 6-mo birthday	96	89, 100	28		NA	

[a] 95% confidence interval = P ± 1.96 (SE), where P = percent and SE = $\sqrt{p(1-p)} \div \sqrt{N}$.

[b] In some cases, neither ovulation nor the "event" occurred, making it impossible to determine whether the "event" was a viable predictor of ovulation.

breast-feeders and 40% of the comparison group had ovulated. At 3 months, the study group was breast-feeding, on average, six times during the day and four times at night. The five mothers who had ovulated by 3 months averaged four breast-feeding episodes per day and two episodes per night. The nonovulating mothers breast-fed an average of seven times per day and four times per night.

By 6 months postpartum, 43% of the breast-feeders and 87% of the comparison group had ovulated. (When those who had totally weaned their babies (n = 4) by 6 months are excluded, the percentage of breast-feeders who had ovulated decreases to 37.) At 6 months postpartum, the average frequency of breast-feeding for the 22 women* still nursing was seven feedings per day and four feedings per night. Among the six breast-feeding women who had already ovulated by this date, the average frequency of breast-feeding episodes was four feedings per day and three per night. The corresponding frequency for the 16 nonovulatory women was eight episodes per day and four per night. None of the differences in the mean breast-feeding frequencies, at 3 or 6 months, between the ovulatory and nonovulatory women, is significantly different (at the $P = 0.05$ level). Regardless of when it occurred, during the week of the first ovulation, the mothers breast-fed an average of four times per day (range, zero to seven) and three times per night (range, zero to six).

Table 4 describes for the breast-feeders the association of time until ovulation (for those who ovulated) or time until termination from the study (for those who did not ovulate) with two variables: the frequency of breast-feeding at the time of the terminating event (ovulation or termination) and the mother's Quetelet index or QI (a measure of body mass, or weight per height squared) at the time of

* Two of these 22 women actually terminated from the study a few days (7 and 9) before the 6-month birthday. Their data at the last follow-up are treated as if they had been observed for a full 6 months. One woman terminated from the study at 5 months at which time she was pregnant and still breast-feeding. Another ovulating woman terminated from the study at 3 months while she was still breast-feeding. These 2 have not been included in the 22.

Table 4 Time to Terminal Event,[a] Breast-feeding Frequency (BF), Maternal Weight, and Quetelet's Index (QI)[b] at Terminal Event and Pearson Product-Moment Correlation Coefficients of Time to Terminal Event with BF and QI

	N[c]	Time (days) from delivery to terminal event		BF frequency per 24 hours		Maternal weight (kg)		QI		Pearson coefficient BF with days		Pearson coefficient QI with days	
		mean	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*r*	*P*[d]	*r*	*P*[d]
Ovulators	13	147	59–308	8	4–12	62	47–78	25.3	19.6–33.8	−0.057	0.427	−0.518	0.035
Nonovulators	13	338	184–377	12	3–30	55	42–73	23.0	17.0–27.5	−0.128	0.338	+0.057	0.427
Total	26	243	59–377	10	3–30	58	42–78	24.1	17.0–33.8	+0.252	0.107	−0.436	0.013
T-test[d]		$t_{24} = -6.91$		$t_{24} = -1.95$		$t_{24} = 2.04$		$t_{24} = 1.74$					
Ovulators versus nonovulators	26	$P = 0.000$		$P = 0.032$		$P = 0.026$		$P = 0.047$					

[a] For ovulators, the terminal event is the estimated day of ovulation; for nonovulators, it is the day of termination from the study.

[b] Quetelet's index is calculated as ($kg/cm^2 \times 100{,}000$), where kg = maternal weight at the time of the terminal event and cm^2 is the mother's height in centimeters squared.

[c] Two cases were excluded from this table, one because acute illness precipitated abrupt weaning and ovulation, and one because extreme obesity biased QI.

[d] One-tailed test of significance.

the terminating event. Breast-feeding frequency would be expected to be positively correlated to ovulation time if the amount of breast-feeding had the effect of postponing fertility. Breast-feeding frequency did not have a significant effect on the time to ovulation or termination. An overall positive association was seen between breast-feeding frequency and time to ovulation or termination. The QI would be expected to have a negative association with time to ovulation or termination if, consistent with the critical body composition hypothesis,[8-10] the greater the body mass, the sooner ovulation should occur. A significant negative association was observed for the ovulators and for all of the women as a whole.

Night feedings were defined as feedings between 8:00 P.M. and 7:59 A.M. Eighty-seven percent of the cases ovulated before night feedings were completely terminated (Table 3.). The 13 breast-feeding women who did not ovulate during the study were still nursing at night when they left the study (11 of them after 11 or 12 months). Conversely, during the week of first ovulation, the 2 breast-feeding women who ovulated before either bleeding or supplementation were also nursing their babies (three to five times) at night.

Twenty-two percent of the breast-feeding women ovulated before their children received supplements to mother's milk (Table 3.). Among the breast-feeders, the median time until the first supplement was 4.7 months. The non-breast-feeding mothers, of course, initiated supplements soon after delivery.

DISCUSSION

The present study differs from others mentioned later in that it puts forth a concept about the conditions for the realistic use of lactational infertility which others have repeatedly documented. This study attempts to evaluate some "easily observed" events as they relate to the return of fertility postpartum. These events are: (1) the first vaginal bleeding episode, (2) the initiation of supplements, and (3) the child's monthly birthday.

Table 3 summarizes the role of some predictors which mothers could use, without medical assistance, as signs of their returning fertility. In this sample, 18% of the breast-feeding mothers were ovulatory before their children reached 3 months of age. Before the occurrence of either the 3-month birthday or the first episode of vaginal bleeding, however, only 7% were ovulatory. Before either of these signals and before the introduction of supplements, none were ovulatory. This is consistent with a study of Chilean mothers[11] that found full nursing to provide as much protection as reversible methods up to the third postpartum month, and diminished protection for women after menses resumed. (The same study found no difference in breast-feeding frequency between fully breast-feeding mothers who conceived and those who did not conceive, consistent with the current findings of similar frequencies among ovular and nonovular breast-feeders.)

Before either bleeding or supplementation, 96% remained nonovulatory at 4, 5, and 6 months post-

partum. A previous study in Scotland[12] found ovulation to precede bleeding in 33% of breast-feeders who had apparently begun solid supplements before ovulation. A current study in the Philippines[13] has found that 58% of women ovulate prior to menses, but bottle-feeding appears to have preceded menses here. Although both are longitudinal prospective studies and measured ovulation through the estimation of ovarian hormones, neither has controlled these figures for time postpartum and for supplementation status. The possibility of intercultural differences in the recovery of ovulation, however, should not be ignored.

The predictors in Table 3 vary in usefulness, specifically in terms of the lead time between the appearance of the sign and the occurrence of the first postpartum ovulation. For example, one volunteer introduced supplements on May 4 and had her first ovulation on May 12 (8 days later). Another volunteer, however, initiated supplements on June 9, had several anovulatory bleeding episodes, and had her first ovulation on February 12 (more than 8 months after supplementing.)

The percentages of ovulatory mothers given different milestones, as in Table 3, are simply percentages of women who had ovulated over all women observed during the relevant time (e.g., 6 months postpartum) or vis-à-vis the relevant milestone (e.g., first bleed). Importantly, the denominators for these percentages are very small—never greater than 28. Although the low percentages of ovulatory breast-feeding women found are consistent and expected, larger studies are required in order to make responsible clinical or policy decisions. The extent to which these findings can be generalized to the rural Mexican population of breast-feeders or to others breast-feeding in a similar fashion is not known.

The first date of any vaginal bleeding, other than lochia, was the bleeding event of interest.* The term "menses" is not used here because it implies a phenomenon that marks the beginning of a menstrual cycle; it is not necessarily true that the recorded days of bleeding were either preceded or followed by ovulation. This event can be considered an empirical marker because women observe bleeding with a fair amount of objectivity. Although this definition may represent a useful concept, vaginal bleeding, like all of the predictors discussed, sports a false-positive rate. For example, one volunteer experienced 4 days of anovular light bleeding in her second postpartum month and experienced no other bleeding (or ovulation) throughout the rest of her year of follow-up.

A 7-fold difference in pregnancy rates between the groups was observed and probably reflects a true difference in pregnancy risk. Yet other important factors influencing this difference must be mentioned. First, for many reasons, the comparison mothers may have been less interested in preventing pregnancy than the breast-feeders. For instance, they had fewer living children and were younger, although these differences were not statistically significant. Second, although there was no taboo against coitus during lactation, and although there was no significant difference in coital frequency over the exposure period, the breast-feeders sometimes reported periods with several weeks of abstinence. This pattern of abstinence may have been the consequence of work migration of the partner or discomfort during sexual relations due to the vaginal dryness that often accompanies breast-feeding. None of the comparison group women reported such abstinence. Third, women from both groups used condoms and/or spermicides, although use was apparently highly erratic. All of these factors affect the measure of exposure to conception, which in turn influences the pregnancy rates.

Researchers in Scotland[14] have reported the absence of ovulation during exclusive breast-feeding. The present study noted 26% of breast-feeding mothers ovulate before supplementation. This compares with findings in another Latin American (Chilean) sample in which 14% ovulated during full breast-feeding.[15] Since the Mexican women fully breast-fed for a longer period than the Chilean mothers, it is not unreasonable that the current study saw a greater percentage ovulate during full breast-feeding. An argument can be made that the Mexican mothers are more similar to the Chilean breast-feeders than to the Scots.

The frequency of breast-feeding evident in this study is higher than that observed for ovulatory women in previous studies of suckling frequency and ovulation. Researchers in Scotland[16,17] and Denmark[18] found a frequency of five suckling episodes per 24 hours sufficient to prevent ovulation. Even in a central African population, six suckling episodes per day were found to be effective in maintaining significantly high levels of prolactin

* Reports of bleeding episodes beginning at 7, 11, 17, 18, and 23 days postpartum were presumed to be lochia. None of these reports came from the non-breast-feeding mothers.

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for 12 months.[19] Fifty-three percent of all of the breast-feeders who ovulated during the study were nursing at frequencies of over nine per 24 hours when they ovulated. Seventy-three percent were nursing seven or more times. Since this study did not measure the duration of the feeding episodes, it does not provide evidence to support or refute the proposed threshold of at least five feedings for a total of at least 65 minutes' suckling duration.[16,17] It does imply, however, that even high suckling frequencies are subject to a modifying effect of suckling duration. As in other reports, this study also suggests that the correlates of lactational infertility do indeed vary across breast-feeding styles, and as such, the family planning advice to women who breast-feed in a western pattern differs from the advice given to rural women in developing settings.[20] Even within rural developing settings, the correlates with lactational infertility may vary by other factors, but especially breast-feeding characteristics. An anthropological study of breast-feeding in two rural Mexican communities,[21] including Durango, identified profound differences in breast-feeding patterns across setting.

The lack of association between breast-feeding frequency and time to ovulation in Table 4 does not necessarily mean that there is no relationship between the amount of breast-feeding and the duration of lactational infertility. This lack of association may be due to the phenomenon of older, supplemented babies suckling as frequently as younger, unsupplemented ones, but for shorter durations, and with less vigor. In other words, breast-feeding frequency alone may not be a good measure of the amount of breast-feeding.

The negative association between body mass and time to ovulation, also in Table 4, is one that is not often studied in breast-feeding women. The causes of anovulation in lactating women are thought to be different from those of anovulation in cases of anorexia, obesity, and in athletes and ballet dancers.[22] To our knowledge, no minimum standards of required weight for height exist regarding the return of menses or fertility in lactating women. It is possible that the entire sample under study fell above a hypothesized threshold of body mass compatible with ovulation since there was overlap in QI between the groups. Additionally, at least in the early postpartum, all women were above their prepregnancy weights which were, obviously, compatible with ovulation since they all conceived. It can be argued that, above a threshold, the woman's QI would not matter, i.e., above the threshold other factors (such as the amount of breast-feeding) would determine time to ovulation. Regardless of whether QI serves a threshold function, the strong negative correlation between QI and the terminal event is not likely to have occurred unless QI and fertility were related. The association between QI and ovulation suggests that multiple causes of lactational anovulation may exist involving body composition at least as an effect modifier.

None of the women in the current study was undernourished, and many had high body mass, which, as seen in Table 4, may be a factor contributing to the early return to ovulation. In rural areas of Southeast Asia, where women may breast-feed at equally high frequencies, mothers may enjoy longer durations of contraceptive protection because of their leaner body masses. In the Philippines,[23] as well as in Mexico,[21] numerous superstitions are documented about when mothers may breast-feed, which may interfere with an otherwise "standard" rural breast-feeding pattern. Conditions (low body fat) and possibilities (superstitious behavior) such as these underscore the need to repeat and improve the design of present studies in many settings where culture, body type, and breast-feeding style vary.

Longitudinal studies of breast-feeding and subsequent ovulation, both in western and in less developed settings, have yielded insight into the physiologic mechanism of lactational infertility. Equally important, however, is the information generated that can be practically applied to exploit the family planning benefits of breast-feeding. The implications of the simple guidelines outlined above are profound for the developing world, where breast-feeding provides more protection from pregnancy than all other contraceptives combined.[24] Childbirth is often the only interface that an urban poor or rural mother has with a health-care provider (frequently a traditional birth attendant) who can dispense contraceptives. Too often, mothers are double-protected in the early postpartum,[20] having received family planning commodities at the time of delivery. The products are consumed while the mother is naturally protected and the mother becomes unprotected when her fertility is returning. There are various programmatic implications of the three milestone guidelines. For example, maternal/child health and family planning outreach can be scheduled for the baby's 3-, 4-, or 5-month birthday with instructions to the mother to abstain or to start a cycle of progestin-

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only pills in the event of vaginal bleeding or supplementation. In areas of easier access to health care, the mother can plan to attend clinic at a given monthly birthday unless bleeding or supplementation occurs first, signalling the mother to attend immediately. Where western breast-feeding patterns are popular, additional studies should be conducted.

Accurate, practical advice on the use of breast-feeding as contraception is scarce, but especially before desired family size is achieved, breast-feeding should be considered for its merits among the list of available contraceptives.[25] Guidelines must be based on data from larger numbers of representative breast-feeders from a specific population.[20] In developing settings, the simplicity of using the three milestones may be its strength.

Acknowledgments. We acknowledge the assistance of Peter Howie, M.D., M.B Ch.B., F.R.C.O.G. in the design of this study, of Alan McNeilly, B.Sc., Ph.D., D.Sc., in interpreting the data, and of Lynn Wilkens, M.S.P.H., Holly Hughes, M.P.H., and Hyla Cohen, M.S., in data analysis.

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APPENDIX B

(Actual size is 11" x 17")

بچہ کو کھلانے کا نقشہ

نام _____

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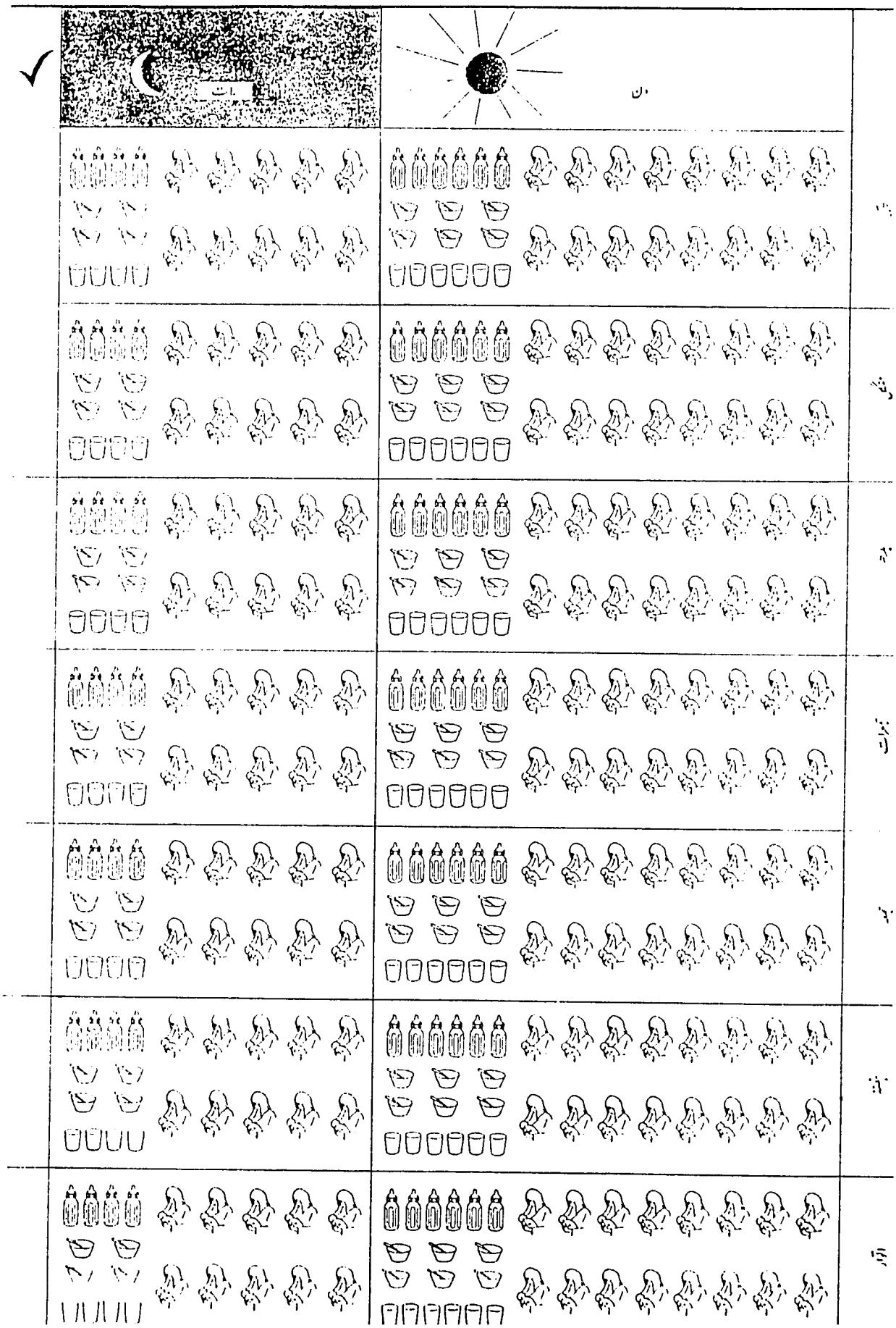

APPENDIX C

THE USE OF BREASTFEEDING AS A FAMILY PLANNING METHOD

Although the benefits of breastfeeding for infant health are universally recognized, there remains unwarranted skepticism over t use of breastfeeding as a viable, alternative family planning metho An international group of scientists gathered in August 1988 at the Bellagio Study and Conference Center, in Italy with the support of the Rockefeller Foundation, Family Health International and the WHO Special Programme of Research, Development and Research Training in Human Reproduction. This group came to consensus about the conditio under which breastfeeding can be used as a safe and effective metho of family planning. It was recommended that lactational amenorrhea be regarded as an appropriate method of fertility regulation for ma women and that it should be incorporated into family planning programs and presented as one element of informed choice, particularly when other family planning methods are not readily available or desired.

Two alternative strategies were proposed to take maximum advantage the period of lactational infertility: breastfeeding can be used either as a birth spacing method in its own right, especially when there are no alternatives available or if a couple chooses not to us other family planning methods; or it can be used as a means to dela the introduction of other family planning methods. Where there are problems with family planning availability, acceptability or continuation (especially during breastfeeding), the use of the natural infertility of breastfeeding followed by the use of another family planning method, rather than the simultaneous employment of both, may serve to maximize the interbirth interval.

The consensus was that the maximum birth spacing effect of breastfeeding is achieved when a mother "fully" or nearly fully breastfeeds and remains amenorrheic (ignoring bleeding before the 56th postpartum day). When these two conditions are fulfilled, breastfeeding provides more than 98% protection from pregnancy in th first six months. At six months, or if menses return or if breastfeeding ceases to be "full" or nearly full before the sixth month, the risk of pregnancy increases. As soon as one of these events occurs, consideration must be given to using other means of family planning if a high degree of protection is desired or needed.

"Full" or nearly full breastfeeding is associated with longer period of lactational amenorrhea and infertility than partial breastfeeding Suckling frequency and the duration of the longest period of no suckling activity have sometimes been used as measures of the amount of breastfeeding. However, it may be difficult to define these variables and to implement them as part of a set of general recommendations.

Women who wish to or need to rely on the birth spacing effect of breastfeeding should delay for as long as possible the introduction of other regular feedings to the infant's diet but <u>without</u> jeopardizing infant growth and development. When additional foods need to be introduced, (usually between the fourth and sixth month

postpartum), women should be encouraged to continue breastfeeding frequently, day and night if they wish to maintain a milk supply.

It is hypothesized that if additional foods are introduced into the baby's diet gradually, over an extended period of time, and that if breastfeeding is continued, it may still exert a significant antifertility effect for a year or more. The key here is that breastfeeding is not reduced and other foods do not replace breastfeeding. This appears to be the breastfeeding pattern in many settings with long durations of lactational amenorrhea. It is important that local, operational definitions of "full breastfeeding" be used and evaluated.

In general, lactational infertility decreases with time. After the sixth month postpartum, when breastfeeding will probably cease to be "full" or nearly full, it is increasingly likely that fertility will precede the first vaginal bleed. On the other hand, the period of lactational infertility is longer in populations where the natural duration of lactation is very long, and this may be dependent--at least in part--on the pattern of feeding and supplementation. Pregnancy rates associated with lactational amenorrhea after the sixth postpartum month--although low--have not been quantified precisely by time postpartum or breastfeeding pattern. Demographic survey data suggest that the risk of pregnancy among lactating amenorrheic women in developing countries is not greater than ten percent after six months, and in many such settings, lactational amenorrhea may last up to a year or more.

Guidelines specific to a particular country or population for using breastfeeding as a postpartum family planning method can be developed based on this consensus. Local infant feeding practices and the average duration of amenorrhea should be considered in adapting these general guidelines.

Family Health International
Durham, NC, USA

A copy of the report of this conference is available from Kathy Kennedy, Research Associate, Family Health International, P.O. Box 13950, RTP Branch, Durham, NC, USA.