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# Multicenter study of the lactational amenorrhea method (LAM) III: effectiveness, duration, and satisfaction with reduced client–provider contact[1]

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**Abstract**

The objective of this effort was to assess the use and efficacy of the Lactational Amenorrhea Method (LAM) with reduced numbers of client–provider contacts. A co-sponsored multicenter study of LAM was performed to test the efficacy and acceptability of the method under "post-marketing" conditions, with investigator-initiated contact occurring only twice: at the time of intake and then again at month 7 of postpartum. These data are assumed to provide an assessment of LAM's use, efficacy, and performance that more closely reflects the prevailing conditions of these populations during normal use. Three hundred and sixty-two subjects were recruited through centers that had participated in the previous, more contact-intensive studies. Using a cooperatively developed protocol, data were gathered prospectively on at least 10 and up to 50 LAM acceptors at nine sites, and entered and cleaned on site. Data were further cleaned and analyzed at the Georgetown University Institute for Reproductive Health (IRH) and the Department of Nutrition at the University of Connecticut. Using country-level and pooled data, descriptive statistics and life tables were produced. LAM efficacy in this sample is 100% because there were no pregnancies at any of the participating sites. Satisfaction with the method was high, and the rate of continuation on to another method after LAM was 66.7% at 7 months postpartum. Of the women who had never used family planning prior to LAM, 63.0% went on to use another method of family planning in a timely manner. LAM can be highly effective as an introductory postpartum family planning method when offered in a variety of cultures, health care settings, and industrial and developing country locales. Under conditions of limited client–provider contact, LAM remains effective and leads to acceptance of another method by about two-thirds of the acceptors. Women are able to use LAM effectively without extensive counseling or follow-up, with a high level of user satisfaction. 

*Keywords:* Breastfeeding; Fertility; Family planning; Natural planning; Efficacy; Client satisfaction

## 1. Introduction

The Lactational Amenorrhea Method (LAM) is a family planning method that, when presented properly, simultaneously promotes child spacing, enhances the duration of postpartum infertility, and supports optimal breastfeeding for nutrition and disease prevention for the infant [1,2]. Previous research has shown that women who use LAM will breastfeed longer and will have better breastfeeding

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practices than women who breastfeed but do not use LAM [3,4]. The influence of breastfeeding on the suppression of ovulation and fertility after childbirth, and hence on the birth interval, is well known; LAM is based on the natural physiology of lactational infertility and codified for effective use. At the Bellagio Consensus Conference in August 1988 [5], researchers agreed that a mother who meets three criteria (amenorrhea, fully or nearly fully breastfeeding, and under 6 months postpartum) has less than a 2% chance of pregnancy during the first 6 months postpartum. These three criteria were subsequently codified as an algorithm which was given the name Lactational Amenorrhea Method (LAM) in a 1989 meeting at Georgetown University. A fourth criterion also emphasized at this meeting was the need to use another family planning method when any of the three criteria changed, thus maintaining the same high level of protection against pregnancy as well as maintaining birth intervals consistent with optimum maternal and child health [6]. The method itself and the policy considerations are described fully in other articles [7–10].

Although the efficacy of the method has been demonstrated in several populations [6,11], the present set of studies were planned to confirm the effectiveness in a wider range of populations and to assess aspects of acceptability, utilization, and clinical support necessary in these populations. The collaborative multicenter LAM study was designed with two protocols through a collaboration among Georgetown University, the World Health Organization, and the South-to-South Cooperation for Reproductive Health. Protocol I was designed to have monthly clinical contact with acceptors for the first 6 months postpartum, and two subsequent follow-up visits at months 9 and 12 postpartum. The results from Protocol I showed LAM to be a highly efficacious family planning method, with life table percent efficacy of 98.5 $\pm$ 0.7. Among the 519 women in the first protocol, 62% continued to use LAM successfully into the sixth-months postpartum, with only five pregnancies during the 2,718 woman-months of use. Details on the efficacy, satisfaction, and continuation of family planning methods for Protocol I of this study are explained in more detail in other articles [8,9].

A second protocol was designed to assess use "post-marketing," with investigator/provider-initiated contact only at the time of intake and at 7 months postpartum. This article covers issues of effectiveness, satisfaction, and continuation of family planning after LAM use ended under Protocol II.

The objectives of the study remain the same as under the first protocol: (1) to confirm efficacy of the Lactational Amenorrhea Method under real-life conditions; (2) to assess the acceptability of LAM in a variety of defined populations; (3) to assess correctness of LAM use as a postpartum introductory family planning method, including timely acceptance of complementary family planning after the use of LAM; (4) to document the outcomes for clients who do not adhere to the recommended LAM guidelines; (5) to document issues related to the introduction of family planning methods after LAM use; and (6) to improve the clinical guidance for utilization of LAM by analyzing circumstances that may have led to unplanned conceptions.

The coordinating institution, the Institute for Reproductive Health (IRH), Department of Obstetrics and Gynecology at Georgetown University, supported research sites in Birmingham, England; Dusseldorf, Germany and Milan, Italy; Merida, Mexico; Manila, the Philippines; Stockholm, Sweden; and Washington, DC, USA, through its Cooperative Agreement with the United States Agency for International Development. Additional sites were supported by the World Health Organization's Special Programme of Research, Development and Research Training in Human Reproduction (Sagamu, Nigeria), and the South-to-South Cooperation for Reproductive Health (Assiut, Egypt and Jos, Nigeria). The Indonesian site, which participated in the previous protocol of this study, was unable to complete this second protocol due to site difficulties.

## 2. Methodology

### *2.1. Overall*

LAM acceptors were recruited based on interest in using the method and, after being counseled on the method and surrounding issues and providing entry data, were followed up only once at 7 months postpartum. Client-initiated contact could occur at any point during the study, and study participants were encouraged to call or visit the site for counseling or referral when they had any questions or problems. The reason for each client-initiated contact was recorded, as were any problems encountered with the method. These data should allow for a better understanding of services needed by LAM users. In the first Protocol, monthly contact allowed investigators to assess LAM eligibility during each visit, and the investigator would indicate if the client did not meet the three criteria, thus discontinuing use per the protocol; in this study, client self-assessment led to continuation or discontinuation. Study participants were not required to keep any records. Each site recruited at least 10 and up to a maximum of 50 LAM acceptors.

### *2.2. Instruments*

All of the data collection instruments used in the study were drafted by IRH, with additional input from the World Health Organization and the principal investigators at each site. Each form was standardized and used by all investigators at all sites, with the only modification being a translation into the local language. All data collection forms were pre-tested and revised, as necessary, before initiation of client intake.

The screening and intake forms were the same as used in the first protocol [12,13]. The screening form assessed eli-

gibility and willingness of women to participate in the LAM study. Questions included amenorrhea breastfeeding status, birth date of the infant, and whether the woman desired child spacing. The study criteria required that neither the woman nor her partner be sterilized, that neither the woman nor her infant have any serious health problems, and that the woman has no absolute contraindications to pregnancy. If the woman met the study and LAM criteria, she was then counseled on all methods. If she then accepted LAM, informed consent was obtained and an intake interview initiated and completed.

The intake interview gathered background information on the mother, including age, education, religion, and marital and employment status. Questions about the type of birth (vaginal or caesarian), problems relating to labor and delivery, and health problems of the baby or mother were also assessed. The women were also queried on previous births and previous infant feeding, including number of pregnancies and live births, whether they had previously breastfed and if so the number of months, where the baby slept, and when menses had returned after the previous birth(s). Plans for breastfeeding the current infant and plans for future use of family planning were also discussed.

Follow-up at 7 months included data collection on experience during method use, the conditions of discontinuation, and family planning method selection after LAM. Data were gathered to assess the number and purpose of contacts made by each client. Discontinuation data were collected at 7 months postpartum, or earlier if the client visited and was no longer using LAM. In addition, each client's infant feeding practices, the return of menses, knowledge of LAM criteria, satisfaction with the method, family planning intentions, and pregnancy status were recorded. Data collected at the start of the seventh month postpartum provided additional information about plans for the continuation of family planning after the period of LAM use. If lactational amenorrhea were still being used as the method at this time, a practice not recommended in the protocol, the client was asked the reason for continued use.

### *2.3. Recruitment and data collection*

Between January 1994 and September 1995, 362 women were screened for intake at the same study sites by the same study personnel in Protocol I [12,13]. All clients were counseled on LAM and alternate forms of family planning, stated intention of resuming sexual activity by month 3 postpartum, and agreed to make contact with study personnel at 7 months postpartum. The acceptors were not asked to keep records of any kind. Of the 362 women who chose to use LAM, 302 (83.4%) are included in the analyses. Reasons for exclusion include: 45 (12.4%) were lost to follow-up, 9 (2.2%) had durations of LAM use under 56 days (and per the protocol, were excluded), 5 (1.2%) were not sexually active, and one woman's infant died (0.2%) at day 51 postpartum. There were no known pregnancies among the women who were not included in the final analyses.

Analyses were undertaken to determine any differences between those women included in the analyses and those excluded, including lost to follow-up. Attrition was found to be highest in Jos, Nigeria, the Philippines and Mexico. Those excluded were less likely to be employed in the previous year, but the differences were not statistically significant. Also, those excluded were less likely to have previously used family planning, were significantly younger, had fewer children, and had a lower level of education.

### *2.4. Data handling*

Data entry and editing were performed on location at each site using the EpiInfo software program data entry screens prepared by IRH, and the cleaned and edited data were transferred periodically to IRH in Washington, DC, for further cleaning, queries, and analyses. The sites also responded to specific data queries sent out by IRH. The data from all sites were pooled, and the final analyses were performed at the University of Connecticut. The data analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 8.0 [10]. Life tables were generated to estimate the monthly probability of pregnancy, and the probability of remaining amenorrheic through the first 6 months postpartum.

## 3. Results

### *3.1. Description of the study population*

This analysis includes 302 LAM acceptors from a variety of national and ethnic backgrounds at nine sites (Table 1 and Fig. 1). Each site submitted an average of 34 cases, with a range from 10 to 49. The mean maternal age was 28.2 (range of means = 24.4–33.3), mean parity 2.8 (range of means = 1.4–4.3), mean years of education 9.8 (range of means = 1.3–16.4), and included a wide variety of religious backgrounds. The differences between the sites generally reflect the parity, maternal age, education, and religion among childbearing women in each site or country.

Overall, 26.8% of the study population were primiparous, generally lower in the industrialized countries. Six percent of the women in the study worked outside the home at 6 months postpartum, although three sites (Egypt, the Philippines, and the United States) had no women who were doing so, and three other sites (Mexico, Sagamu, and the United Kingdom) showed 5% or less of the participants to be doing so. Previous research has shown that employment often plays a limited role in decisions concerning breastfeeding, and that the great majority of breastfeeding women in developing countries are either not employed or take their young infants under six months of age with them to their workplace [11].

Table 1
Characteristics of LAM acceptors

| Site | n | Mean age in years | Mean years of schooling | Mean parity | Primiparous (%) | Work outside home at 6 months postpartum (%) | Never used family planning before (%) |
|---|---|---|---|---|---|---|---|
| Egypt | 49 | 28.1 | 1.3 | 4.3 | 12.2 | 0.0 | 65.3 |
| Mexico | 35 | 24.4 | 6.1 | 2.7 | 40.0 | 2.9 | 45.7 |
| Nigeria, Jos | 42 | 25.3 | 10.5 | 2.6 | 31.0 | 16.7 | 31.0 |
| Nigeria, Sagamu | 49 | 28.7 | 11.7 | 2.6 | 26.5 | 2.0 | 24.5 |
| Philippines | 40 | 26.8 | 9.2 | 2.9 | 7.5 | 0.0 | 65.0 |
| Germany/Italy | 36 | 29.6 | 13.4 | 1.4 | 68.6 | 16.6 | 25.0 |
| Sweden | 10 | 29.7 | 15.0 | 1.9 | 30.0 | 10.0 | 0.0 |
| United Kingdom | 20 | 33.2 | 15.6 | 2.6 | 15.0 | 5.0 | 0.0 |
| United States | 21 | 33.3 | 16.4 | 3.3 | 14.3 | 0.0 | 0.0 |
| Total | 302 | 28.2 | 9.8 | 2.8 | 26.8 | 6.0 | 35.8 |

The range in the proportion of women who had never used family planning prior to LAM was broad: 90% of the women at industrialized country sites had used contraception previously, while for the developing countries, it ranged from 34.7% in Egypt to 75.5% at the Sagamu, Nigeria, site.

### 3.2. LAM efficacy and duration

There were no reported pregnancies in this study. Therefore, a 6-month life table efficacy of LAM is 100%. Using conventional life table techniques, estimates for the duration of LAM use were derived. Data were available for 296

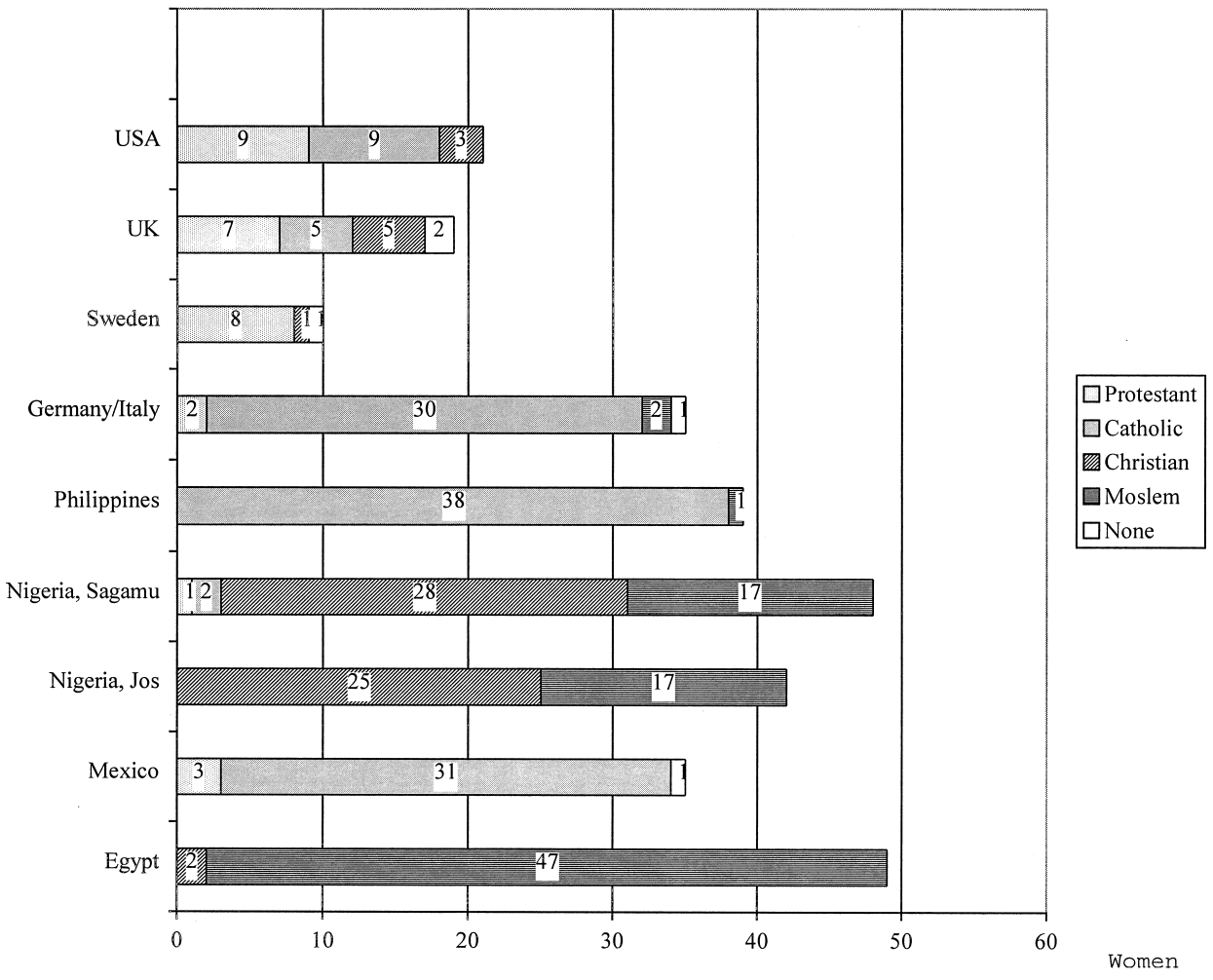



Fig. 1. Religious affiliation of study participants.

Table 2
Reasons for discontinuing LAM among those reporting reasons

| Site | Menses resumed | Stopped full BF | Long intervals | Stopped BF | Infant reached 6 months of age | maternal employment | Use of contraception | Other | Total at site |
|---|---|---|---|---|---|---|---|---|---|
| Egypt | 6 | 1 | – | – | 42 | – | – | – | 49 |
| Mexico | – | 6 | – | 4 | 13 | 1 | 5 | 6 | 35 |
| Nigeria, Jos | 13 | – | – | – | 29 | – | – | – | 42 |
| Nigeria, Sagamu | 2 | 23 | – | 1 | 23 | – | – | – | 49 |
| Philippines | 3 | 3 | – | 4 | 3 | 4 | – | 1 | 18 |
| Germany/Italy | 12 | 11 | 1 | – | 11 | – | – | 1 | 36 |
| Sweden | 2 | – | 1 | – | 1 | – | – | 1 | 5 |
| United Kingdom | 1 | 2 | 2 | – | 12 | – | – | – | 17 |
| United States | 2 | 3 | 3 | 1 | 1 | – | – | – | 10 |
| Total n | 41 | 49 | 7 | 10 | 135 | 5 | 5 | 9 | 261[b] |
| % | 15.7 | 18.7 | 2.7 | 3.8 | 53.3 | 1.9 | 1.9 | 3.4 | |

[a] BF, breast feeding.
[b] This is 86.4% of total population.

LAM acceptors and 1,705 woman-months of LAM use. The life table probability of continuing LAM through the sixth month postpartum among eligibles was found to be 84.7 ± 2.6%.

The reasons for discontinuation of LAM are shown in Table 2. More than half completed the 6 months of LAM use. Resumption of menses was the reported reason for discontinuation in only 15.4% of those reporting Estimates of the exact duration of amenorrhea are limited since the final end-of-study visit was performed at the start of the seventh month postpartum. At this time women were questioned as to whether their menses had resumed; 65.2% (n = 197) of the women remained amenorrheic at month 7, and five sites (Egypt; Sagamu, Nigeria; Sweden; the United Kingdom; and the United States) had 70% or more of their study population remaining amenorrheic at this point (n = 40, 40, 7, 19, and 18, respectively).

### 3.3. Satisfaction with LAM

Satisfaction with using LAM was high among the study population (Table 3). Overall, 86.4% (n = 261) of the women said they were very satisfied with LAM, and 91.7% (n = 277) said they had no problems with using the method. Additionally, 89.4% and 90.7% (n = 270 and 274, respectively) of the study participants said they never had problems with daytime breastfeeding and nighttime breastfeeding, respectively. These numbers for acceptability and satisfaction are in the same range as given for other methods of family planning [12–14].

After discontinuing use of LAM, the study participants were asked to name those features of using LAM they considered to be positive and negative (Fig. 2). These questions were intended to be open-ended, and the respondents were allowed to give more than one answer for each of the questions. Positive responses in terms of economic benefits and health benefits predominated in the less industrialized settings, while positive features, such as easy and natural, were more often noted in developed settings. When the women participating in the study were questioned about what they liked least about using LAM, a majority (68.2% of the responses, (n = 199) indicated that there was nothing negative about using the method. Efficacy worries were the main concern in the developed country settings and con-

Table 3
Satisfaction with LAM use

| Site | Very satisfied with LAM % (n) | No problems with LAM % (n) | No daytime BF problems % (n) | No nighttime BF problems % (n) |
|---|---|---|---|---|
| Egypt | 91.8 (45) | 100 (49) | 100 (49) | 79.6 (39) |
| Mexico | 65.7 (23) | 94.3 (33) | 88.6 (31) | 97.1 (34) |
| Nigeria, Jos | 97.6 (41) | 100 (42) | 81.0 (34) | 95.2 (40) |
| Nigeria, Sagamu | 98.0 (48) | 91.8 (45) | 93.9 (46) | 100 (49) |
| Philippines | 80.0 (32) | 87.5 (35) | 87.5 (35) | 100 (40) |
| Germany/Italy | 80.6 (29) | 94.4 (34) | 88.9 (32) | 83.3 (30) |
| Sweden | 70.0 (7) | 70.0 (7) | 100 (10) | 90.0 (9) |
| United Kingdom | 95.0 (19) | 80.0 (16) | 95.0 (19) | 90.0 (18) |
| United States | 81.0 (17) | 76.2 (16) | 66.7 (14) | 71.4 (15) |
| Average (Total) | 86.4 (261) | 91.7 (277) | 89.4 (270) | 90.7 (274) |

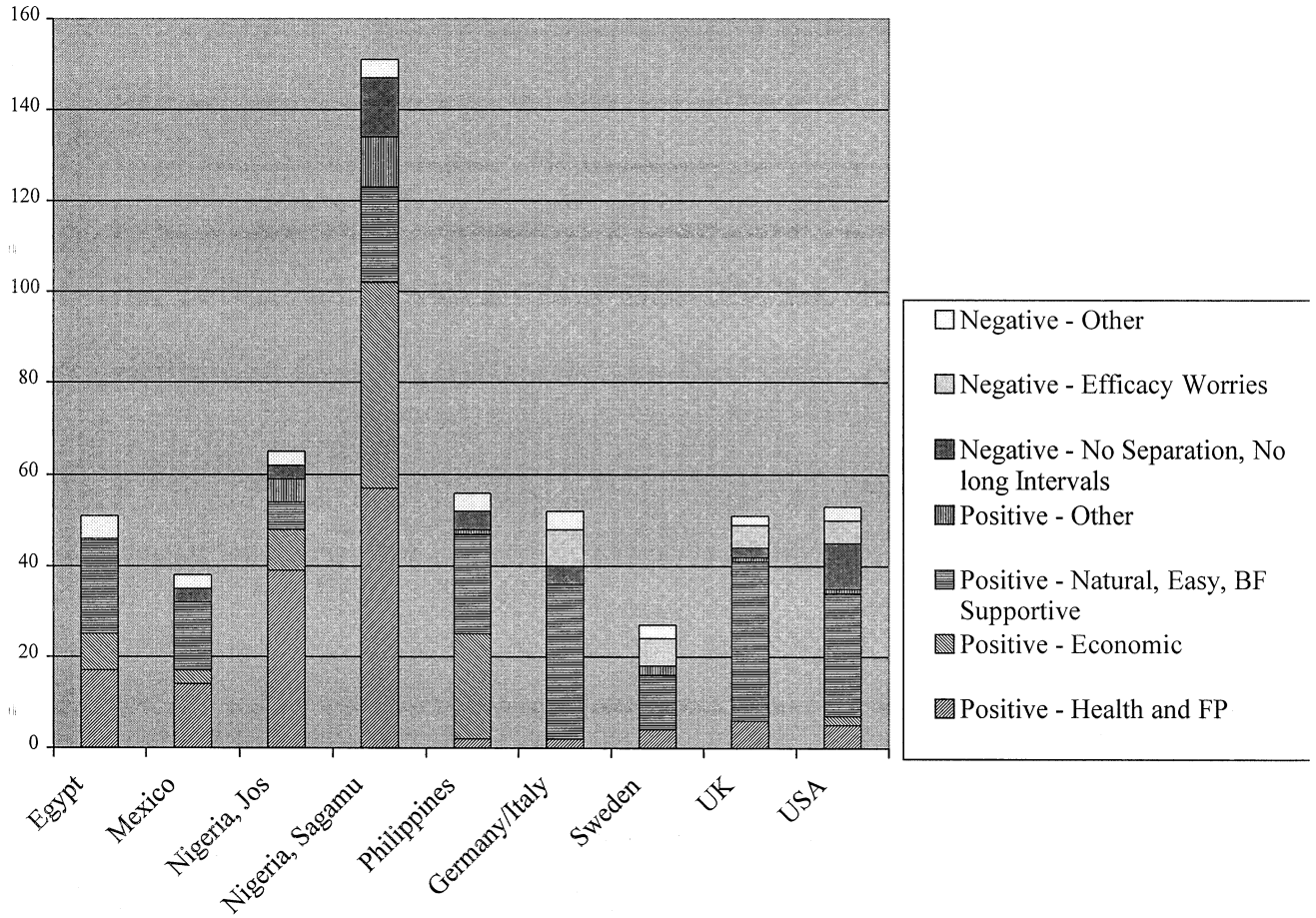



Fig. 2. Number of reported positive and reported negative aspects of LAM use.

cerns that one must be with the child were mostly noted in Nigeria.

### *3.4. Knowledge of LAM*

As mentioned in the introduction, LAM use requires that three main criteria be met (amenorrhea, fully or nearly fully breastfeeding, and under 6 months postpartum). If at any point any of these criteria are not met, the risk of pregnancy increases, and alternative methods of family planning must be utilized. Therefore, there is a fourth criterion, which dictates the initiation of another family planning method, for continued protection and for the health goal of 3–4 years birth interval, whenever any of the first three criteria are not met. The study investigators were interested in determining the level of knowledge of the three LAM criteria, and of other behaviors important to successful LAM use that were stressed during LAM counseling (timely use of family planning when any of the three criteria are not met, no long intervals between breastfeeds, and the importance of night breastfeeds) (Table 4). During the follow-up interview (after LAM had been discontinued), each participant was asked: "Can you tell me the criteria of the Lactational Amenorrhea Method?" For each criterion, it was noted whether the participant's response was recalled spontaneously, if prompting was needed, or whether there was no recall. If prompting was needed, the question, "Is there anything else that was important to the use of LAM?" was asked, and the response noted.

For the study population as a whole, the level of unaided recall was as follows: 75.5% (n = 228) recalled the bleeding criterion, 71.2% (n = 215) recalled the 6-month criterion, and 82.8% (n = 250) recalled the criterion for full breastfeeding. There is a wide variation among the sites in terms of unaided recall for the three main criteria; however, when aided recall is also considered, most sites exceed 95%. The exceptions to this are as follows: Mexico and the United States for the bleeding criterion, and the United States for the 6-month criterion. The differences in the ability to recall the criteria could be a result of counseling differences among the sites, or in differences in the populations entering the study at each site.

Although the three main criteria were generally well known, two behavioral aspects of LAM use were not recalled as well. Only 65.6% and 63.2% (n = 198 and 191, respectively) of the study participants recalled unaided the need for no long intervals between breastfeeds and the importance of night breastfeeds, respectively. This is not

Table 4
Knowledge of four LAM criteria and two encouraged behaviors by unaided recall at 6 months postpartum

| Site | Bleeding criterion % (n) | 6-month criterion % (n) | Full or nearly full BF criterion % (n) | Timely use of family planning % (n) | No long intervals between BF % (n) | Importance of night feedings % (n) |
|---|---|---|---|---|---|---|
| Egypt | 100 (49) | 100 (49) | 93.9 (46) | 81.6 (40) | 87.8 (43) | 98.0 (48) |
| Mexico | 37.1 (13) | 11.4 (4) | 37.1 (13) | 22.9 (8) | 5.7 (2) | 8.6 (3) |
| Nigeria, Jos | 88.1 (37) | 83.3 (35) | 69.0 (29) | 59.5 (25) | 40.5 (17) | 42.9 (18) |
| Nigeria, Sagamu | 89.8 (44) | 95.9 (47) | 100 (49) | 98.0 (48) | 79.6 (39) | 59.2 (29) |
| Philippines | 72.5 (29) | 55.0 (22) | 80.0 (32) | 50.0 (20) | 52.5 (21) | 67.5 (27) |
| Germany/Italy | 88.9 (32) | 88.9 (32) | 88.9 (32) | 88.9 (32) | 91.7 (33) | 91.7 (33) |
| Sweden | 30.0 (3) | 50.0 (5) | 100 (10) | 50.0 (5) | 90.0 (9) | 70.0 (7) |
| United Kingdom | 50.0 (10) | 50.0 (10) | 90.0 (18) | 45.0 (9) | 85.0 (17) | 60.0 (12) |
| United States | 52.4 (11) | 52.4 (11) | 100 (21) | 4.8 (1) | 81.0 (17) | 66.7 (14) |
| Average (Total n) | 75.5 (228) | 71.2 (215) | 82.8 (250) | 62.3 (188) | 65.6 (198) | 63.2 (191) |

surprising because these are not the prime messages given during counseling; however, these behaviors may affect duration of LAM use. The fourth criterion, timely use of family planning, also was not consistently recalled at most sites, although Egypt, Sagamu, Nigeria and Germany/Italy all show unaided recall above 90%.

### *3.5. Continuation of family planning after LAM use*

Family planning use after LAM discontinuation is important for maternal and child health reasons, and is necessary to reach the recommended birth interval of at least 2 years. Because of this, the investigators were very interested to see the timing of initiation of use of the follow-on method and the method chosen. The rate of continued family planning use in this study is quite high: 71.9% (n = 210) of the study population chose to use another family planning method after they had discontinued LAM. Of those women who had switched to another method of family planning, 79.5% (n = 167) did so within the first 2 weeks of discontinuing LAM, and 88% (n = 185) did so within 4 weeks of ending LAM. At three of the sites, Jos and Sagamu in Nigeria, and Sweden, 100% of the study participants used another family planning method after discontinuing LAM. At 2 additional sites, the United Kingdom and the United States, continuation of family planning was at or above 75%.

The methods chosen are shown in Table 5. Natural family planning/periodic abstinence was the most commonly chosen method, with 19.7% (n = 42) of women opting for these methods. This is not surprising as LAM is considered by many to be a "natural" method. The other methods chosen include the IUD (16.4%, n = 35), condom (15.0%, n = 32), and withdrawal (12.2%, n = 26). Combined oral contraceptive pills accounted for 5.2% (n = 11) of the choices, while the progestin pill, diaphragms, and injectables each accounted for under 5% (n = 5, 5, and 8, respectively). The use of jelly/foam and female sterilization each were chosen only 0.5% (n = 1) of the time. The selections of method show distinct site preferences, perhaps

Table 5
Family planning method used after LAM

| Site | Progestin pill | Combined OC[a] | IUD | Condom | Diaphragm | Jelly/ Foam | Injectable | NFP/periodic abstinence | Withdrawal | Female sterilization | Other | Total using FP after LAM |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Egypt | 2 | – | 9 | 2 | 1 | – | 4 | – | – | – | – | 18 |
| Mexico | 1 | 2 | 2 | – | – | – | 4 | 1 | 6 | 1 | – | 17 |
| Nigeria, Jos | – | – | 11 | 7 | – | 1 | – | 14 | 8 | – | 1 | 42 |
| Nigeria, Sagamu | – | 2 | 9 | 12 | – | – | – | 16 | 3 | – | 7 | 49 |
| Philippines | – | 1 | – | – | – | – | – | – | 6 | – | 18 | 25 |
| Germany/Italy | – | 6 | 2 | 4 | – | – | – | 6 | 1 | – | – | 19 |
| Sweden | 1 | – | 2 | – | – | – | – | – | 2 | – | 5 | 10 |
| United Kingdom | 1 | – | – | 4 | – | – | – | 4 | – | – | 9 | 18 |
| United States | – | – | – | 3 | 4 | – | – | 1 | – | – | 7 | 15 |
| Total n/% of FP users (% of Total) | 5 | 11 | 35 | 32 | 5 | 1 | 8 | 42 | 26 | 1 | 47[b] | 213 |
| | 2.3% | 5.2% | 16.4% | 15.0% | 2.3% | 0.5% | 3.8% | 19.7% | 12.2% | 0.5% | 22.1% | (70.5%) |

[a] OC, oral contraceptive; NPF, natural family planning.

[b] Of these 47 women, 45 were using "Extended LAM" and two were using a traditional ring.

Of the 45 women who were still using LAM, their reasons for doing so were as follows: 32 had not had a return of menses, 3 said they showed no signs of fertility, I wanted to get pregnant, I had no time to arrange a doctor's appointment to receive FP, and 8 gave no response.

Table 6
Family planning use among women who had never used family planning prior to LAM and method chosen

| Site | Percentage of previous non-users using a method in month 7 | Progestin only pill | Combined pill | IUD | Condom | Jelly/ foam | Progestin injection | Combined injection | NFP/periodic abstinence | Withdrawal | "Extended LAM" |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Egypt | 34 | 2 | – | 4 | 2 | – | 3 | – | – | – | – |
| Mexico | 50 | 1 | 1 | 1 | – | – | – | 1 | 1 | 3 | – |
| Nigeria, Jos | 100 | – | – | 4 | 1 | 1 | – | – | 5 | 2 | – |
| Nigeria, Sagamu | 100 | – | – | 1 | 2 | – | – | – | 4 | 1 | 4 |
| Philippines | 61.5 | – | – | – | – | – | – | – | – | 5 | 11 |
| Germany/Italy | 5.6 | – | – | – | – | – | – | – | 2 | – | – |
| Total (n) | | 3 | 1 | 10 | 5 | 1 | 3 | 1 | 12 | 11 | 15[a] |
| (%) | 100 | 4.8% | 1.6% | 16.1% | 8.1% | 1.6% | 4.8% | 1.6% | 19.4% | 17.7% | 24.2% |

[a] Of these 15 women, 9 stated that "extended LAM" was an interim method and that they intended to use the following family planning methods after they discontinue LAM: 5 combined oral contraceptives, 1 IUD, 1 condoms, 1 NFP/PA, and 1 withdrawal.

indicating counseling biases, supply constraints, or cultural predilection.

Forty-five of the 47 women in the "other" method category were using "extended LAM" (extended LAM is defined as amenorrhea, continued frequent breastfeeding day and night with breastfeeding preceding all complementary feeds, for up to 12 months), and two were using a "traditional ring." Of the 45 women who were using "extended LAM," their reasons for doing so were as follows: 32 noted that they had not had a return of menses, three said they showed no signs of fertility, one was not avoiding pregnancy, one had no time to arrange a doctor's appointment to receive family planning, and eight gave no further response.

Also of particular interest to the investigators was the number of women who had never used family planning prior to LAM who would go on to use another method of family planning after discontinuing LAM. As noted in Table 1, 35.8% (n = 108) of LAM acceptors had never used family planning previously. Of these women, 63.0% (n = 68) went on to use another method of family planning when LAM no longer provided protection. Table 6 shows the methods chosen by the sub-group of women who had not used family planning prior to LAM. Methods selected are similar to those selected by all women in Table 5, with a slight increased percentage selecting withdrawal and a slight decreased percentage in combined OC and sterilization uptake.

### *3.6. Client-initiated contact*

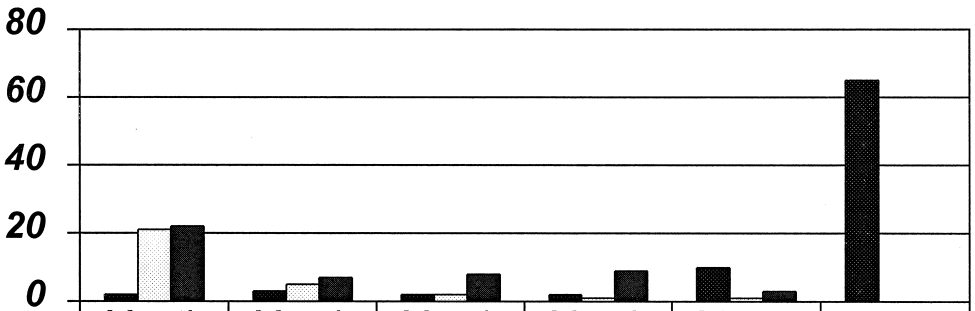
The correct use of LAM requires that the breastfeeding mother fully understands all of the parameters; if she does not adhere to the requirements, or does not understand them, her risk of pregnancy increases. At the time the second protocol began, it was quite reasonable to expect that the study personnel knew the intake counseling procedures well and fully counseled the clients at this time.

This protocol was designed as a "post-marketing" assessment, attempting to better understand method counseling and use as it will be offered outside of study protocols, in order to determine the level of service provider input necessary to support method use. Therefore, it is of interest for future service provision that we assess how many additional times women involved in the study initiated contact with the provider of the method, and the reasons for the contact (Fig. 3). In the first month, 45 women (15% of the study population) initiated contact with study personnel; during month two, 15 women (5%) did so. In months 3, 4, 5, and 6, 12, 12, 14, and 65 women, respectively, initiated contact. All of the client-initiated contacts in month 6 were to discontinue LAM.

Other than for discontinuation of LAM, the issues addressed during the contacts included LAM, breastfeeding, and other mother and baby health issues. In month 1 and 2, 26 contacts were LAM-related, 2 were breastfeeding-related, and 27 were for other health questions. In months 3 through 5, 4 contacts were LAM-related, 8 were breastfeeding-related, and 12 were for other health questions. The majority of contacts had nothing to do with LAM or breastfeeding, and would not necessarily be addressed by a LAM provider, per se. Contacts made to discuss breastfeeding issues were also a small percent (6.1%) of the overall number of contacts.

## 4. Discussion

This study shows that LAM can be used effectively in a wide range of ethnic and cultural situations and service-delivery settings, with limited counseling. Duration of use and satisfaction were high both in industrialized and developing countries. Study acceptors may not be fully representative of the total population of family planning clients at the sites, and the sites in this study may differ from other sites where LAM will be offered. However, in a study such as this, there are certain inherent limitations, such as small sample sizes, the problematic nature of pooling data, the generalizability of findings due to self-selection, self-reporting of data, and site personnel having already gone through the experience of Protocol I. The authors believe the sample




| | Month 1 | Month 2 | Month 3 | Month 4 | Month 5 | Month 6 |
|---|---|---|---|---|---|---|
| Discontinuing LAM | 2 | 3 | 2 | 2 | 10 | 65 |
| Continuing LAM | 21 | 5 | 2 | 1 | 1 | 0 |
| Other Non-LAM | 22 | 7 | 8 | 9 | 3 | 0 |

Fig. 3. Number of client-initiated contacts by reason for contract and by month postpartum.

size is adequate for the conclusions that are drawn, that qualified and experienced counseling teams, as described previously, constitutes a fair initial trial of LAM, and that the data need to be taken in the context of the other papers in the series [12,13].

It is important to note that there is no demonstrated requirement for significant breastfeeding support programs to be in place before the LAM method can be introduced. This study shows LAM acceptance and successful use in a variety of settings where there is no formal breastfeeding support. Rather, LAM introduction per se seems to support improved levels of breastfeeding success and continuation.

The reasons for discontinuation of LAM seem to reinforce that LAM is a feasible method of family planning. The responses show that for the most part women were able to use LAM successfully without extensive counseling. The feasibility of method use is also reflected in the data for reported undesirable aspects of LAM, with a majority of responses citing no undesirable aspects. However, the breastfeeding pattern demanded by LAM was not an insignificant cause of discontinuation; slightly more than a quarter of the reasons given pertain to breastfeeding issues. It should also be noted that almost 70% of these breastfeeding responses came from two sites, Sagamu, Nigeria, and Germany/Italy, perhaps due to differences in cultural constraints or counseling emphases. From these responses, providers may discover areas that need special attention during counseling.

Study participants' knowledge of the LAM criteria at month 7 postpartum was similar to recall of the criteria during the first protocol of this study, and the concern that women would not be able to recall the criteria, and thus use LAM improperly, was part of the stimulus for the study, and was an issue the overall study was designed to address. The data show that in a variety of sites with different problems, populations and biases, the level of knowledge women were able to recall is in line with other research done on LAM knowledge and the occurrence of pregnancies [16]. Although higher levels of unaided recall would be desirable, this is an area in which further research on LAM counseling practices would be helpful as there were marked differences among sites for retention of information.

The median survival in a life table for duration of LAM is 6.5 months, and the probability of remaining amenorrheic through the sixth-month postpartum is shown to be 71.4 $\pm$ 2.8%, with 65.2% of women amenorrheic at this point. These numbers are also consistent with those in the previous protocol of this study: 68.4% of those women were amenorrheic through 6 months postpartum. Although LAM use is recommended for only the first 6 months postpartum, it is interesting that such a large proportion of the population still fit the condition of the menses parameter at the end of recommended LAM use. When these data are viewed in combination with rates for continuation of family planning, a seamless chain of protection is provided for most of the women; of the 71.9% of women who had moved onto another method of family planning, 79.5% did so within the first 2 weeks after discontinuing LAM. While previous research has found that few women used another method after the protection from LAM expired [16], no special family planning promotion or advocacy was included in that research. The data from this study shows the compelling interest and importance of counseling women who use LAM to continuing family planning use after LAM.

Care must be taken in generalizing these findings. Participants in this study may not have been typical of the general population of new mothers: the participants were planning to breastfeed optimally and were willing to try a new method based on physiology rather than device or medication. In addition, those lost to follow-up were statistically younger, of lower parity and less educated. There-

fore, the external validity of these findings merit further investigation.

Although this second protocol had significantly reduced client contact, the results in many areas are similar to those of the first protocol, which had monthly client contact. The levels of acceptance of a follow-on family planning method were similar.

It is of note that only one woman stated that she delayed switching to another method due to lack of time to seek a doctor's appointment. Also of interest is that those LAM acceptors who had used family planning previously, and those who had no previous family planning use, chose a similar distribution of methods when switching, with possible exception of increased choice of sterilization among previous family planning users.

As the third part of a line of inquiry on LAM, this article supports earlier reports of the effectiveness of and satisfaction with LAM in different settings. The results of this study provide yet another solid basis for worldwide acceptance of the method, and further justification that LAM should be offered along with other modern methods. LAM is a very important addition to family planning options for postpartum women, for it confers simultaneous benefits for both mother and child; it also benefits family planning programs by providing a means of integrating reproductive health into family planning.

Nonetheless, additional research may be needed, and two extant documents outline in detail other related research that could improve our understanding of the method and its introduction [3,15], the findings of this study provide additional support for the potential for efficacy and integration of LAM into all family planning and reproductive health services.

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