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Multicenter Study of the Lactational Amenorrhea Method (LAM): I. Efficacy, Duration, and Implications for Clinical Application

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A multicenter study of the Lactational Amenorrhea Method (LAM) was carried out to test the acceptability and efficacy of the method. Additionally, the data are used to test new constructs for improvement of method criteria. A protocol was designed at the Institute for Reproductive Health (IRH), Department of Obstetrics and Gynecology, Georgetown University Medical Center, a World Health Organization (WHO) Collaborating Center, and was reviewed and modified in collaboration with the co-sponsors, the World Health Organization and the South to South Cooperation for Reproductive Health, and the principal investigators from each site. Data were gathered prospectively on LAM acceptors at 11 sites. Data were entered and cleaned on-site and further cleaned and analyzed at IRH, using country-level and pooled data to produce descriptive statistics and life tables. The 98+% efficacy of LAM is confirmed in a wide variety of settings. In addition, the results yield insight on the possibility of continued use beyond 6 months. LAM is found to be highly effective as an introductory postpartum method when offered in a variety of cultures, health care settings, socio-economic strata, and industrial and developing country locales. In addition, LAM acceptance complements breastfeeding behaviors without ongoing breastfeeding support services. The parameters studied yield high efficacy and method continuation. Therefore, the basic tenets of the 1995 Bellagio consensus on LAM is reconfirmed and it is recommended that LAM be incorporated into hospital, maternity, family planning, maternal and child health, and other primary health care settings. CONTRACEPTION 1997;55:327–336 © *1997 Elsevier Science Inc. All rights reserved.*

KEY WORDS: Lactational Amenorrhea Method (LAM), breastfeeding, family planning, efficacy, postpartum, lactational amenorrhea

Introduction

Modern methods of family planning are becoming increasingly available worldwide. Nonetheless, efficacious methods currently in use require commodities, which are susceptible to stock-outages and may be expensive, or demand special behaviors related to the sexual act, such as timing of intercourse in the use of periodic abstinence or modifying activities during intercourse, as in the use of withdrawal. There is need for an increased number of methods that can be used when other methods are not acceptable nor available, or when couples prefer to rely on their own understanding of fertility to regulate the timing of their conceptions.

The influence of breastfeeding on the re-establishment of ovulation and fertility after childbirth, and on the corresponding birth interval, is well known. At a Bellagio Consensus Conference in August 1988, it was proposed that a mother who is fully or nearly fully breastfeeding her infant and who remains amenorrheic would have less than a 2% chance of pregnancy during the first 6 months after childbirth.[1] The

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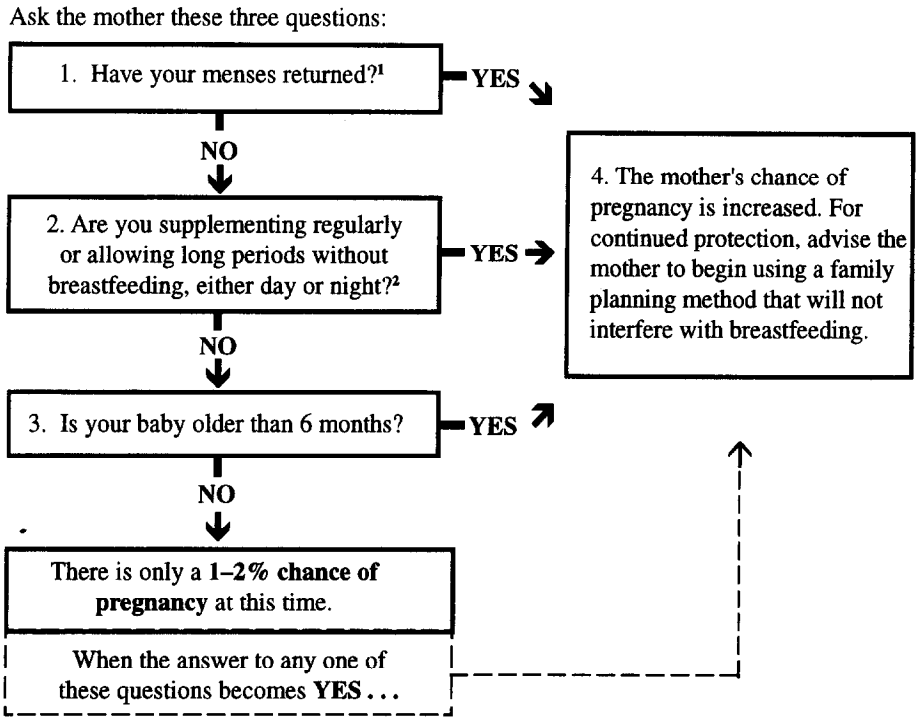

Figure 1. LAM algorithm.

consensus statement was based on previously published theoretical constructs and on clinical data and hormonal profiles obtained prospectively.[2–4] The clinical guidance for the consensus statement was then developed as the Lactational Amenorrhea Method (LAM) at Georgetown University.[5,6] The first clinical efficacy study of LAM was completed by 1991. That study, conducted in Santiago at the Pontificia Universidad Catolica de Chile in collaboration with the Institute for Reproductive Health (IRH), Department of Obstetrics and Gynecology, Georgetown University Medical Center, showed a cumulative 6-month life table pregnancy rate of 0.45% among women who relied on LAM as their only family planning method.[7]

LAM is an introductory family planning method that simultaneously promotes child spacing and breastfeeding, with benefits that include optimal nutrition and disease prevention for the infant, and a delay of fertility return and subsequent pregnancy for the mother.[5,7] LAM relies on the physiology of lactational infertility for protection from pregnancy and has three criteria, all of which must be met for optimal method efficacy. LAM requires and supports the maintenance of appropriate breastfeeding practices to prolong lactational infertility, with the concomitant delay in menses return. The method generally is presented as an algorithm (Figure 1) and is described fully in other articles.[5–8] LAM is currently being used successfully in more than a dozen countries.

Although the efficacy of the method has been demonstrated, the present study, the Collaborative Multicenter LAM Study, was designed to provide additional information on clinical application of this method of family planning, its acceptability and efficacy in different populations, cultural groups, and health care settings, and other related parameters. Hence, the purpose of the study is to confirm the efficacy and improve clinical guidance for LAM through a longitudinal examination and analysis of its use among acceptors. The coordinating institution, IRH, under a Cooperative Agreement with the United States Agency for International Development, supported research sites in Birmingham, England; a combined European site in Dusseldorf, Germany and Milan, Italy; Mérida, Mexico; Manila, the Philippines; Stockholm, Sweden; and Washington, DC, USA. Additional sites were supported by the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (Jakarta, Indonesia and Sagamu, Nigeria), and the South to South Cooperation for Reproductive Health (Assiut, Egypt and Jos, Nigeria).

The Multicenter LAM Study had six objectives: (1) to confirm efficacy of the Lactational Amenorrhea

Method, taking into account results of the Chilean study;[8] (2) to assess the general acceptability of LAM in a variety of defined populations; (3) to assess correctness of LAM use as a postpartum introductory 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 the introduction of other family planning methods following LAM use; and (6) to improve the clinical guidance for utilization of LAM by analyzing the circumstances that may have led to unplanned conceptions.

This paper covers efficacy and related issues. Since LAM is an interim method of child spacing, the timely acceptance of another family planning method that complements post-LAM breastfeeding also is evaluated in a companion paper.[9]

Methodology

Overall

The protocol, instruments, and procedures were drafted by IRH staff with input from WHO and the site-specific principal investigators. The protocol was pretested and revised before initiation of client intake. Initial training was conducted during investigators' meetings. Operational plans were developed in conjunction with each site team to inform and acquaint local health and breastfeeding support organizations with LAM, and with the study. Approval for the research was obtained from the Institutional Review Board of Georgetown University and from local ethics committees at each site.

The principal investigators from each site attended one or more preparatory meetings with IRH staff and WHO collaborators. The preparatory meetings included review of study design, instruments, and procedures. Counseling guidelines and a prototype for a client information pamphlet also were developed by IRH and adapted and translated for use in advising mothers at each site. IRH provided technical monitoring and assistance for the study procedures by mail, through telephone calls and facsimile transmissions, and with site visits as needed.

In order to achieve consistency in the protocol across sites, operational definitions were agreed upon during the first investigators' meeting in June of 1993. The formulation of operational definitions for breastfeeding in such a study presents difficulties inasmuch as criteria relating to the timing of breastfeeding is required. However, it is not expected that women using LAM will time breastfeeding episodes nor measure the amount of supplementation. Therefore, the following definitions were developed as a framework for the investigators, and not as clinical guidance for participants. A *breastfeeding episode* is defined as a feeding at the breast that continues for at least 4 min post let-down. To meet the definition of *fully or nearly fully breastfeeding*, all of the following must be met: (a) *breastfeeding frequency* must be a pattern comparable to at least 10 short or 6 long breastfeeds within 24 h; (b) *supplemental feeding* of no more than 1 ounce (30 ml) per week of supplement in month 1, no more than 2 ounces (60 ml) per week in month 2, 3 ounces (90 ml) per week in month 3, etc.; (c) no replacement of breastfeeds with other feeds, and no more than 10% of feeds or food can be other than direct breastfeeding; and (d) breastfeeding must be maintained with both day and night feeding and no long intervals between feeds. LAM was discontinued when there was a single interval of 10 h or frequent intervals of more than 6 h between any two feeds. Frequent was defined as greater than twice per week. Other long intervals were considered carefully by the co-investigators at each site. *Expressed milk*, when fed to the infant, was considered a supplemental feeding.

It is known that during lactational amenorrhea many women have bleeds that are different from menses. Therefore, the other critical operational definition decided upon at the first investigators' meeting included *resumption of menses*, defined as: two contiguous days of bleeding that the client considered similar to a menstrual bleed or heavier, or two contiguous days of spotting and one day of bleeding, or three contiguous days of spotting. Any lesser bleeding or spotting was recorded for later analysis but was not a cause to discontinue LAM use.

Participants were initially screened in order to assess their eligibility for both the study and for LAM. During the screening interview, the following information was collected: background information, including age, education, birth date of infant, employment status, previous family planning use, and parity. For study and LAM eligibility, information was collected on any contraindication to pregnancy, the health of the infant, and sterilization status for both mother and father. The age of the infant was assessed, as well as the woman's desire to delay her next pregnancy, breastfeeding status, and whether the respondent had bled since the 56th day postpartum. Informed consent was obtained at the time that eligibility and willingness to participate was determined, and an intake interview completed.

At the time of intake, the background information listed above was verified, including religion, and a medical history was obtained, including the following information: type of birth (vaginal or caesarian), any birthing problems encountered, use of any anesthe-

sia/sedatives during birth, birth weight of baby, and whether the mother smoked or drank alcohol. History on infant feeding and menses return for previous births was also obtained, as were plans for breastfeeding and family planning with the current birth. Intake procedures required that all participants were informed of the three requirements of the method; amenorrhea, full or nearly full breastfeeding, and less than 6 months postpartum. Participants were advised that the risk of pregnancy increases when any of these conditions are not met, and were advised to initiate another method of family planning when menses resumed, when the baby started receiving regular supplementation, or at 6 months postpartum. In addition, each participant was counseled in optimal breastfeeding practices for LAM, desirable infant feeding routines, and on the need for appropriate child spacing. The study centers also provided lactation counseling to their clients if requested.

Regularly scheduled follow-up visits were conducted monthly from intake to the end of the sixth month postpartum, with additional contact at the end of months 9 and 12 postpartum. At the monthly follow-up visits, the following information was collected: employment status, to determine if the woman had returned to work, including when she started, type and location of work, child care arrangements, and employment hours per day/week; current infant feeding patterns, including breastfeeding frequency (day/night/total) during the last 24 h, longest interval between feedings, and use and number of feeds of supplements; average weekly intercourse rates during the last month; contraceptive use, including introduction of another contraceptive while LAM was still in effect; status of amenorrhea, consisting of bleeding days, spotting days, start/end date of each episode, and whether menses had returned; and knowledge of the three LAM criteria. Participants also were asked about knowledge of referral sources for continued family planning.

At the time of LAM discontinuation, participants were questioned about satisfaction with the method, problems associated with full breastfeeding, and advantages and disadvantages of the method. At the same time, knowledge of the method was assessed by asking the women to recall the criteria for LAM and other essentials for the method to be used properly.

Recruitment and Data Collection

Between January 1994 and May 1995, 1425 women who met the following criteria were screened for the study: amenorrhea, full or nearly full breastfeeding since the birth of the child, intending to resume or having resumed intercourse, able to understand and willing to accept LAM as a family planning method, and no more than 3 months postpartum. Women who wanted to use LAM as their family planning method were recruited from a variety of health care settings, mainly maternities, natural and other family planning clinics, as well as other contact sites. No medical criteria were used to exclude acceptors except sterilization of a member of the couple or absolute contraindication to pregnancy. Recruitment criteria were intended to be broad in order to be similar to actual use of the method in the community setting. All eligible postpartum women were counseled about LAM, as well as other family planning methods, and were invited to participate in the study. Consenting women were interviewed by a counselor, in most cases a nurse who was trained in family planning, lactation counseling, and LAM. Although more than 1400 women were screened for the study, in several centers data were not submitted for those women who were screened but chose not to participate. Of the women who were screened, 643 were eligible and chose to participate in the study.

Of the 643 women who were recruited for the study, 519 (81%) were followed according to the protocol and are used in this analysis. One hundred twenty-four women (19%) were excluded from the analysis for the following reasons: 9 (0.01%) had not resumed sexual activity by month 6 postpartum, 2 (0.003%) withdrew before day 56 postpartum and were replaced, and 6 (0.01%) were excluded for other reasons, such as serious medical problems encountered by the mother or child. Sixty-six (10.3%) discontinued LAM or were lost to follow-up prior to day 56 postpartum; per the protocol, all such losses were replaced. Forty-one cases (6.3%) were not included in the analyses due to improper protocol adherence by the site investigators. Among the 124 excluded cases, only one pregnancy was reported.

Of the 519 women used in this analysis, 28 (5.4%) were lost to follow-up after day 56 postpartum. Twenty-one moved or were not traceable, and 7 were lost for unknown reasons. It may be possible that some of these women subsequently became pregnant, but there is no reason to believe that the rate would be any higher than in the non-relocating population.

Standard question formats developed in collaboration with all sites were translated as necessary into local languages at each site for interviewers and counselors. A take-home diary was given to each participant to record, on a daily basis, any bleeding or spotting, any supplementary feeding, and coital frequency. These diaries were used as a reference source by interviewers at face-to-face monthly follow-up visits or by mothers in answering questions for telephone follow-up. Where face-to-face interviews were

Table 1a. Parameters for life tables: Efficacy of various approaches

Life Table Description	Definitions	Entrance	Outcome Variable	Exit Variable, Earliest of:
1. "Correct use" of LAM: "Method failure"	Exit variables defined by IRH Protocol	Date of birth or Date of intake	Pregnancy	Discontinuation of LAM: Regular Supplements Long intervals Return of menses 6 months Withdrawal (W/D) Lost to follow-up (LTF)
2. "Incorrect use" of LAM or "User failure"	Women who continue to "rely on LAM" after any or all of the criteria no longer applies, until a pregnancy is planned	Date of birth	Unplanned pregnancy	Another method 12 months from DOB LTF or W/D Desire for pregnancy
3. Pregnancy rate during lactational amenorrhea among LAM acceptors	Menses return defined as per protocol for first 6 months, then as "any bleeding"	Date of birth	Pregnancy	Another method Menses resumption LTF or W/D

Table 1b. Parameters for life tables: Menses return

4. Amenorrhea	Menses return defined as per protocol	Date of birth	Menses	LTF or W/D Pregnancy

conducted, the interviewer reviewed the diary with the client and entered the information on follow-up forms. For telephone interviews, the client was asked to bring the diary to the telephone and use it in answering questions.

Data Handling

Data entry and editing were performed on location at each site using the EpiInfo software program prepared by IRH, and the cleaned and edited data were transferred periodically to IRH for further cleaning, queries, and analysis. The data from all sites were pooled, and the final analyses were performed at IRH in Washington, DC. The data analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 6.1.2.[10] Life tables were generated to estimate the monthly probabilities of pregnancy for method failure (correct use), user failure (incorrect use), and under lactational amenorrhea only (Table 1a). The authors chose to use the term "correct use," rather than "perfect use," because the protocol allows for variance from perfect use of the method. Correct LAM use is defined as the adherence to the three LAM criteria through 6 months postpartum, allowing for some monthly deviation from the feeding criteria. Incorrect LAM use is the continued reliance on LAM when any of the three criteria are no longer met. Life table techniques were also used to assess the timing of menses return (Table 1b).

The parameters, definitions, and entrance/exit variables used for each life table are listed in Table 1. It should be noted that, in order to be conservative, all of the life tables include one pregnancy that was forced into the sixth month due to an uncertainty of date of conception, which was estimated to be some time near the beginning of the seventh month.

Concerns have been raised in previous literature[11] as to the coital frequency of the participants in LAM studies. Although a paper by Kazi, Kennedy, et al.[12] clearly demonstrates that the results differ little whether the months without coitus are included or excluded, the data from the current study initially were explored to assess whether the exclusion of cases with no coitus during the month was necessary. When sample life tables were generated excluding months without intercourse, the results did not differ in any significant way from the results presented here. Average monthly coital frequency is shown for each study site and month postpartum in Table 2.

Complementary Studies

The postmarketing and focus group studies[13] were planned to yield findings that might add to the programmatic and clinical understanding of method acceptance and use.

Results

Description of the Study Population

Each site submitted an average of 52 cases, with a range from 47 to 61. The mean maternal age was 27.5 years (range of means = 23.0–31.9), mean parity 2.4

Table 2. Average monthly coital frequency

Site	Month 2	Month 3	Month 4	Month 5	Month 6
Egypt	2.5	2.5	3.3	4.2	3.7
Indonesia	4.0	4.0	4.2	5.2	5.8
Mexico	5.8	6.7	6.0	6.0	6.3
Nigeria, Jos	5.4	6.5	7.4	7.5	6.8
Nigeria, Sagamu	4.3	4.2	4.8	5.0	5.2
Philippines	2.7	4.5	5.1	4.8	4.8
Germany/Italy	3.7	4.4	5.3	6.3	6.8
Sweden	4.9	5.6	5.2	5.7	5.8
United Kingdom	3.2	3.4	4.1	4.1	4.5
United States	3.6	4.7	4.7	4.4	4.2
Total	4.1	4.7	5.0	5.3	5.4

(range of means = 1.9–3.2), mean years of education 10.5 (range of means = 4.1–15.3), and a wide variety of religious backgrounds. The differences between the sites generally are reflective of the ambient parity, maternal age, education, and religion of the specific site or country. The study population is described in depth in a companion article.[9]

LAM Efficacy

The 6-month life table for correct use (see Table 1), estimates the efficacy of LAM from date of birth to be 98.5 ± 0.7%. Sixty-two percent of the participants (n = 324) continued to use LAM in the sixth month postpartum, yielding 2718 woman-months of use. The mean duration of LAM use, for all sites, was greater than 5.0 months. If entry into the life table is at the time of intake, and the exit parameters remain the same, the 6-month efficacy rate is 98.4 ± 0.7%. Table 3 summarizes the 6-month life table of correct use for each site. There are no significant differences among the countries.

"User failure," or incorrect use, is calculated with the assumption that any unplanned pregnancy occurring after any one of the parameters changes, but before the introduction of another family planning method, is attributable to user failure, or incorrect use. The 12-month life table with these assumptions shows the 6-month efficacy to be 98.3 ± 0.6%, with 332 women, or 64%, still included at the end of 6 months (2886 woman-months of use). The 12-month efficacy rate is 92.2 ± 1.8%. There were only 71 women, or about 14%, who had not as yet begun the use of another method by that time. Since these calculations include both correct and incorrect users, they could be considered a proxy for typical use. Table 4 presents the life table results for all parameters of LAM use.

Table 3. Life table analyses by country: Correct use

Site	♀-Months of Use	Number of LAM Pregnancies	Efficacy %	SE %
Egypt	330	1	98.0	2.0
Indonesia	318	1	98.4	1.6
Mexico	249	2	92.5	5.1
Nigeria, Jos	352	0	100	—
Nigeria, Sagamu	245	1	95.8	4.1
Philippines	236	0	100	—
Germany/Italy	237	0	100	—
Sweden	261	0	100	—
United Kingdom	250	0	100	—
United States	240	0	100	—
Total	2718	5	98.5	0.7

Lactational Amenorrhea Efficacy

The efficacy of lactational amenorrhea alone, calculated from among LAM users until another form of family planning was introduced, is 98.0 ± 0.7% at 6 months, and 91.2 ± 2.0% at 12 months. Three hundred ten subjects (59.7%) entered month 7, and 61 women (11.8%) survived to the start of the 13th month postpartum, with 3882 woman-months of use in this analysis. Although this calculation is for lactational amenorrhea alone, it must be noted that all participants initially were trained in and using LAM.

Duration of Amenorrhea

The life table probability of remaining amenorrheic through 6 months postpartum is 72.4 ± 2.0%, and 355 (68.4%) women in this study were amenorrheic until this point. The probability of remaining amenorrheic until the start of the 13th month is 42.1 ± 2.3%, with 192 women (37.1%) reaching this point. Figures 2a and 2b show menses return by country. Menses return is gradual, with more rapid changes appearing after month 6 postpartum in the majority of countries.

Table 4a. Life table results: Efficacy studies

Life Table Parameters	Life Table Outcome: % Efficacy/Effectiveness	% Remaining at End of Interval/ ♀-months in Life Table
1. "Correct use" of LAM: "Method failure"	98.5 ± 0.7% at 6 months	39.5% 2718 ♀-months of use
2. "Incorrect use" of LAM: "User failure"	98.3 ± 0.6% at 6 months	64.0% 2886 ♀-months of use
	92.2 ± 1.8% at 12 months	13.7% 4002 ♀-months of use
3. Lactational amenorrhea efficacy among LAM acceptors	98.0 ± 0.7% at 6 months	59.7% 2828 ♀-months of use
	91.2 ± 2.0% at 12 months	11.8% 3882 ♀-months of use

Table 4b. Life table results: Duration of amenorrhea

4. Amenorrhea	72.4 ± 2.0% at 6 months	68.4% 2883 ♀-months of use
	42.1 ± 2.3% at 12 months	37.1% 4476 ♀-months of use

Duration of LAM Use

Duration of use is affected by changes in any of the three criteria, as well as by the definitions chosen for those criteria. Given the algorithm for LAM use, which strongly suggests the introduction of another family planning method when any of the original three criteria are not met, duration of use could also be defined as time until another method is introduced or until the woman expresses the desire to become pregnant. Figures 3a and 3b illustrate continuation under this definition. Correct users with timely introduction had a mean duration of over 5 months and efficacy of 98.5 ± 0.7%. While it is clear that developing countries have, on the whole, longer durations of use, women in industrialized countries, which are generally less supportive of

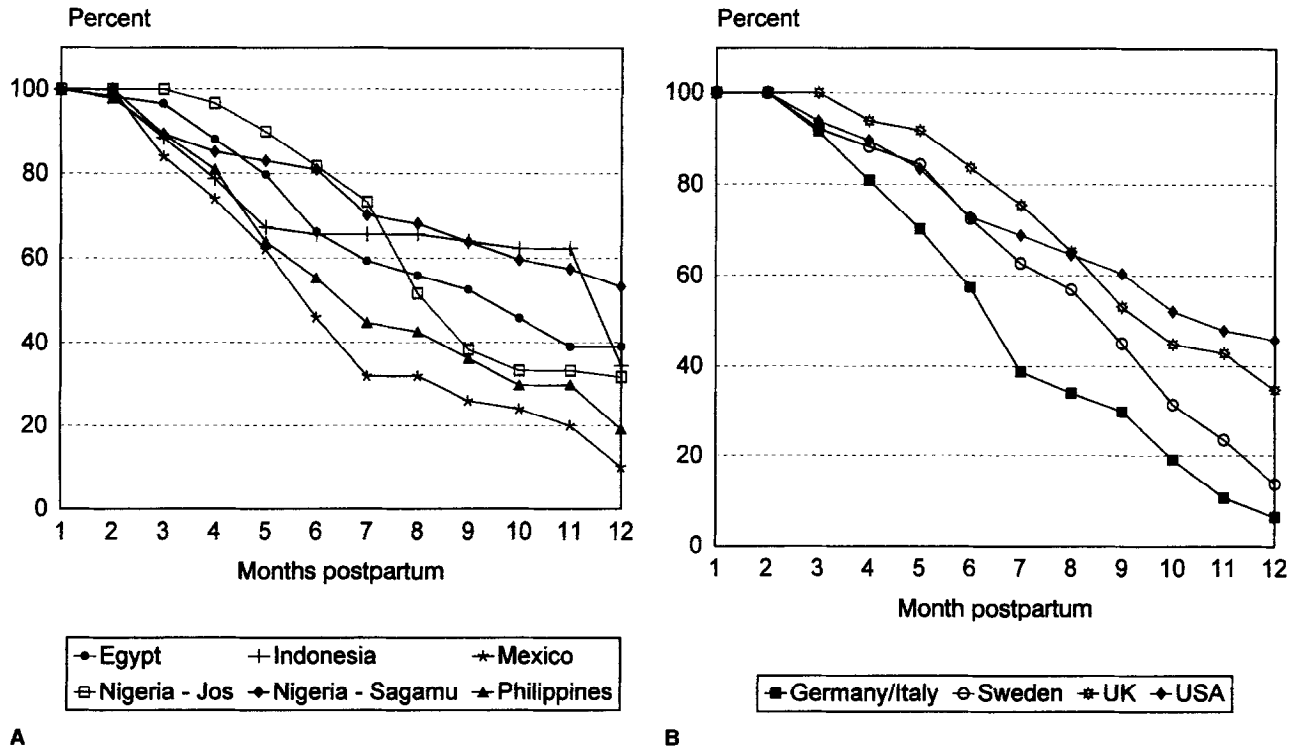

Figure 2. Percent amenorrheic each month, by country.

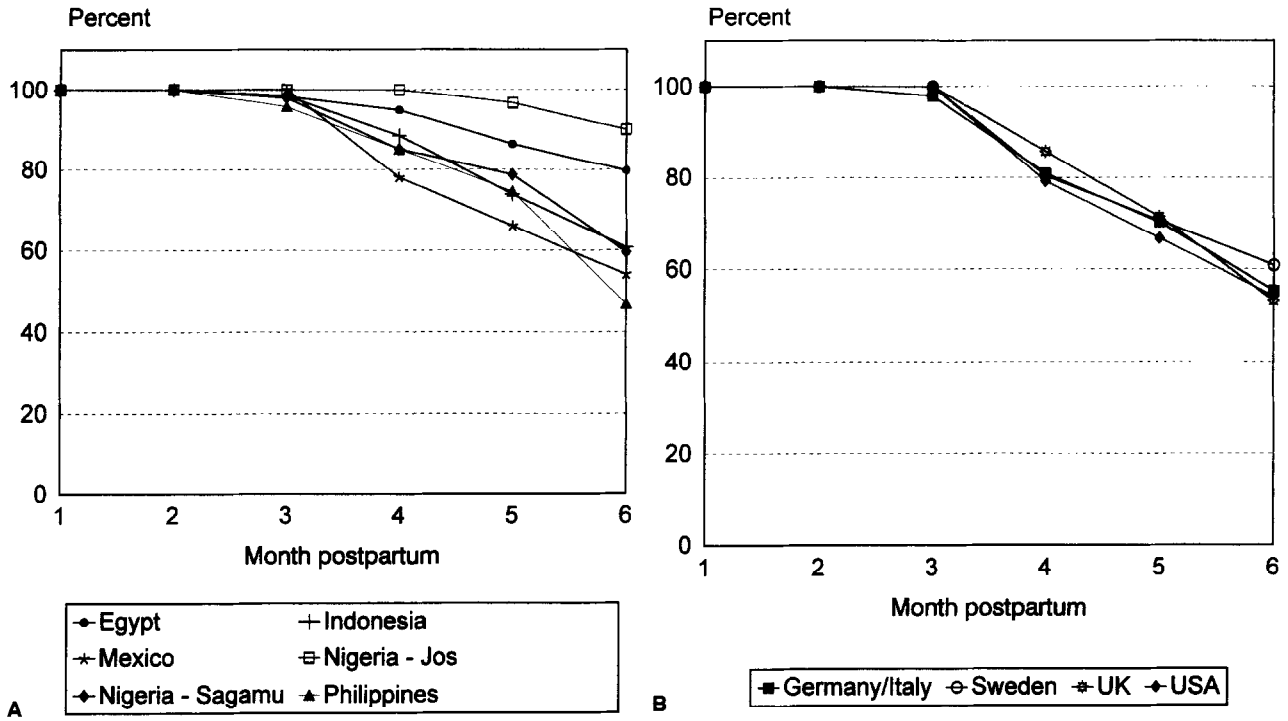

Figure 3. Percent continuing LAM use each month, by country.

breastfeeding, also have a median of use of nearly 6 months.

Discussion

Replicability of High Efficacy

The high efficacy of LAM achieved in a variety of cultural and socio-economic settings, when a woman follows the criteria carefully, should allay concerns that LAM is applicable only in limited situations. Some researchers have argued that LAM is a very dangerous method in that, the moment any parameter changes, there will be a vast increase in pregnancies. While correct usage in this study has an efficacy of 98.5% at 6 months; if no other family planning method is accepted by 12 months postpartum, an efficacy of 92.2% results. It is difficult to compare these figures to other methods reported in the literature, since LAM is used only postpartum, and, by definition, only for 6 months. If doubling the rate found in a 6-month life table is used as a simple proxy for a 12-month life table, one can estimate the annualized correct use unplanned pregnancy rate as 3.0. If we use this same figure derived for correct use and the calculated 12-month rate for incorrect use, the 12-month efficacy could be compared using 3.0 and 7.8 as pregnancy rates, for correct use and all use, respectively. These levels are comparable or better than rates reported for perfect and typical use of spermicides, periodic abstinence, withdrawal, cervical cap, diaphragm, and condom use in the United States.[14] Pill use in some countries yields efficacies very similar to the LAM correct and typical use reported in this paper.[15]

Acceptable and Efficacious in All Settings

The high efficacy of LAM is due, in part, to the fact that few women, contracepting or not, will become pregnant during the first 6–12 weeks postpartum. The strength of LAM is its proven efficacy after 2 months postpartum and its concomitant support for optimal breastfeeding. In addition to the replicability of the high efficacy, the findings underline the utility of this method. Women in the study had high efficacies, long durations of use, and reported improved breastfeeding patterns because of their choice to use LAM. Focus groups and key-informant interviews show that many women welcome their early months postpartum as a period of time when they need not rely on pills or other commodity-based methods that may disrupt breastfeeding. Women report that LAM changes their breastfeeding behaviors[13] and the data support that contention. The 5.3% loss to follow-up is not extraordinary for this type of study, and there is no reason to believe it is masking unplanned pregnancies.

Menses Return

LAM is associated with delayed menses return. Average return of menses for a previous birth was 7 months. However, a comparison with this interval can only be calculated for those women who had early menses return with a previous birth, since this current cohort was only followed for 12 months. Among women who had menses return by 6 months following their previous birth, 64 experienced menses return by 3 months postpartum and 62 during months 4–6 postpartum. Among these same 126 women, with the use of LAM, 14 experienced menses return by month 3 postpartum, 35 during months 4–6 postpartum, and 58 during months 6–12 postpartum; 19 remained amenorrheic beyond the start of month 13 postpartum.

Concomitant with the delay in menses return is the duration of use of the method. Some family planners argue that it is not worthwhile teaching LAM as it can only be used for a few weeks. However, this study's findings demonstrate an average duration of use of 6 months. This relatively long duration of use complements the efficacy of the method. Many women, particularly in developing countries, are choosing to continue to rely on a version of extended LAM with some success.[16]

Full or Nearly Full Breastfeeding

The definition of full or nearly full breastfeeding used in this study is based on scientific evidence[17,18] and allows for a more physiological description of effective feeding patterns than does the WHO definition of "predominantly breastfed" which allows indiscriminant use of non-milk fluids that are known to affect return of fertility.[19] Although this protocol definition was discussed with all subjects, data show frequent deviations from the patterns suggested by IRH. Therefore, even the "correct" users have deviated frequently from correct use.

Efficacy of Lactational Amenorrhea Alone

The data on pregnancy during lactational amenorrhea must be viewed with caution since all women in this study were trained in and accepted LAM breastfeeding patterns, including the necessity of breastfeeding during the night and avoiding long intervals during the day, encouragement of close proximity of mother and child during the night, and discouragement of regular supplemental feedings. Data currently available on pregnancy rates during lactational amenorrhea, in months 6 through 12 postpartum, are derived from populations who initially breastfed intensively.[12,20] Therefore, we cannot derive from these data what the efficacy might be during these same months of lactational amenorrhea among all women who are breastfeeding.

Clinical Application

Acceptance into generalized clinical use has not been universal, due to concerns regarding efficacy, counseling difficulties, and expensive breastfeeding support mechanisms. This study demonstrates that LAM use can be successful in a variety of settings with limited breastfeeding support, and that minor deviations from the standard protocol do not appear to increase pregnancy rates.

Conclusions

This study clearly demonstrates that LAM can be used effectively in a wide range of ethnic and cultural situations and service-delivery settings. This study has addressed issues that previously might have caused hesitation among policy makers in the acceptance of LAM:

- Deviation from specific use of each of the three criteria did not cause a significant upsurge in pregnancy rates.
- There is no demonstrated requirement that large, hospital-based, breastfeeding support programs must be in place before LAM can be used.
- LAM is equally effective in developing and industrialized countries.
- Duration of use is high both in industrialized and developing country settings.
- The method is very flexible and the definitions of the criteria may vary without significant increase in unplanned pregnancies under the three criteria. There is no dramatic increase after the criteria no longer apply (see incorrect use).

The results of this study provide a solid basis for worldwide acceptance of the method. The Lactational Amenorrhea Method is an important addition to family planning options for postpartum women: it confers simultaneous benefits for both mother and child; it is very flexible while maintaining high efficacy; and it is acceptable and well used in a wide variety of settings. LAM also benefits family planning programs by providing a means of integrating reproductive health into family planning, and vice versa.

In sum, analyses presented address many of the previous major concerns regarding LAM. Findings support the potential for full integration of the method, with all of the new clinical and programmatic findings, into all family planning and reproductive health services, as was proposed at the 1995 Bellagio Consensus Meeting.[21] This integration would strengthen both the cafeteria of family plan-

ning services and the practice of more optimal breastfeeding.

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