albuminuric hypertension in late pregnancy. *Br J Obstet Gynaecol* 1977; **84:** 108–11.
11. Crowther CA, Boumeester A, Ashurst H. Home management versus hospitalisation for women with non-proteinuric hypertension in pregnancy. In: Chalmers I, Enkin M, Keirse MJNC, eds. Effective care in pregnancy and childbirth, vol 1. Oxford: Oxford University Press, 1989: 624–32.
12. Crowther CA, Chalmers I. Bed rest and hospitalisation during pregnancy. In: Chalmers I, Enkin M, Keirse MJNC, eds. Effective care in pregnancy and childbirth, vol 1. Oxford: Oxford University Press, 1989: 624–32.
13. Davey D, MacGillivray I. The classification and definition of the hypertensive disorders of pregnancy. *Am J Obstet Gynecol* 1988; **158:** 892–98.
14. Lilford RJ. Classification of hypertensive disorders of pregnancy. *Lancet* 1989; ii: 112–13.
15. Cartwright A. Interviews or postal questionnaires? Comparison of data about women's experiences with maternity services. *Milbank Q* 1988; **66:** 172–89.
16. Cartwright A. Some experiments with factors that might affect the response of mothers to a postal questionnaire. *Stat Med* 1986; **5:** 607–17.
17. Burnell I, McCarthy M, Chamberlain GVP, Hawkins DF, Elbourne D. Patient preference and postnatal hospital stay. *J Obstet Gynaecol* 1982; **3:** 43–47.
18. Dawson AJ, Middlemiss C, Coles EC, Gough NAJ, Jones ME. A randomised study of a domiciliary antenatal care scheme: the effect on hospital admissions. *Br J Obstet Gynaecol* 1989; **96:** 1319–22.

Contraceptive efficacy of lactational amenorrhoea

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Pregnancy is rare among breastfeeding women with lactational amenorrhoea. The lactational amenorrhoea method (LAM) is the informed use of breastfeeding as a contraceptive method by a woman who is still amenorrhoeic, and who is not feeding her baby with supplements, for up to 6 months after delivery. Under these three conditions, LAM users are thought to have 98% protection from pregnancy. It can be difficult, however, to determine when supplementation of the baby's diet begins. We have analysed data from nine studies of the recovery of fertility in breastfeeding women to assess the effectiveness of lactational amenorrhoea alone, irrespective of whether supplements have been introduced, as a fertility regulation method post partum.

Cumulative probabilities of ovulation during lactational amenorrhoea were 30·9 and 67·3 per 100 women at 6 and 12 months, respectively, compared with 27·2 at 6 months when all three criteria of the LAM were met. Cumulative pregnancy rates during lactational amenorrhoea were 2·9 and 5·9 per 100 women at 6 and 12 months, compared with 0·7 at 6 months for the LAM.

The probability of pregnancy during lactational amenorrhoea calculated from these studies is similar to that of other modern contraceptive methods, and it seems reasonable for a woman to rely on lactational amenorrhoea without regard to whether she is fully or partly breastfeeding. So that amenorrhoea and fertility suppression can be maintained, counselling about good breastfeeding and weaning practices remains important.

Lancet 1992; **339**: 227–30.

Introduction

Extended periods of breastfeeding can have a substantial effect on population fertility rates,[1] but breastfeeding is widely regarded as being unreliable for personal contraception. These two seemingly contradictory truths have been reconciled in the Bellagio consensus statement on the use of breastfeeding as a family planning method, which concluded that amenorrhoeic women who are fully or nearly fully breastfeeding are 98% protected from pregnancy for 6 months after delivery.[2,3] The lactational amenorrhoea method (LAM) has been developed as a way for individual women to apply this advice for family planning.[4]

The Bellagio guidelines suggest that natural contraceptive protection is conferred only before the introduction of supplements to the baby's diet. Supplementation is thought to reduce the baby's need to suckle, which reduces the neuroendocrine stimulus at the breast and hastens the return to fertility. Thus, supplementation is often associated with the return of menses and the recovery of fertility.[5,6] However, the introduction of supplements does not automatically mean a return to fertility, since supplements do not, at least initially, always replace or substitute for breastfeeding. Few women solely breastfeed their babies for a long time, so most women may think that they cannot use the LAM.[7] Since post-partum fertility is influenced more strongly by lactational amenorrhoea than by supplementation, interest has emerged in quantifying the degree of contraceptive protection associated with lactational amenorrhoea irrespective of whether supplements have been introduced.

Only 3–10% of women are likely to conceive during lactational amenorrhoea[8–10] and time post partum is positively associated with the risk of pregnancy.[11,12] We have calculated the risk of ovulation and pregnancy among breastfeeding women from four continents irrespective of whether there was amenorrhoea or supplemention of the infant's diet; when there was amenorrhoea but irrespective of supplementation of the infant's diet; and when women were fully breastfeeding and amenorrhoeic. The sample size is larger than in other studies[11,12] and women from both developed and emerging countries are included, so there is a wide variety of infant-feeding patterns.

Methods

Data were collected from nine prospective studies of lactating women by Family Health International in Mexico,[13] Thailand,[14] Egypt,[15] Pakistan,[16] rural[17] and urban[18] Philippines, and Canada, Australia, and England (unpublished; copies available from the authors). Six studies included ovarian hormone assays of serum or

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TABLE I—LIFE-TABLE RATES OF OVULATION, ADEQUATE OVULATION, AND PREGNANCY AMONG BREASTFEEDING WOMEN 6 MO AND 12 MO POST PARTUM

—	Life-table rate per 100 women (95% CI)	
	6 mo	12 mo
First ovulation (n = 156)		
Overall	39·0 (31·2, 46·8)	79·7 (72·8, 86·7)
During amenorrhoea	30·9 (22·8, 38·9)	67·3 (56·7, 78·0)
During amenorrhorea and before supplementation	27·2 (15·8, 38·5)	..*
First adequate ovulation (n = 74)		
Overall	24·5 (14·4, 34·6)	69·5 (58·0, 81·0)
During amenorrhoea	13·8 (4·8, 22·6)	37·5 (22·6, 52 4)
During amenorrhoea and before supplementation	13·7 (−0·1, 27·6)	..*
Pregnancy (n = 346)		
Overall	7·6 (4·4, 11·0)	17·2 (11·8, 22·6)
During amenorrhoea	2·9 (0·6, 5·2)	5·9 (1·2, 10·6)
During amenorrhoea and before supplementation	0·7 (−0·6, 2·0)	..*

95% CI = 95% confidence interval
*All infants received supplements before 12 mo

TABLE II—CUMULATIVE PROBABILITY OF PREGNANCY DURING LACTATIONAL AMENORRHOEA BY TIME POST PARTUM

—	Probability of pregnancy (%)			
	Australia (n = 101)*	Chile (n = 256)	FHI pooled† (n = 74)	FHI pooled (n = 346)
3 mo	..	0·9	0·4	0·4
6 mo	1·7	0·9	3·5	2·9
9 mo	..	7·2	9·4	2·9
12 mo	7·0	12·2	9·4	5·9
24 mo	13·0	..	..	..

*Estimated rate for breastfeeding women having unprotected intercourse only during amenorrhoea and adopting effective contraceptive methods after resumption of menses.
†Estimated cumulative probability of ovulation in cycles with at least minimum adequate luteinisation multiplied by 25% (probability of conception during a single normal cycle[24]).

urine to detect ovulation. A colorimetric method[19] was used in Mexico, and radioimmunoassay in Thailand and Egypt, to measure pregnanediol glucuronide in early-morning urine samples collected once a week as part of the World Health Organisation matched reagents programme. The studies in Canada, Australia, and England used an enzyme immunoassay to measure pregnanediol glucuronide[20] in samples collected daily or 3 times a week. The criteria used to define a possible ovulation in these studies are generous; most ovulations during breastfeeding are followed by short or insufficient luteal phases, and pregnancy under these conditions is rare. Furthermore, the probability of a short or insufficient luteal phase is greatest for the first ovulation—ie, the one that occurs before the first menses after pregnancy.[21] Frequent sample collection would improve detection of ovulation, but the additional ovulations thus identified would have had very short luteal phases. All hormone assays in the Canadian, Australian, and English studies were done by the same method and in one laboratory and there is enough information to show whether a given ovulatory event met minimum criteria for luteal phase length (10 days) and progesterone production (9·0 μg/24 h pregnanediol glucuronide).

Hormone data were not collected in the studies in Pakistan and the Philippines, but the duration of lactational amenorrhoea is known. Data on subsequent pregnancy were collected in all nine studies.

Life-table rates for time to first ovulation were calculated for 156 breastfeeding women from the six centres with ovarian hormone data, with a woman being censored from the life-table when she stopped breastfeeding or was lost to follow-up. Life-table rates for time to first ovulation during lactational amenorrhoea were then calculated for the same data set, with a woman being censored when she stopped breastfeeding, was lost to follow-up, or experienced her first vaginal bleeding episode (excluding post-partum bleeding). Finally, life-table rates for time to first ovulation during full breastfeeding and lactational amenorrhoea were calculated, with a woman being censored at the end of breastfeeding, if she was lost to follow-up, experienced a vaginal bleeding episode, or began to give her infant supplements regularly. The same rates were then calculated for a subset of these women (74 women in Canada, Australia, and England) for the time to the first adequate ovulation. Further analyses calculated the observed gross life-table pregnancy rates under the same three sets of conditions for all breastfeeding women in six centres who did not practise another form of contraception (Mexico, Thailand, Egypt, Pakistan, Manila, and Dumaguete), but the studies in Canada, Australia, and England had to be excluded because their participants were actively practising natural family-planning methods. The resulting data set comprised 346 women. Censoring was as above.

Net life-table discontinuation rates (considering pregnancy, supplementation, and bleeding as competing reasons for the discontinuation of the method) were calculated for the LAM (ie, during amenorrhoea while fully breastfeeding for up to 6 months) and for lactational amenorrhoea alone, again with the censoring methods as above.

The duration of lactational amenorrhoea was defined as the time between delivery and the onset of any vaginal bleeding or spotting (other than post-partum bleeding) whether or not the woman thought that it was like her pre-pregnancy menses. The date of first supplementation was defined as the first day of daily supplementation with any non-breastmilk foods. All survival analyses used either SAS Proc Lifetest[22] or Lifetab.[23] Fewer than 10% of the women in the studies were lost to follow-up.

Results

Lactational amenorrhoea seems to provide protection from ovulation and pregnancy; the protection was generally greater for women who were fully breastfeeding (table I). The cumulative rates of ovulation were higher when bleeding status was ignored than when only amenorrhoeic women were considered, but when supplementation and bleeding were both used as criteria for censoring, the rate of ovulation fell only slightly. All the women gave supplements before 12 months and were censored.

For ovulations considered adequate to support a pregnancy, the rates were lower but, because of the smaller sample size in this group, the 95% confidence intervals are quite large.

The 6-month and 12-month overall life-table rates of pregnancy during breastfeeding were 7·6 and 17·2 per 100 women, respectively. The pregnancy rates were only 2·9 and 5·9 per 100 women, respectively, when amenorrhoea was required. When the supplementation variable was included as a censor point, the pregnancy rate was only 0·7 per 100 women at 6 months, although nearly all the women were censored in the first 5 months.

There are clear differences between the rates of ovulation and of pregnancy during lactational amenorrhoea. Ovulation is a prerequisite for pregnancy but the probability of conception during a single normal cycle is only 25%.[24] Thus, even when progesterone production was adequate, the estimated pregnancy rates during amenorrhoea would be very low (3·5 and 9·4 per 100 women at 6 and 12 months, respectively).

The probabilities of pregnancy are similar for studies in Australia[12] and Chile[11] and the pooled studies we have assessed (table II), with the exception of the 12-month pregnancy rate observed in Chile, where few breastfeeding women remain amenorrhoeic for a full year.

TABLE III—NET DISCONTINUATION RATES FOR LAM AND FOR LACTATIONAL AMENORRHOEA ALONE

—	Discontinuation rate per 100 women (95% CI)			
	3 mo	6 mo	9 mo	12 mo
LAM				
Pregnancy	0	0·3 (−0·3, 0·9)	..	..
Supplementation	33·4 (28·4, 38·5)	71·1 (65·8, 76·3)	..	..
Bleeding	10·5 (7·3, 13·8)	20·5 (16·2, 24·8)	..	..
6 mo post partum	..	8·2 (6·4, 9·9)	..	..
Aggregate net discontinuation	43·9 (38·7, 49·2)	100	..	..
Total discontinuations*	45·1 (39·8, 50·3)	100	..	..
Lactational amenorrhoea alone				
Pregnancy	0·3 (−0·3, 0·9)	1·9 (0·4, 3·5)	1·9 (0·4, 3·5)	2·8 (0·9, 4·7)
Bleeding	20·8 (16·4, 25·2)	49·8 (44·1, 55·4)	65·5 (59·9, 71·1)	77·4 (72·2, 82·6)
Aggregate net discontinuation	21·1 (16·7, 25·6)	51·7 (46·1, 57·3)	67·4 (62·0, 72·8)	80·1 (75·3, 85·0)
Total discontinuations*	27·1 (22·5, 31·9)	59·8 (54·7, 65·0)	75·7 (71·2, 80·3)	87·3 (83·8, 90·8)

*Includes weaning and loss to follow-up

Net life-table discontinuation rates for the LAM and for lactational amenorrhoea alone are shown in table III. All the women discontinued use of the LAM by 6 months post partum, since that is one of the criteria of the method. However, only 8% of the women received the full 6 months of LAM protection. Among women who used the LAM according to the Bellagio guidelines, 0·3% discontinued use at 6 months owing to pregnancy, 20·5% because of bleeding, and 71·1% because they had introduced supplements (table III).

Removal of the criterion of exclusive breastfeeding reduced the aggregate discontinuation rate while only slightly increasing the percentage of discontinuations due to pregnancy. At 6 months, 49·8% of women had discontinued use because of bleeding and 1·9% because of pregnancy. At 12 months, 77·4% had had bleeding and 2·8% were pregnant. Only 13% of women were still amenorrhoeic at 12 months (table III).

Discussion

The natural contraceptive effect of lactational amenorrhoea is substantial, and in settings as different as Bangkok and Birmingham women experienced 3% and 6% cumulative probabilities of pregnancy by 6 and 12 months, respectively, post partum. This degree of protection is greater than or similar to that associated with typical first-year use of modern contraceptive methods in the USA.[25]

The LAM, as it is currently formulated, is characterised by low pregnancy rates and high discontinuation rates. In the pregnancy analysis only 47 of 346 women were still amenorrhoeic at 12 months. To remain protected from pregnancy, the other women would have had to adopt another contraceptive method from the time of their first vaginal bleed. LAM, with or without supplementation taken into account, cannot be depended on by every woman to provide the complete amount of birth spacing she may desire, and it is not meant to be a replacement for any other method. It can, however, be very useful for timing the introduction of other contraceptive methods, especially those which women may be reluctant to use post partum.

Counselling about good breastfeeding practices remains important and needs to cover all aspects of breastfeeding behaviour. A breastfeeding mother relying on lactational amenorrhoea for pregnancy protection needs to know which kinds of feeding practices can lead to a reduction in suckling stimulus and put her at increased risk of pregnancy. No woman included in our analysis was consciously trying to use the LAM. Good breastfeeding education can improve breastfeeding practices and lengthen the duration of lactational amenorrhoea,[18] and even better results may be possible among women deliberately using lactational amenorrhoea as their post-partum contraceptive method.

The original Bellagio guideline that women must be fully (or nearly fully) breastfeeding seems to be the least important feature of the LAM, and in many settings it could be dispensed with. This change could make the LAM easier for women to learn and to apply, thus extending its use. It remains important that women attempting to use the LAM acquire good breastfeeding skills and start another method of contraception immediately after menstruation resumes.

This study was supported by Family Health International through a cooperative agreement with United States Agency for International Development. We thank Dr Malcolm Potts, Dr Nancy Williamson, Dr Roberto Rivera, Dr Soledad Diaz, Dr Alan McNeilly, Dr Roger Short, Dr Suzanne Parenteau-Carreau, and Ms Rosalie Dominik for helpful review of the paper.

REFERENCES

1. Bongaarts J. The proximate determinants of natural marital fertility. In: Bulatao R, Lee D, eds. Determinants of fertility in developing countries. New York: Academic Press, 1983 103–38.
2. Family Health International. Breastfeeding as a family planning method. *Lancet* 1988; ii: 1204–05.
3. Kennedy KI, Rivera R, McNeilly AS. Consensus statement on the use of breastfeeding as a family planning method. *Contraception* 1989; **39:** 477–96.
4. Labbock M, Lovich R, Rodriquez-Garcia R, Schaefer LA. The lactational amenorrhea method: example of a teaching unit. In: Rodriquez-Garcia R, Schaefer LA, Yunes J, eds. Lactational education for health professionals. Washington, DC: Pan American Health Organization, 1990: 70–96.
5. Howie PW, McNeilly AS, Houston MJ, Cook A, Boyle H. Fertility after childbirth: postpartum ovulation and menstruation in bottle and breastfeeding mothers. *Clin Endocrinol* 1982; **17:** 323–32.
6. Gray RH, Campbell OM, Apelo R, et al. Risk of ovulation during lactation. *Lancet* 1990; **335:** 25–29.
7. Trussell J, Santow G. Is the Bellagio consensus statement on the use of contraception sound public health policy? *Health Trans Rev* 1991; **1:** 105–07.
8. Van Ginneken JK. Prolonged breastfeeding as a birth spacing method. *Stud Fam Plann* 1974; **5:** 201–06.
9. Rolland R. Bibliography (with review) on contraceptive effects of breastfeeding. *Bibliog Reprod* 1976; **28:** 1–4: 93.
10. Simpson-Hebert M, Huffman SL. The contraceptive effect of breastfeeding. *Stud Fam Plann* 1981; **12:** 125–33.
11. Diaz S, Aravena R, Cardenes H, et al. Contraceptive efficacy of breastfeeding in urban Chilean women. *Contraception* 1991; **43:** 335–52.
12. Short RV, Lewis PR, Renfree MB, Shaw G. Contraceptive effects of extended lactational amenorrhoea: beyond the Bellagio Consensus. *Lancet* 1991; **337:** 715–17.
13. Rivera R, Kennedy KI, Ortiz E, Barrera M, Bhiwandiwala PP. Breast-feeding and the return to ovulation in Durango, Mexico. *Fertil Steril* 1988; **49:** 780–87.
14. Israngkura B, Kennedy KI, Leelapatana B, Cohen HS. Breastfeeding

and return to ovulation in Bangkok. *Int J Gynecol Obstet* 1989; **30:** 335–42.
15. Shaaban MM, Kennedy KI, Sayed GH, Ghaneimah SA, Abdel-aleem AM. The recovery of fertility during breast-feeding in Assiut, Egypt. *J Biosoc Sci* 1990; **22:** 19–32.
16. Khan T, Kennedy KI, Kazi A, Steiner M. A study of breastfeeding and the return of menses and pregnancy in Karachi, Pakistan. *Contraception* 1989; **40:** 365–76.
17. Savina G, Kennedy K. The effect of a breastfeeding education program on lactational amenorrhoea in the Philippines. *Stud Fam Plann* 1989; **20:** 203–14.
18. Benitez I, De la Cruz J, Suplido A, Oblepias V, Kennedy K, Visness C. Extending lactational amenorrhoea in Manila: a successful breastfeeding education program. *J Biosoc Sci* (in press).
19. Goldzieher JW, Nakamura Y. A clinical method for the determination of urinary pregnanediol and pregnanetriol. *Acta Endocrinol* 1962; **41:** 371.
20. Brown JB, Blackwell LF, Cos RI, Holmes J, Smith MA. Chemical and homogeneous enzyme immunoassay methods for the measurement of oestrogens and pregnanediol and their glucuronides in urine. *Prog Biol Chem Res* 1988; **285:** 119–38.
21. Howie PW, McNeilly AS, Houston MJ, Cook A, Boyle H. Fertility after childbirth: adequacy of postpartum luteal phases. *Clin Endocrinol* 1982; **17:** 609–15.
22. SAS Institute, Inc. SAS user's guide: statistics, version 5 edition. Cary, NC: SAS Institute, Inc: 1985.
23. Family Health International: LIFETAB: A program for lifetable analysis of clinical trials. Durham, NC: Family Health International, 1989.
24. Wood JW. Fecundity and natural fertility in humans. *Rev Reprod Biol* 1989; **11:** 61–109.
25. Trussell J, Hatcher RA, Cates W, Stewart FH, Kost K. Contraceptive failure in the United States: an update. *Stud Fam Plann* 1990; **21:** 51–54.

VIEWPOINT

Funding research and development in the NHS

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Introduction

In the new strategy for National Health Service (NHS) research[1,2] the emphasis will be on research relating to the effectiveness of clinical practice, the dispersal and use of existing knowledge, and the contribution of medical interventions to the health status of individuals and the population. NHS regions will play an important part in implementing the plan and will be held accountable for it. Regional health authorities will be required to prepare, publish, finance, and implement their own research and development plans.[2] To permit the development of the NHS research and development (R & D) programme, a national expenditure target has been set. This target, of 1·5% of the NHS budget, will be achieved over 5 years by harnessing R & D resources now in use throughout the service and by seeking new funds through the public expenditure process.

The new R & D plan is to be welcomed, but it also has to be recognised that the NHS is in the midst of the most wide-ranging reform since its inception. In particular, the separation of the roles of purchaser and provider and the establishment of contracts for services in an "internal market" are likely to have a profound effect on all NHS activities, including R & D. Concerns have already been raised, by those charities sponsoring clinical research, that the reforms may make NHS authorities wary about covering the costs of care for patients enrolled in research studies.[3-5] This has the implication that funds originally allocated for research could be diverted to providing treatment. Furthermore, regions faced with an expenditure target for research could redefine activities so as to ensure that the target is met—eg, activities such as medical audit and quality assurance that should be part of routine NHS practice might be redefined as an R & D activity.

Defining R & D

In the context of the changes in NHS funding, it is important to make a distinction between "research" and "development". Research activities are usually associated with the acquisition of new knowledge of broad relevance beyond the setting in which the research took place. Development activities, on the other hand, are usually to do with the application of existing knowledge and sometimes have specific relevance to the setting in which they are undertaken. The distinction between research and development is important since, under the new contracting arrangements, one can see a stronger case for a purchaser to pay for development than for research.

Impact of NHS reforms on R & D

The major impact of the reforms will arise from the specification of contracts. Purchasers will question whether the higher costs of some providers implicitly include an R & D component. In turn, providers will take a harder look at all their staff contracts, including joint appointments, since manpower represents the largest component of NHS expenditure. Also, the closer examination of NHS treatment technologies, by both purchasers and providers, is likely to identify practices that contribute to research knowledge rather than patient outcome. All these changes will be assisted by improvements in NHS financial information systems, which are necessary for operating the internal market.

One of the most difficult issues will be that of selecting the criteria that determine whether or not the purchaser pays for the clinical care of patients enrolled in research protocols. Peckham[1] pointed to the anomaly whereby a health authority refused to pay for care when a clinician wanted to allocate patients to either normal-dose or low-dose regimens of a given drug in a randomised clinical trial. Paradoxically,

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