# Forum

## Is the Bellagio consensus statement on the use of contraception sound public-health policy?

**James Trussell and Gigi Santow**

*Office of Population Research, Princeton University, 21 Prospect Avenue, Princeton, NJ 08544–2091, USA.*
*Health Transition Centre, NCEPH, ANU.*

Conventional public health wisdom suggests that breastfeeding has an important fertility-reducing effect for a *population* but is an unreliable contraceptive for an individual woman or couple (Hatcher et al. 1989, 1990). The primary reason is that ovulation can precede the post-partum return of menses, so there is no reliable signal of the return of fecundity and hence risk of pregnancy. Nevertheless, Kennedy, Rivera and McNeilly (1989:479) report that the consensus of a panel of experts (Bellagio Consensus Conference on Lactational Infertility, held in August 1988) is that for women fully breastfeeding *(i.e.* the child's diet is not supplemented[1]), 'breastfeeding provides more than 98 per cent protection from pregnancy in the first six months.' The evidence supporting this statement is impressively documented[2]. The real question is the implication of this fact for public heath policy.

The Bellagio consensus statement concludes that lactational amenorrhoea is an appropriate temporary method of fertility regulation, and that at six months post partum, or at the time when either menses return or the infant's diet of breastmilk is supplemented (if either of these events happens before the infant's six-month birthday), 'consideration must be given to other means of family planning' (Kennedy et al. 1989:479). Furthermore, 'the use of the natural infertility of breastfeeding followed by the use of another family planning method, rather than the simultaneous use of both, may serve to maximize the interbirth interval' (Kennedy et al. 1989:478). There is no mention of any possible role for post partum IUD insertion or post-partum sterilization. There is no evidence presented to justify nor even any discussion to motivate the link between the principal finding and the policy recommendations. Presumably, however, the reasoning underlying these policy conclusions is that redundant protection against conception is wasteful when individual or state resources are scarce and perhaps even counterproductive if contraceptive discontinuation rates are high.

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1 Actually, very little of the evidence pertains to women who *exclusively* breastfeed their children, excluding even water. Instead, in most studies it is known or presumed that full breastfeeding means that 'small amounts of other non-breastmilk, caloric foods (ranging in quantity from a few swallows to just less than one feeding per day) have been given' [Kennedy et al. 1989:486].

2 However, there is no mention of the confounding effect of post-partum sexual abstinence on the observed contraceptive effect of breastfeeding, and the three studies cited as evidence in which the dependent variable was pregnancy (in the remaining ten studies, the dependent variable was ovulation) do not mention the frequency of intercourse or even the proportion of women who had experienced intercourse.

Nevertheless, this reasoning ignores the cost of pregnancies that will result while 'considering' the alternatives.[3] Only one of the events precipitating the use of contraception - the infant's six-month birthday - is foreseeable with certainty. Supplementation of the diet may be unexpected or may not be planned far enough ahead to allow time to obtain a contraceptive or even may occur without the mother's knowledge, and the return of menses, which is not under the control of the woman, may also find her unprepared. Consequently, we conclude that the best public health strategy would be to promote (l) the *provision* (by programs) or *acquisition* (by women) of contraception (including progestin-only pills) within six weeks post partum even for fully breastfeeding women; and (2) an educational message about the timing of initiation of use (including obtaining progestin-only injectibles and implants) that minimizes the likelihood of an unprotected period, even at the cost of some redundant protection. We suspect that in many instances practical realities - including the difficulty of communicating understandably such a complex rule as to start use at the earliest of the infant's six-month birthday, return of menses or supplementation - will dictate the adoption of the simple message that use should start no later than six to eight weeks post partum.

Use of oral contraceptives containing oestrogen appears adversely to affect breastfeeding performance (McCann et al. 1984) and should be discouraged. However, given the evidence that women who do view breastfeeding and oral contraception as incompatible often choose oral contraception, and even are encouraged to do so by clinicians (Millman 1985; Potter, Mojarro & Nunez 1987), the challenge for family planning clinicians is to promote breastfeeding *and* the use of an appropriate contraceptive method (Hatcher et al. 1989, 1990). Breastfeeding and contraception are not physiologically incompatible, although in many societies they might be perceived as incompatible because a lactating woman would not be expected to be sexually active. Nevertheless, most women do resume sexual relations while breastfeeding. Again the public health challenge is to avoid presenting breastfeeding and contraception as mutually exclusive alternatives and instead to promote them both by emphasizing their health benefits for mothers and children.

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[3] The use of the word 'consider' in this context is unfortunate, and the statement surely cannot be taken to mean what it literally says. The proper time to consider contraception is well before it is needed, not afterwards. The real questions for the women or couple are when to *obtain* contraception and when to *use* it, not when to *consider* its use; for the family planning program, the challenge is educating women about these matters.

# Rejoinder to Trussell and Santow

**Kathy I. Kennedy[1], Roberto Rivera, Alan S. McNeilly, Nancy E. Williamson, James Shelton, Paul F.A. van Look, Anna Glasier, James B. Brown, Barbara Gross, Anna M. Flynn, D. Malcolm Potts, Roger V. Short, Soledad Diaz**

*[1]Family Health International, PO Box 13950, Research Triangle Park, NC 27709, USA.*

Trussell and Santow offer some interesting and important perspectives. The issues they raise regarding the Bellagio consensus appear to be that:

(1) the consensus ignores the conventional wisdom put forth by Hatcher et al. (1990) that breastfeeding is an unreliable contraceptive for individual women;
(2) no role of postpartum IUD insertion and sterilization is mentioned in the report;
(3) no evidence or discussion links the data presented with the recommendations put forth;
(4) the cost of pregnancies that occur between the end of protection from lactational amenorrhoea and the beginning of protection by a different method is not considered;
(5) the commencement of supplementation is an unwieldy aspect of the guidelines for use of lactational amenorrhoea; and
(6) it may be more practical to initiate use of another method at 6-8 weeks post partum than according to the Bellagio guidelines.

These items are addressed here, respectively.

(1) The misperception that the conditions 'breastfeeding' and 'lactational amenorrhoea' are synonymous is pervasive, even among reproductive health care providers and researchers. The statement 'breastfeeding provides more than 98 per cent protection from pregnancy in the first six months' has been taken out of context. The consensus clearly reads: 'When these two conditions are fulfilled, breastfeeding provides more than 98 per cent protection from pregnancy' (Family Health International 1989; Kennedy, Rivera & McNeilly 1989). The two conditions mentioned in the sentence immediately preceding, are: during full or nearly full breastfeeding and during lactational amenorrhoea. Another popular misperception is that a lactating woman who ovulates is fertile. Indeed, ovulation can occur during lactational amenorrhoea in the first six months post partum, but only rarely do the ovulation and luteal phase have normal characteristics. Thus, despite having ovulated, only the rare woman will conceive during lactational amenorrhoea, especially in the first half year post partum. We agree that 'breastfeeding' is an unreliable contraceptive for the individual woman because 'breastfeeding' could mean as little as a token feed per day. 'Lactational amenorrhoea' on the other hand is quite reliable in preventing pregnancy, especially in the first half-year.

(2) Indeed there is no mention of a possible role of post-partum IUDs or sterilization. Neither does the consensus document discuss prenatal vasectomy, post-partum insertion of Norplant, spermicidally lubricated condoms, nor any other contraceptive technology. The intention of the Bellagio meeting was not to address the use of contraceptives by breastfeeding women. The consensus documents establish the validity of the guidelines for using lactational amenorrhoea as a contraceptive, and suggest that the guidelines be used under these conditions: '...when there are no alternatives available or if a couple chooses not to use other family planning methods; or...to delay the introduction of other family planning methods'. The latter is clarified further, in recognition that current methods are imperfect and often used imperfectly:

where there are problems with family planning availability, acceptability or continuation (especially during breastfeeding), the use of the natural infertility of breastfeeding followed by the use of another family planning method, rather than the simultaneous employment of both, may serve to maximize the interbirth interval.

Thus, the consensus statement does put forth the scientific basis of the informed use of lactational amenorrhoea, and suggests some programmatic applications. It *does not* offer a litany of the existing post-partum family planning alternatives, nor does it attempt to offer strategies or policies for lactating (or other post-partum) women to whom it does not apply, i.e., those who make other family planning choices.

(3) The first two conclusions reported by the Bellagio group are more policy-oriented, while the last two follow directly from the data presented (Kennedy et al. 1989). The policy-oriented conclusions were published because they were actual conclusions of the consensus group, and not because they resulted from policy analysis. The policy-oriented conclusions are that the consensus guidelines should be regarded as a potential method in all maternal and child health programs and that post-partum women should be offered the choice of using the guidelines and be provided with counselling about how to do this correctly. These are based simply on the concepts of informed choice and quality of care. It is sound policy that women should be allowed to choose a method for themselves, and the consensus group did espouse this. The Lactational Amenorrhoea Method (LAM), i.e., the informed use of the Bellagio guidelines for contraception, is potentially available to all post-partum women, and if women make LAM their informed choice, there is no reason to believe that it would be misused more or less than any other user-driven method (Labbok et al. 1990). Also, family planning professionals have operated for years under the assumption that the greater the number of available methods, the greater the chance that people will like one and use it. LAM is simply a new item in the cafeteria. Recently, attention to the quality of family planning services has been given serious attention (Bruce 1989). It is speculated that services would be improved if the personal needs and desires of the individual client were considered. If providers recognize that these needs and desires change over the reproductive career, then contraceptive use and satisfaction would improve. The basic assumption that post-partum women are highly motivated to use contraception has been challenged recently because of the lack of any data to support it (Winikoff & Mensch 1991). Indeed, the opposite possibility should be carefully considered in the case of lactating post-partum women. Their current low use of family planning may reflect their desire *not* to use the available methods. Quality of care principles suggest that providers should be ready to teach LAM to those women who choose it, and to deliver complementary methods in a manner that suits the client.

(4) There was no consideration to the gap between LAM use and uptake of another method because, like Trussell and Santow, the consensus participants felt that there was no reason for a gap to exist. User-dependent methods (e.g. pills, barriers, hormone-releasing vaginal ring) can be given as early as the day of delivery with instructions about when to start using them. Barriers in particular might be a good option to provide temporary protection (e.g. in case of early menses or supplementation) until the mother can get to the family planning clinic if she eventually wants a method that requires an intervention by family planning personnel (e.g. injectables).

(5) The information available at the time of the Bellagio meeting (1988) unequivocally established that full breastfeeding provided the level of protection given in the guidelines. Some of the Bellagio participants suggested that full breastfeeding was not a condition *sine qua non*, and that some supplementation did not affect the contraceptive efficacy of lactational amenorrhoea. Indeed, there are two studies in 1991 which show that lactational amenorrhoea alone, without the fully breastfeeding caveat, provides such high levels of protection that we can move ‘beyond Bellagio’ to the use of

lactational amenorrhoea alone for at least six months post partum (Diaz et al. 1991; Short et al. 1991). However, it was agreed at Bellagio, and rightly so, that our conclusions should be based on the scientific facts then available, and not on suggestions. Supplementation is indeed the weakest aspect of LAM. The 1991 studies suggest that in some populations, the full breastfeeding requirement of LAM may be unnecessary.

(6) Practical and programmatic issues are very important, and in many places, such as the USA, the six week postpartum checkup may be a key time and circumstance. Nowhere does the consensus advocate changing systems that work, except to *add* LAM to the contraceptive cafeteria, for the reasons mentioned above. The addition of LAM to the contraceptive cafeteria is meant to improve the number of options, users, and satisfaction. Like the recent introduction of Norplant to the field, it is not intended to deflect users away from other methods. We have already mentioned programmatic conditions in which LAM is thought to apply best. We are finding an additional practical aspect of LAM in current prospective studies of the method: comprehensive family planning counselling is being offered in study clinics towards the goal of informed choice. The women who are choosing LAM are those who have never used contraception previously. While they are learning the method and being followed up with their babies, they are developing rapport with family planning workers where previously there was none. These workers are fully prepared to help the women initiate use of another method should they desire it. In other words, LAM is providing an entrŽe to family planning services to heretofore unreached women. It is conceivable that this LAM approach will do more to improve contraceptive coverage than a blanket policy to initiate contraception at 6 weeks in these clinics serving women who breastfeed well and are reluctant to contracept.

We concur entirely that women who want to contracept and use LAM should be prepared with a method in hand or clear access to one well before their protection from LAM expires, plus the information that they need about when to start using the method. We also concur that breastfeeding and contraception are physiologically compatible. It is unclear why readers of the consensus would view it as a presentation of mutually exclusive activities, breastfeeding versus contraception. Various consensus participants have published titles such as ‘Breastfeeding and family planning programs: a vital complementarity’ (Labbok 1989) and ‘Lactation and contraception’ (Kennedy 1990).

Although Hatcher et al. (1990) admit the validity of the Bellagio consensus, they caution clinicians repeatedly not to try and use LAM in the USA. This is understandable since the status of breastfeeding in the US is atrocious. However, LAM may yield high returns in Zimbabwe, for example, where the average duration of amenorrhoea is about 12 months, where breastfeeding is still quite popular and where oral contraception is one of the most commonly used methods. In 1988, 29 per cent of the total contraceptive use after the last birth in Zimbabwe overlapped with post-partum amenorrhoea. The total fertility rate is greater than would be expected given the contraceptive prevalence rate because of this double protection (Adamchak & Mbizvo 1990). As global scientists, the Bellagio participants suspected that such scenarios existed, and felt hard-pressed to suggest that every program should provide a commodity and counselling by a given time, such as six weeks post partum. Rather, to quote the consensus report:

Guidelines specific to a particular country or population for using breastfeeding as a postpartum family planning method can be developed based on this consensus. Local infant feeding practices, the average duration of amenorrhea and the ongoing changes in women's status and health practices should be considered in adapting these general guidelines (Kennedy et al.:485).

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# Rejoinder to Trussell and Santow

**Miriam Labbok**

*Georgetown University Medical Center, 3900 Reservoir Road NW, Washington DC 20007-2197, USA.*

Drs Trussell and Santow raise a very interesting question in their commentary: did the group of researchers, program planners and technical donors at the Bellagio Consensus Meeting create 'sound' public policy? Their challenge to this is based partly on the fact that the conclusions fly in the face of conventional wisdom and other published guidance and partly on the fact that not all alternative approaches are fully explored in the Bellagio Consensus Statement. I am very sympathetic to their concern that research findings are not automatically translatable into program policy. I would like to respond to their comments as one of the researchers present throughout the Bellagio meeting, but also as the Director of the Breastfeeding Division of the Institute for International Studies in Natural Family Planning (IISNFP) in the Department of Obstetrics and Gynecology at Georgetown and as a family planning program planner and evaluator with experience in more than a dozen countries.

The road from research to public policy is always difficult and often long and rocky. How is public health policy developed? There were research findings in hand eight to ten years before the Bellagio meeting upon which a method could have been, and was developed and published (Labbok 1983). However, what does it take to get the clinical and financial support to test a new method? Since the Bellagio Consensus Meeting, the Institute has been able to launch prospective studies of the Lactational Amenorrhea Method (LAM) (Labbok et al. 1990), which were derived from the consensus statement, and have been able to obtain donor agency approval for these efforts. Before Bellagio, we were unable to find organizations willing to fund or programs willing to test these guidelines.

Policy statements must be carefully considered and consensus meetings provide an excellent forum for thinking through all ramifications of a suggested approach. At Bellagio, a group of interested and well-informed researchers, program planners, and technical donors discussed possible alternative approaches in great detail and were able to contribute pros and cons from personal experience as well as from review of current guidance. The policy options offered by Trussell and Santow are balanced, but do not encourage care providers to take into account women's rights to informed choice.

Women may wish to use the natural fertility effects of breastfeeding (Nag 1990) and have the right to complete and accurate information on this highly efficacious method. If options offered by Trussell and Santow had been discussed by a group of researchers and family planning providers, I am sure the issue of informed choice would have been raised as well as other implementation issues.

Secondly, how does one change 'conventional wisdom'? Conventional wisdom tends to lag far behind known scientific findings, especially in clinical areas of an intimate nature. In my field of fertility regulation, we find that conventional wisdom regarding breastfeeding and time of ovulation is often dated and frequently incorrect. In the field of family planning, the conventional wisdom lags as well; for example, clinicians still receive a Physicians Desk Reference that does not differentiate between the side effects of combined and progestagen-only contraceptives. In order to change conventional wisdom, alternative, and scientifically sound 'wisdom' must be published and tested.

Third, the Bellagio Consensus Statement primarily offers a public health approach for the appropriate timing of family planning introduction. Many alternatives were discussed in order to achieve consensus. Those of us who have taken this consensus statement, and from it, have created a

method of family planning (LAM), offer this method not as an alternative to family planning but as yet another in the cafeteria of methods and one that is vitally linked to timely introduction of a complementary method. No one suggested that this is intended to replace family planning. It may be used in sequence with other methods, since the method itself notes that a complementary family planning method is necessary to achieve adequate spacing (Figure 1) (Labbok et al 1990).

The LAM method as illustrated here, derived from Bellagio discussions, is very conservative, extremely effective, and a relatively easy concept to teach. The Institute-supported study conducted by Dr Alfredo Perez (1990a,b) in Chile resulted in a 0.4 per cent pregnancy rate by six-month life table. Programmatically, we recommend that a woman have her complementary method in hand or readily accessible, i.e. that she be given a temporary method as well at the time she accepts LAM. Even if she were to delay the initiation of the complementary method and even if she is meeting only two of the three criteria, her risk of pregnancy remains very low. Whereas support for breastfeeding may have many facets, LAM itself is not complex. Materials have been developed and tested for teaching the method to illiterate women who seem to find the concepts familiar and easy.

Finally, policy considerations must go beyond research and explore how a new element will impact on related issues. The LAM method is a door opener for those who would not be using family planning otherwise. It reduces redundant protection, an element that can have profound impact programmatically. Our studies have shown that introduction to LAM increases total family planning coverage at six months post partum (Perez 1990 a,b) and that it is an acceptable method of family planning. Other ongoing studies may illustrate that it increases referral for family planning among women who had not spaced their children previously (IISNFP 1990). LAM also gives family planning providers a methodology for breastfeeding support (Labbok et al. 1990); simply telling family planners to ‘promote BF’ is not enough.

Our studies, and those being carried out by FHI and the Population Council, probably would not exist if it had not been for the Consensus Meeting. The Consensus Statement drew attention to the potential public health policy application of the research findings and gave a basis for the programmatic exploration. It laid the groundwork for the construction of the pathway from research to public health policy which is now under way.

We appreciate the opportunity to respond to this editorial and hope to continue to share our field research findings on the use and acceptability of LAM and the resulting policy changes with your readership in the future. Thank you for providing a new forum for this discussion.

**Figure 1**
**Use of Lactational Amenorrhea Method (LAM) for child spacing during the first 6 months post partum[1]**

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