



**HEALTH SERVICES RESEARCH NEEDS AND APPROPRIATE
 METHODOLOGIES IN BREAST-FEEDING AND FERTILITY**

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PREFACE

As part of the World Health Organization's activities in the area of infant and young child nutrition and feeding, a global programme of research and programme policy promotion on breast-feeding and fertility has been developed. This programme, which is funded through the World Health Organization Regular Budget and the United Nations Fund for Population Activities (UNFPA), has been set-up in order to:

- . enhance family planning programme policies and service capabilities, as an integral part of MCH programmes, especially in high risk populations, by building on natural child spacing associated with prolonged breast-feeding; promoting the timely introduction of appropriate contraceptive methods; and encouraging sound mother and child nutrition;
- . disseminate information on, and promote the concept of, lactation amenorrhoea as an important component of child spacing;
- . collaborate with national authorities in defining locally the effectiveness of prolonged, frequent and complete breast-feeding on child spacing, including the duration of lactation amenorrhoea; and in determining the appropriate timing for introduction of specific contraceptive methods;
- . identify and promote innovative health care and social support measures that facilitate the effective combination of breast-feeding and contraceptive practices;
- . support and coordinate research on the impact of different patterns of weaning on breast-feeding performance, including the volume and composition of milk, the duration of breast-feeding, and postpartum amenorrhoea.

As part of this programme, this Consultative Group was convened to identify health services research needs in this area and describe methodologies that might be developed in order to meet these needs and, in so doing, enhance the promotion of breast-feeding and its role in birth spacing.

I. INTRODUCTION

While the scientific community has, for some time now, recognized the importance of the nutritional and immunologic contribution made by breast-feeding to infant survival, awareness about the contraceptive role of breast-feeding is much more recent. It has only been during the past decade that clear evidence has emerged about the impact of certain breast-feeding practices on post-partum ovulation. Yet from a population point of view the effectiveness of breast-feeding is impressive. In many societies its child spacing impact is as strong as that of other currently known methods, including oral agents, IUDs, etc. In countries where, for whatever reason, alternative methods are unavailable, unacceptable, or likely to be incorrectly used, breast-feeding is a vital resource in delaying a too early new pregnancy.

It has also become increasingly clear that by enhancing spacing between births, breast-feeding provides health benefits to infants and young children well beyond those simply resulting from the nutritional and anti-infective properties of breast milk. It permits better care of the index child and a better recuperation of the mother who, in most cases, is the principal child caretaker. The promotion of breast-feeding by both health care providers and family planning workers can therefore have multiple benefits.

Because breast-feeding promotion as a family planning strategy has received attention only recently, however, many issues still remain unresolved. This report specifically deals with health services research matters, but in Annex I it also outlines a series of basic physiologic and epidemiologic research needs.

Several types of health services research are called for. In many countries, for example, reliable data are currently unavailable on breast-feeding patterns and the associated duration of postpartum infertility. Policy makers invariably need such national data in order to develop programmes that are appropriate to their own local circumstances. By extension, the knowledge and attitudes of mothers, fathers, health care and family planning providers, and the general public, on the role of breast-feeding as a fertility regulating method needs to be assessed before meaningful large-scale interventions can be implemented.

Health services research is similarly needed in order to determine what are the most feasible and optimal interventions for increasing the prevalence and duration of breast-feeding and improving its contribution to child spacing. For instance, having health care providers discuss the maternal and child health benefits of breast-feeding with pregnant women may result in an enhancement of the duration of birth spacing even if family planning *per se* is never mentioned. Especially for women who do not have access to, or do not plan to use, other forms of contraception during the birth interval, any promotion of breast-feeding that in turn extends the duration of postpartum infertility will enhance mother and child health, both directly and indirectly. Studies that demonstrate how breast-feeding can best be promoted and what particular breast-feeding practices increase the duration of lactation anovulation (e.g. frequency of suckling) are thus essential.

On the other hand, for breast-feeding women who do plan to use other forms of contraception during the postpartum period, there is a need to determine when such contraceptive use should be initiated and which methods are most appropriate given the possible effect of some contraceptives on breast milk production. In population groups where contraceptive continuation rates are low, the overlap between postpartum amenorrhoea and contraceptive use also needs to be minimized in a way that rationalizes biological and complementary contraceptive mechanisms.

The nature and level of such studies will vary considerably, depending on the country, its socio-cultural practices, particularly those influencing child-bearing and rearing, and its health care infrastructure. For example, while for some countries getting more mothers to initiate breast-feeding may itself be a major challenge, for others the main issue may be prolonging exclusive breast-feeding. Statistics show that the percentage of institutional deliveries can vary from country to country and range between 5 and 100 per cent; intervention strategies to promote breast-feeding may be different for settings where the majority of births take place in institutions versus settings where a majority of births occur in the home. The nature and level of health services research may also depend on other child-bearing and child-rearing practices, such as who assists deliveries at home; who provides health care and family planning services; where infants are taken for treatment of illness; and what the level of contact is between health workers and mothers during the pre-, peri-, and postnatal periods.

Health services research offers a potentially more productive vehicle for bringing about national modifications in health care practices than does either the more traditional policy analysis, or more basic laboratory and epidemiologic research. Involving local staff in research on strategies to improve the effectiveness of breast-feeding promotion, for example, provides them with a vital opportunity to participate in a systematic review and evaluation of current practices and their impact. Moreover, it often confers status on participants while, at the same time, reducing their resistance to the adoption of resulting recommendations. Such research can be an equally important way of identifying priorities for continuing education of health care and family planning providers. Finally, the production and use of local data for decision making increases the capacity of health services staff themselves to identify and resolve problems affecting the coverage, quality and cost of their services.

The objectives of this Consultation on Health Services Research Needs and Appropriate Methodologies in Breast-feeding and Fertility were therefore:

- (1) to identify outstanding health services research needs pertinent to the promotion and implementation of integrated breast-feeding and fertility regulating activities; and
- (2) to outline key characteristics of study designs responding to some of these needs.

The report first discusses research needs for policy formation; it examines each of these from both a diagnostic (assessment) and therapeutic (intervention) component. Needs assessment research is discussed with reference to descriptive studies of breast-feeding patterns; family planning practices; and knowledge and attitudes of the public or of health care providers with regard to breast-feeding, birth spacing, and breast-feeding as a birth spacing method.

The following section outlines specific interventions that address the general public and recipients of health care and family planning services, the providers of these services, and the institutions that deal with them during the prenatal, perinatal, and later postpartum periods. The report then goes on to discuss appropriate methodologies for both diagnostic and intervention studies. Finally, the concluding section attempts to synthesize the recommendations of the Consultation and indicates the need for combinations of interventions, as well as their respective costs to be considered.

II. HEALTH SERVICES RESEARCH PRIORITIES

A. Diagnostic Studies/Needs Assessment

A diagnostic needs assessment should be the first step in planning intervention studies. Needs assessment should be goal-oriented, i.e. directed at obtaining baseline data that can be used to choose and implement the interventions (discussed in the following section); it should also be focused, rather than global, with a view to determining what types of interventions are feasible in particular settings. The kinds of questions to be addressed in such needs assessments include:

- What are the prevailing breast-feeding practices (initiation rates; day- and night-time suckling frequencies; duration of exclusive and partial breast-feeding; weaning methods) in given cultural areas? What are the predominant historical and socio-economic reasons for these practices? What is the corresponding duration of postpartum amenorrhoea?
- Are newborns routinely fed colostrum? If not, why not? What additional or alternative foods or liquids are given during the pre-lacteal period? Are mothers who bottle-feed at this stage those who go on to terminate breast-feeding within the first one or two months? What are the beliefs and practical factors underlying these practices?
- What are the perceptions of mothers, fathers, and other family members about breast milk versus other foods and about the appropriateness and timing of them? What are the reasons for these perceptions and how do these relate to birth spacing and family planning?
- Do health care providers (doctors, paramedical staff, village practitioners, village health workers, traditional birth attendants, etc.) and family planning workers know that breast-feeding can help delay a new pregnancy? If not, what type of information, education and training is required to overcome this knowledge gap?
- To what extent are mothers and providers informed about the contraceptive effect of:
 - . day- and night-time frequency of breast-feeding episodes?
 - . the duration of exclusive breast-feeding?
 - . the appropriate timing and method of introducing supplemental feeding?
- How are physicians, other health care providers and family planning workers best influenced (e.g. mass media, textbooks, journals, conferences) with respect to new information?
- Where births occur in hospitals or other health care settings, what are the prevailing practices concerning early maternal-infant contact, rooming-in, frequent on-demand feeding, and supplementation? What are the reasons for these practices and what is their impact?
- How are infant formulas and other baby foods marketed and advertised, both to consumers and health care providers? What are the current regulations and codes affecting government pricing policy and company practices?

- What are the prevailing breast-feeding practices of working mothers? In rural areas do these vary seasonally with climatic conditions and agricultural activities? If so, what is the effect on suckling patterns and subsequent fertility? What institutional arrangements exist for breast-feeding employees (maternity leave, job protection, flexible hours, day care, nursing breaks)? What is the position of local workers' associations and unions with regard to breast-feeding and what are their reasons?

B. Intervention Studies

Diagnostic needs assessment will usually serve to identify these areas where interventions are required. Research on specific interventions designed to influence the promotion of breast-feeding, either alone or as part of family planning strategies, are discussed below. These interventions have been categorized according to whether they set out to influence:

- (a) the community as a whole, including the general public and users (generally mothers) of health care or family planning services;
- (b) providers of these services; and
- (c) institutions.

1. The Community

(a) General public

As a target group, it may consist of the following important subgroups: politicians and civil authorities, women's support groups, mothers' clubs, and local opinion leaders (such as businessmen, teachers and clergy). Depending on the results obtained from needs assessments, the priority target for intervention may be the public at large, or one or more specific subgroups.

There are two basic ways of influencing general public opinion: mass media and personal communication. Mass media refers here to newspapers, radio, or visual media (e.g. posters, films, television). Personal communication may include face-to-face contacts with community leaders or groups where the case is made for the support of, for example, breast-feeding. Both these types of intervention strategies can be attempted and compared. Although its costs may be high, the potential impact of such an approach, particularly in areas where the health care structure is weak, may be warranted. Where such interventions are coordinated with health educators, community health workers, and local marketing and advertising personnel, the impact will be even further enhanced.

(b) Users of services

- Prenatal period

In some settings it may be relevant to change the health care content of prenatal visits by adding new information and ideas concerning the use of breast-feeding as a child spacing method, and assessing the impact of this new information on the subsequent duration of exclusive lactation and the

timing of onset of menses. A simple experimental design to determine the efficacy of different information approaches might include:

- (i) an experimental group for whom birth spacing is discussed only with respect to "modern" contraceptive methods;
- (ii) an experimental group, for whom exclusive breast-feeding is presented with a view to improving birth spacing, as well as infant health, and with instructions to return for more information on other spacing methods after delivery; and
- (iii) a control group, with whom breast-feeding is discussed only in terms of its benefits to infant health.

The design and implementation of interventions such as these should always be coordinated with health educators and the health staff normally responsible for the design and provision of both prenatal and family planning services.

- Perinatal period

In order to maximize its potential impact, research should ideally focus on how to improve the practices of the health care staff, as well as the policies and practices of hospitals and birthing centres, rather than on the attitudes and practices of the recipient. In addition, it might be worthwhile to include interventions designed to test the impact of providing information to the mother on techniques for dealing with problems she might encounter during the later postpartum period (e.g. engorgement, perceived milk insufficiency). The experimental group could also be given information on whom to contact for assistance, should specific problems arise, and what steps can be taken to prevent those types of problems from emerging.

- Postpartum period

Two possible interventions are considered for this period. The first consists of including in family planning programmes explicit instructions on the use of breast-feeding as a first step in birth spacing. The "treatment" conditions might include making available nothing but modern contraceptives; nothing but breast-feeding; or a combined, integrated approach.

A second type of intervention needed in order to examine how best to promote the extended duration of breast-feeding would be to test the relative impact of the community health worker or one of the community support groups (for example, breast-feeding mothers' groups, La Leche League affiliates, or women's groups) on the duration of exclusive breast-feeding, the onset of menses, and the use of other contraceptive methods postpartum.

2. Service Providers

In designing interventions to extend breast-feeding promotion within the health care system, either for health or for family planning purposes, it is useful to consider the following categories of providers:

- (a) physicians (including ward, centre, or clinic directors);
- (b) non-physicians (including a variety of nursing, auxiliary and community health personnel); and
- (c) family planning workers.

Interventions involving physicians will typically involve the organization of activities designed to change either prevailing attitudes or service norms that run contrary to the effective promotion of breast-feeding. It should be recognized at the outset that physicians are authority figures and thus potential change agents within the services. In many countries, physicians are in key positions at all levels of the service provision infrastructure. It is therefore important to demonstrate to physicians the advantages of early mother/child contact, suckling frequencies, etc., so that they can go on to influence others, such as health planners, Ob/Gyn professors in medical faculties, and those whose influence throughout the health care system is likely to be of greater and longer-term scope. In general, interventions should address issues on which the physician is most likely to have an immediate impact, such as rooming-in arrangements, service practices, and other activities that fall directly under his line of authority or service. Other interventions should be aimed at training modalities (using well-known figures) that enhance physician knowledge on breast-feeding and fertility, and the communication of that knowledge to mothers on ways of changing their breast-feeding behaviour.

Another concern relating to physician attitudes and practices involves the feeding of low-birth-weight (LBW) infants. Because the LBW infant who is formula-fed is at high risk, there is a need for research on how to promote breast-feeding among LBW infants. Studies could test the effect on the infant of continued hospitalization of mothers of LBW infants in order to promote on-demand feeding, in comparison to the current practice of discharging mothers, with infants being breast-fed only a few times a day, if at all. The impact and cost-effectiveness of these routines on growth, morbidity and mortality of LBW infants needs to be assessed, as well as the effect on duration of breast-feeding and postpartum amenorrhoea.

Interventions concerning non-physician health care personnel will vary from country to country, and from service to service; typically they will consist of setting up different types of training. In this respect, research is needed to test the cost-effectiveness of alternative models for training courses that attempt to teach the advantages of breast-feeding (and of breast-feeding as a method of family planning). It would be important to know, for example, whether auxiliary nurse-midwives (ANMs) can, after re-training, be deployed to do prenatal home visiting to identify pregnant women interested in breast-feeding as a child spacing method. They would be expected to organize courses for these women, followed by a pre-determined postnatal visit schedule that would encourage frequent on-demand breast-feeding, discourage early supplements, and provide advice concerning action to be taken once menses return.

The variety of service situations that obtain in different countries, the enormous growth of primary health care systems and workers, the customs pertaining to use of services (for example, of going to a health centre for services, or of being visited by centre personnel) must all be taken into consideration in the design of these interventions.

Family planning workers (where these are different from health care personnel), could also be trained to counsel mothers postpartum on the use of breast-feeding as a family planning method, preferably integrated with the provision of more

traditional methods. One research strategy might compare the contraceptive behaviour of women contacted by workers with, and without, such training.

3. Institutions

- Prenatal period

In the prenatal period, the main "institutions" that tend to impact on subsequent breast-feeding are the infant formula and baby food companies on one side, and governmental laws, codes and regulations, on the other. Pregnant women may be exposed to advertisements in the mass media, by posters in clinics, hospitals, or doctors' offices, or by mail from companies with access to their names and addresses. Government policies, however, should by now be restricting such forms of advertising. Major interventions in this area are unlikely to be forthcoming from manufacturers; they will probably require legislation or regulations concerning company promotional activities and pricing policy. In order to best evaluate their efficacy, these interventions should ideally be introduced in selected regions or communities, with relevant similar "status quo" areas included as controls. Generally, however, this type of approach may not be possible, and a before-and-after comparison for the entire country may be the only feasible alternative.

- Perinatal period

A number of perinatal practices and policies could be similarly subjected to experimental intervention. These include "routine" supplementation practices, either instead of, or in addition to, colostrum and early lacteal feedings; early physical contact between mothers and their infants; rooming-in; and high-frequency, on-demand feeding schedules around-the-clock. These are all hypothesized to impact on duration of breast-feeding, infant health, and duration of lactation amenorrhoea.

Manufacturer advertising-versus-government regulation issues also pertain to the immediate postpartum period just as to the perinatal period, although here the focus may be more on the distribution of infant formula, baby foods, "informational booklets", and other materials to breast-feeding mothers. Test interventions designed to change prevailing practices may, as in the prenatal period, involve the application of government regulations in selected communities or regions. In settings where births commonly occur in hospitals or other health care institutions, however, the institutions themselves may decide to change their internal procedures. Where the distribution of samples or other promotional materials is standard practice, the assessment might include randomizing individual women, different well-baby nurseries within the same institution, or different institutions within the same geographic setting; promotional materials would be withheld or not withheld according to the randomization.

- Postnatal period

Formula and baby food marketing practices can also have an impact on mothers and health care providers during the later postpartum period. As in the prenatal and perinatal periods, specific changes in marketing practices (preferably in selected communities) would provide an experimental intervention that could provide valuable information concerning how to extend the duration of exclusive breast-feeding and influence subsequent fertility.

Other key "institutions" that impact on the mother-infant dyad during the postnatal period concern the workplace. A mother's return to work can and often does constitute a threat to continued exclusive breast-feeding unless institutional protection and support are provided. Interventions involving employers include job guarantees, longer maternity leaves, flexible working hours, provision of nearby day care, and "nursing breaks" during the workday. An assessment of such interventions could be made among selected industries and their effects gauged using indicators such as duration of exclusive breast-feeding and amenorrhoea among women working in "intervention" and "non-intervention" employment, as well as impact on infant morbidity, growth and development. Women's groups, unions and other labour organizations should all be consulted in planning and implementing interventions such as these.

Family planning agencies are yet another example of institutions that should be the focus of postpartum interventions; agency policies concerning breast-feeding promotion and its integration with more traditional contraceptive methods could be selectively changed (in specific clinics or centres, with those unchanged serving as controls) or globally (using the admittedly weaker before-and-after type of research design).

III RESEARCH METHODOLOGIES

Diagnostic studies usually call for cross-sectional sample surveys. In such surveys, a representative sample of subjects (using an appropriate sampling procedure) is selected and interviewed; group interviews sometimes provide data not reliably obtainable from individual subjects. If individual or group interviews involve sensitive issues (e.g. sexual practices during the lactation period) or require detailed information about a particular social/behavioural practice, an anthropological approach using participant observation and in-depth case studies may provide better insights. The selection of one (or more) approach will depend on the availability of time and resources, as well as the subject of inquiry. However, the combination of a cross-sectional sample survey and in-depth case studies is perhaps the best way to assess not only existing knowledge, attitudes and practices, but also the reasons for them.

Where intervention studies are concerned, an experimental design is preferable; experimental interventions are implemented by investigators, rather than by the study subjects or the health care system. Many of the issues concerning research design and statistical analysis will be similar for various types of interventions; these will be discussed together, with indications of what specific variations may pertain to particular types of interventions. The design issues relate to the study subjects, the study interventions, and the study outcomes. These are followed by a brief overview of relevant issues in the statistical analysis of intervention studies of this type.

Studies

Characterization of study subjects should begin by a full and detailed description of the larger community of which the study subjects are presumably representative. This is of crucial importance later in interpreting the results of the study, and particularly in knowing the extent to which results can be generalized to other settings (political, geographic, level of development). Investigators should also state how many subjects in all were approached for participation in the study, as well as the proportion of those who accepted; an attempt should be made to compare participants

and non-participants with regard to characteristics that may be relevant to differences in breast-feeding behaviour and subsequent fertility. Finally, and perhaps most importantly, groups of study subjects receiving different interventions or treatments should always be compared with respect to potential confounding variables (variables with independent effects on breast-feeding behaviour or fertility). This will help ensure that study groups are similar in all respects other than the study intervention itself (as will normally be the case if the study groups are, in fact, well chosen) or, alternatively, will indicate which variables require control in the statistical analysis.

Interventions

Attention needs to be given to the design of the intervention and the way it will be implemented; this should always be done in close consultation with local policy makers and the health care and family planning workers who are likely to be involved or ultimately affected. Because breast-feeding practices appear to be quite labile and because so many of the factors influencing breast-feeding practices are also subject to temporal change, the use of historical controls (i.e. before-and-after comparisons) should be avoided where possible; moreover, one or more concurrent control groups should be studied. Where this is not possible, however, researchers should go on to use the admittedly weaker before-and-after observational (i.e. non-experimental) design to examine the effects of interventions, even if they were not themselves involved in the design and implementation of those interventions.

All else being equal, the strongest design for demonstrating causality will be a randomized clinical trial in which individual mothers are randomly assigned to participate in different interventions. Steps should be taken to avoid the contamination of treatment that occurs if women assigned to different interventions interact with one another; assignment according to health care or family planning provider, rather than the individual mother, may sometimes be preferable. Even so, contact between mothers who see providers randomized to different interventions can sometimes result in contamination; treatment assignment by group (ward, hospital, or community) may thus be required. Because of the possibility of within-group dependence among individuals within given groups, it is often preferable to include a number of groups receiving each intervention and then to use the group as the unit of statistical analysis.

Where it is not feasible to study a sufficiently large number of groups, the use of staggered intervention of treatments among a smaller number of groups (the same intervention introduced at different periods of time in different groups, with the other groups serving as concurrent controls) can also be helpful. Finally, when only two groups are studied, pre-intervention equivalence of the two groups should be ensured by comparing the study groups prior to the intervention with respect to factors related both to the planned intervention and breast-feeding and fertility. Crossing control groups over to receive the intervention at a later period of time provides a further check on the effect of intervention.

The purpose of all these manoeuvres is to ensure that any differences that arise between groups after an intervention can be attributed to the intervention and not to group differences.

A final issue which is relevant, regardless of the individual or group basis of treatment assignment, concerns how to ensure that study interventions are the only treatment differences that occur; in this case care-givers not directly involved in the intervention should be unaware of the intervention received by study participants. If not, they may provide "special treatment" to those receiving a new intervention, and may confound the effect of the study intervention.

Outcomes

Measurement of outcomes always requires careful planning. Prospective data collection (outcomes are measured as they occur and are thus not dependent on maternal recall) is always to be preferred in intervention studies of this type. Standardized and discreet surveillance procedures should be used, i.e. breast-feeding practices, return of menses, and occurrence of pregnancy should be assessed at regular and equivalent intervals in the study groups. Interviewers (those measuring the outcome) should be "blinded" to the intervention status of the mothers they are interviewing. Similarly, where it is ethically defensible, study subjects should not be aware that they are being studied or that they have received a special intervention. Where this is not ethical, keeping subjects "blind" to the research hypothesis will help protect against biased reporting of the outcome by mothers who receive the study intervention.

Statistical issues

In planning of intervention trials, investigators need to specify what difference in outcomes that they consider to be clinically worth detecting; sample sizes will have to be adequate to detect these differences with high probability. (Sample size calculations will need to take account of whether individuals or groups are the units of statistical analysis).

Because most of the intervention studies outlined in this report will involve large numbers of subjects and well-chosen control groups, data analysis will usually be quite straightforward. Simple comparisons of means and rates, cross-tabulations, and histograms or pie charts, will usually be sufficient for a rapid, preliminary report. If later in-depth analysis reveals confounding differences between study groups, appropriate multivariate statistical techniques may be required for determination of cause-and-effect influences in a more definitive way. Because many of the outcomes discussed here (including duration of exclusive, unsupplemented breast-feeding; the return of first menses; and the occurrence of pregnancy) are time-dependent, simple life-table techniques (survival analysis) should be used to maximize the information contained in the data. In those few studies in which confounding differences exist between treatment groups, life-table analyses will need to include appropriate multivariate adjustment.

IV CONCLUSION

Diagnostic needs assessment will dictate which type of intervention should receive priority; thus, no universal recommendation can be made to prioritize the above-mentioned interventions. In general, however, where the proportion of births occurring in hospitals is high, and duration of exclusive breast-feeding is low, interventions affecting hospital practice and training of health and family planning workers on management and promotion of breast-feeding are likely to be of major importance.

It should be understood that many intervention strategies are most suitable if they operate in conjunction with each other. While such research may be unable to delineate in detail which factors are most able to promote breast-feeding individually, it is most important to test methodologies that are practical and easy to implement.

In many cases, interventions can be combined and tested together. For example, prenatal education for pregnant mothers on breast-feeding management can be combined with various training methodologies for health workers. As long as cost data are also

collected, the effectiveness of each type of intervention "package" can be examined in the light of the associated costs.

Estimating the costs of modifications of health service practice is just as important as measuring their health benefits. When health resources are limited or when policy makers have to choose between investments in services in competing areas (for example, breast-feeding promotion versus neonatal intensive care), consideration will be given to the relative cost-effectiveness of the various options. Costs to consider include the following: staff training compensation and benefits; transportation; education and communication for the public; overhead; and administration. In the case of breast-feeding promotion, most costs will be associated with the continuing education of providers and information support for breast-feeding mothers. However, important savings will be achieved through reduced purchases of breast-milk substitutes, improved infant and child health, and prevention of (unwanted) pregnancies.

To increase the impact of research findings on policy decisions, it is essential that policy makers and programme managers be involved in the research from its inception. Wherever possible, an attempt should be made to use the health and family planning workers in the collection and analysis of data. As emphasized in the Introduction, involvement by policy makers and practitioners invariably improves the likelihood of successful interventions.

Similarly, timely dissemination of the findings is crucial for optimizing the utility of any research study. In addition to ultimate publication in standard scientific journals, some of the approaches include:

- (1) rapid presentation of the results directly to policy makers and programme managers;
- (2) mass distribution (including health care and family planning workers) of a brief summary report of the findings written in simple language; and
- (3) preparation of clearly written articles in popular magazines and newspapers.

* * * * *

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ANNEX I

BASIC PHYSIOLOGIC AND EPIDEMIOLOGIC RESEARCH NEEDS

- (1) How many suckling episodes are required during the day and night to ensure the contraceptive effect of breast-feeding? (Data collected as part of the intervention studies outlined in Section II (B) will help answer this question).
- (2) Are there markers (sooner) of ovulation other than the return of menses to indicate that breast-feeding is no longer adequate as a contraceptive?
- (3) How do newly developed hormonal or other contraceptive techniques (e.g. vaginal rings, hormonal implants) influence breast-milk output or composition?
- (4) Does manual or mechanical breast-pumping contribute to the anovulatory effect of breast-feeding?
- (5) For working women, how long can expressed breast milk be safely stored at varying ambient temperatures?

ANNEX II

THE ROLE OF HEALTH SERVICES RESEARCH IN THE IMPLEMENTATION OF
BREAST-FEEDING AS A FAMILY PLANNING METHOD

by

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BACKGROUND

Many Governments in developing countries are becoming increasingly concerned about the rapid population growth currently being experienced. Even in those countries which have pursued successful family planning programmes, the proportion of fertile couples practising family planning has tended to plateau at around 30% or less. In most countries the resources that would be needed to attain even small additional reductions in population growth rates using present methods would be enormous. Thus, much hope is being placed on new breakthroughs in contraceptive technology and family planning.

In spite of this concern, however, breast-feeding, which traditionally has proved the cheapest, most widely available, and most culturally acceptable birth spacing method is being allowed to erode. Indeed, many family planning programmes, far from supporting and having a positive impact on breast-feeding, are counselling women that they should not rely on breast-feeding as a method for spacing births.

Several reasons probably exist for the neglect, and in some instances rejection, of breast-feeding as a child spacing mechanism by family planning programmes. Certainly at an underlying level there is the difficulty a technologically oriented society has in coming to terms with traditional, "soft" approaches to solving problems, such as the use of breast-feeding as a contraceptive. Traditional knowledge regarding the effectiveness of this method was dismissed as "an old wives' tale" until recent research provided overwhelming support for this belief. This information, regrettably, was not widely available when contemporary family planning programmes were being conceived, or when many family planning workers were receiving their initial training.

Thus, even though the scientific justification for the inclusion of breast-feeding in family planning programmes can now be said to exist, the Western medical paradigm will continue to resist its implementation for some time. Where doctor-patient ratios are high and resources abundant, health care delivery systems will inevitably be oriented towards minimizing the chances for error. Even in settings where health professionals know that oral contraceptives are incorrectly used and have an equally high individual patient failure rate as breast-feeding, the pill may be preferentially recommended; blame for failure in these cases rests with the mother rather than on the health care system. The divergence between individual and public health approaches emerges, in part, as a result of such concerns.

Breast-feeding is the only infant food and one of the few contraceptives available to a large proportion of the world's families. The fact that breast-feeding constitutes a relatively "free" source of child spacing may also be partly to blame for its neglect in many development efforts. In Sri Lanka, for example, purveyors of contraceptive pills were found to be undermining a project attempting to introduce IUDs in the same area (Fischer et al, 1985). Any new competitor that minimizes the potential for market benefits may have difficulty arousing enthusiasm among health-related staff and institutions that look to profit-oriented activities as a normal part of health promotion.

Yet in spite of these and other constraints, there is every reason to believe that national health and family planning policies will gradually incorporate breast-feeding as a birth spacing resource. Governments increasingly recognize that modern contraceptives, like other high technology imports, are costly, if not now in foreign exchange, then in dependency on outside donors. Overworked Third World health professionals realize that they must orient their efforts toward doing the most good for the most people, accepting that they cannot be so concerned about making occasional mistakes. They recognize, too, that there is little likelihood of their being blamed by the public for assisting mothers in optimizing the birth spacing effect of breast-feeding when occasionally breast-feeding fails. They realize that they are much more likely to lose credibility among those for whom the "magic pill" fails.

THE ROLE OF HEALTH SERVICES RESEARCH

Health services research is a means, not an end (Taylor, 1984), implying that it will be primarily planned and implemented in connection with action plans. Because resources are limited in most public health endeavours, the least expensive research approaches are increasingly called for that do not compromise given standards of reliability and validity.

The question of how to integrate breast-feeding into family planning programmes may be best answered by health services research that considers four distinct stages of the processes, namely: advocacy, planning, implementation and evaluation.

Advocacy

The task of a change agent or advocate is to raise awareness and to lobby for change at all levels. In the health care field the case for new action can always be enhanced by data emanating from sound research. Arguments may be more convincing, moreover, if the research cited has been done locally or at least in a similar or neighbouring country. Certainly it will be more effective if there is a good understanding of where the "audience" stands already on the issues involved, for example the health implications of high fertility rates or of short birth spaces. It will also be useful to have an understanding of how local family planning is currently organized and how breast-feeding is currently dealt with by the health care system, as well as who the decision-makers are with respect to family planning and health care generally. Arguments may include information on the effectiveness of the existing family planning system which, in turn, could benefit from any existing evaluation studies. Certainly, arguments would benefit from any evidence of the improvements that might be expected from implementing new approaches or changes. Simulation computations on the likely impact on fertility of an increase in the length of exclusive breast-feeding might well be useful in this regard.

Planning

Once a decision has been taken to integrate breast-feeding into family planning, planners will be faced with the question of how best to do so. Health services research can help planning to move from the level of speculation to that of documented experience.

An example is the question of whether breast-feeding as a family planning method should be implemented both through the usual family planning channels and also within prenatal care services. In many cultures the prenatal period is an inappropriate one

for detailed discussion about delaying the next pregnancy because couples may still be too insecure about the outcome of the pregnancy. The important benefits of breast-feeding from birth on are nevertheless appropriate topics of discussion during the prenatal period and it may be possible to make mention of the birth spacing benefits of breast-feeding at this time. Birth spacing aspects of breast-feeding can be ideally discussed in more detail with women who express an interest in it; even those who plan to use other methods may decide to delay introducing them by practising intensive breast-feeding in the early months (since the length of effective use of modern contraceptives is often short, this can be expected to reduce fertility at the population level). Another possible advantage of discussing breast-feeding as a birth spacing method during the prenatal period is that the health professionals traditionally involved in prenatal care may be less likely to be biased against breast-feeding as a family planning method than family planning workers. Any approach which ignores the prenatal stage and simply includes breast-feeding in the traditional family planning programmes, usually engaging the mother in a family planning discussion only on the first postpartum visit to a health centre, may prove to be less effective. This is especially so in societies where supplemental feeds are commonly introduced in the early weeks of life since by the first postpartum contact with the mother, it may already be too late for her effectively to use breast-feeding to delay her next pregnancy.

The above speculations are based on common sense, not past experience. A health services research project to determine whether the addition of a prenatal component would be cost-effective would be justified if the resources necessary for the prenatal component would entail an important reallocation or if, for other reasons, there were scepticism about such an approach.

Implementation

There is a growing awareness that planning is most effective when it is flexible and continues during implementation. Since any initial, large scale integration of breast-feeding within family planning activities will not be able to benefit from past experience, it is more likely to be successful if a substantial research capability is attached, and if some form of process evaluation or operational research that provides continuous feedback to project managers can be included.

Evaluation

Evaluation should have several goals: to guide intervention implementation, to assess its impact, to measure its cost-effectiveness, and to determine the precise mechanisms by which its effects are exerted, both those planned and unplanned, taking into account other factors outside the control of the intervention. Each of these can play a valuable role in the present context of breast-feeding and fertility; if not for a given project itself, at least for the benefit of future efforts in this relatively new area.

METHODOLOGICAL CONSIDERATIONS

Advocacy

Often, an advocate for change will not have the capability, resources or political support for conducting sophisticated or large scale research to support the changes proposed. But even well-funded research projects should make full use of simple, inexpensive but effective background qualitative research techniques. Much

useful background information can be obtained from archival research, that is to say the studying of background documentation, field reports, annual reports, and routinely gathered statistics of various types. Effective qualitative research also includes the use of indepth interviews of key informants, including programme officials and field workers, as well as site visiting and field observation. Focussed group discussions can similarly provide uniquely valuable information that can effectively complement quantitative research. Any family planning or breast-feeding promotion programme should be examined, whether integrated or vertical, public or private, urban or rural, in terms of both its coverage and its psychosocial features.

The advocate needs to learn how past decisions with respect to breast-feeding and with respect to family planning have been made. He needs to learn about the key actors and what has seemed to influence their decisions. Eventually, the advocate should be able virtually to map the various forces, both in favour of and opposed to the proposed change. Among these forces will be various individuals and organizations as well as various cultural, social and economic factors. In Figure 1, an example of a so-called "force-field diagram" is presented, describing how an advocate was able to promote strategies for changing hospital policies with respect to breast-feeding. This allowed her to identify the most appropriate points for intervention.

Advocates can, of course, benefit greatly from research results from other regions, particularly where the process of change has gone further. This is one of the reasons that networking has been so important for advocacy groups in the past. The International Baby Food Action Network (IBFAN), which has been responsible for a great deal of awareness raising and lobbying for the protection of breast-feeding, provides a case in point.

The effectiveness of the advocate is likely to be greatly increased if he were able to estimate even very roughly the impact that the use of breast-feeding for family planning would be likely to have on maternal and infant health and population growth rates. The size of the impact on these variables will depend on the current infant feeding patterns, particularly duration and intensity of breast-feeding, the age of introduction of supplementary foods, and the extent of the use of bottle-feeding. Also to be taken into account are demographic data on birth and death, fertility rates and the extent of use as well as failure rates of various forms of modern contraception.

Data on the length of lactation amenorrhoea are particularly important. If it cannot be found from a national survey, such as the World Fertility Survey, then sometimes local small-scale studies can be conducted. Knodel (1977) provides data which can be used to estimate the impact of breast-feeding on fertility where the length of postpartum amenorrhoea is known, and the WHO has recently prepared a simplified methodology that is effective in this regard and is now being used in a number of countries.

Where policy makers continue to be hesitant even in the face of data from local research on the likely impact of the implementation of breast-feeding for family planning, one approach toward providing the extra level of certainty required is the establishment of a pilot project. This implies a certain level of acceptance and availability of resources. A quasi-experimental research design is usually called for, and Fischer et al (1985) have recommended the use of what they call the principle of the three multiples:

1. Seek multiple data sources to obtain information on the same variables.
2. See multiple measurements over time of the same variables.
3. Seek multiple replications of the study intervention in different field settings."

FIGURE 1
Force field diagram



Source: Hales, D.H. Promoting breast-feeding: strategies for changing hospital policy. *Studies in Family Planning*, 12(4): 167-172, 1981

It should be borne in mind that this is usually a demanding type of research that requires methodological expertise to be available throughout planning, implementation and analysis of the data.

Planning

Almost all types of information useful for advocacy will also be useful later at the planning stage. Planners would be assisted by having access to additional insight into the health care system and family planning system if it is separate. And, again, health service research for obtaining this information could usually be relatively simple and could often utilize qualitative research methods. Important questions to answer include: What do health care and family planning administrators, trainers and workers know about breast-feeding and its relationship to fertility? What are their attitudes towards breast-feeding, particularly as a contraceptive? What do they actually recommend to various categories of potential or actual family planning accepters? Of particular interest is how they respond to women who say they want to use breast-feeding to space their pregnancies. It is important to find out also how health professionals' own infants have been fed (Auerbach, 1985). If representative data for an entire class of health worker and throughout an entire geographic area is felt to be required, then a more quantitative approach with respect to sampling, gathering and analyzing data would be required. Some of the methodological details as discussed by Greiner and Almroth (1982) can be adapted for this purpose.

Implementation

A new and innovative approach such as the one discussed here should not be initiated before it is possible to couple it to an operations research or process evaluation capability. This would allow for monitoring, feedback and reorientation of the effort, since plans rarely can be laid that take into account all of the developments likely to take place once project implementation is underway. Some aspects of this type of research can be built into project implementation by simply adding a certain record-keeping or data-gathering component. In other cases, repeated simple surveys may be valuable. Nevertheless, some of the information needed for guiding the implementation of the intervention is generally more complex than that which can be gathered through routine data collection. Furthermore, the time gap before results can be reported from most epidemiological studies is too great to allow them to be useful in guiding project implementation. An excellent compilation of ideas for simple qualitative research methods for surmounting these obstacles is provided by Pacey (1981).

Evaluation

The most important type of evaluation, process evaluation, has already been mentioned. Only when a process evaluation has shown that project implementation has been relatively satisfactory is it justifiable to move into the level of impact evaluation. This requires a greater degree of sophistication and usually the type of quasi-experimental study design already mentioned above. Before it is possible reasonably to assume that a given intervention has a given impact, it must be possible to rule out alternative explanations, so-called threats to validity. Once it is possible to make a reasonable estimate of the impact of the intervention, then its cost-effectiveness can be calculated, assuming that careful records of costs are available.

Another level of evaluation attempts to determine how an intervention had its impact, and the methods by which it exerted its effects. Called "illuminative evaluation", its basic approach is to utilize a broad array of qualitative methods for "progressive focussing" or concentrating attention on certain topics or areas where cause and effect relationships are expected to lie. The method relies essentially on in-depth description and interpretation rather than the usual research techniques of measurement and prediction. Its goal is to build up a broad explanatory framework, which will be useful for future decision-making, either for improving the intervention involved or for implementing similar interventions elsewhere (Parlett, 1981).

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ANNEX III

BREAST-FEEDING PROMOTION:
METHODOLOGIC ISSUES IN HEALTH SERVICES RESEARCH

by

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BACKGROUND

The last 10-15 years has witnessed a veritable explosion in knowledge about breast-feeding. A large body of recent research has demonstrated a number of important advantages of breast-feeding to infant and child health (1,2). As if rediscovering the wheel, we are only beginning to understand the extent to which millions of years of evolution have succeeded in ways that modern technology cannot even approach. Concomitant with these discoveries, and partly as a consequence, breast-feeding has enjoyed something of a renaissance in developing countries. Despite widespread promotional efforts, however, the trend has been just the reverse in many parts of the developing world (3).

This trend in developing countries is particularly unfortunate since the health benefits of breast-feeding are far larger than those in developed countries. Those who can least afford the health and financial advantages of breast-feeding have been doing so in increasing numbers. Nowhere is this more important than in the area of this conference, i.e. the effects of breast-feeding on fertility regulation (4,5,6). Historically, on a world level, breast-feeding has prevented more pregnancies than any other form of contraception. In parts of the Third World where modern contraceptive technology is not universally available, breast-feeding remains the principal means of limiting family size and preventing over-population.

Successful promotion of breast-feeding depends on effective intervention strategies. Ideally, these strategies should be based on rigorous health services research into potentially modifiable factors with causal impacts on either the initiation or duration of breast-feeding. In this paper we shall review twelve factors that have been suggested to play such a causal role (see Table). For ease of presentation, we have divided our discussion of these factors into those occurring prenatally, those acting in the immediate postpartum period, and later postpartum factors. For each factor we shall briefly summarize previous research findings, highlight the methodologic pitfalls in research studies involving the factor, and suggest priorities for future research. But before considering the individual factors, we shall first examine the important methodologic issues relevant for health services research in this domain.

METHODOLOGIC ISSUES

In investigating the relationship between any given factor and the initiation or duration of breast-feeding, we are particularly interested in the extent to which the factor causes the breast-feeding behaviour. In epidemiologic parlance, the question is: Does exposure cause the outcome? Mere association without causation is less useful, since our primary interest is in identifying factors

that, if modified in the proper direction, will lead to improved breast-feeding rates. Non-causal factors that are merely associated with breast-feeding may be clinically useful as markers, but interventions based on these factors will be ineffective in producing the desired result.

Adequate demonstration of causality requires that a study be internally valid. Internal validity, in turn, is predicated on the absence of analytic bias and proper statistical inference. Furthermore, since other investigators and clinicians may be interested in the extent to which a study's results can be extrapolated to other populations, external validity is also an issue. Each of these major categories of methodologic concern will be discussed in turn, with specific indications of how they pertain to studies of breast-feeding and its potentially modifiable determinants.

Internal Validity

A. Analytic Inference

A research study will be internally valid to the extent that it is able to eliminate, or at least substantially reduce, analytic bias. Analytic bias can occur through any of four mechanisms: (1) confounding bias; (2) reverse causality ("cart-vs-horse") bias; (3) information bias; and (4) selection bias.

In confounding bias the relationship between exposure (here, the modifiable factor under study) and outcome (breast-feeding status) is altered by the existence of a third factor that is associated with both exposure and, independently of exposure, with the outcome. One of the main ways confounding can occur in breast-feeding studies is through the use of historical controls. Here the confounding factor is calendar time; if breast-feeding rates are increasing in a population, before-and-after study of the effect of any new intervention will show that intervention to be effective. Another source of confounding is that of socio-demographic differences between mothers who breast-feed and those who bottle-feed, or among mothers who breast-feed for different durations. Variables such as age, parity, racial/ethnic origin, and socio-economic status are potential confounders because these factors are associated with both infant feeding behaviour and several of its potential determinants. These types of variables, however, are fairly easy to control for through matching, stratification, or multivariate statistical techniques.

But other confounding variables present more difficult analytic problems. Particularly prominent among these are motivational differences that naturally exist between mothers who engage in certain practices or seek certain services. Since these motivational differences may have an independent effect on the outcome (breast-feeding), they are likely to be potent confounders. Because motivation to breast-feed may be difficult to measure, control for this source of confounding may require the use of an experimental research design, such as a randomized clinical trial.

Finally, another source of confounding that can arise even in randomized trials concerns treatment "contamination" secondary to bias by caregivers. In the context of a research study, physicians, nurses, and other caregivers may provide more support or encouragement to women who receive the "experimental" intervention, thus leading to additional treatments or exposures other than the one under investigation and thereby confounding the treatment effect. Blinding caregivers to the treatment status of the subjects, or at least to the research hypothesis (if feasible), is highly advisable in these situations.

The second type of analytic bias is reverse causality bias, in which the study exposure and outcome are causally related but the temporal sequence is the reverse of that indicated by the research hypothesis. In other words, the cart and the horse are reversed; the hypothesized outcome actually preceded and caused the exposure. For example, if breast-feeding mothers who have already decided (or even begun) to wean their infants are less likely to seek certain services or engage in particular practices, these services or practices will be associated with a longer duration of breast-feeding. The association is a true one but the direction of causality is the opposite to the one hypothesized. Reverse causality bias is particularly likely to occur in cross-sectional studies since it is often difficult to know the true temporal sequence between two variables when the two are determined at a single point in time. But no observational study is immune; subtle and inapparent early manifestations of breast-feeding behaviour may lead a mother to choose a service or practice for which the unwitting investigator erroneously then infers a causal role.

In information bias, misclassification (i.e. erroneous measurement) of either exposure or outcome leads to a biased estimate of the association between the two. If measurement errors are random, as would be the case with merely "sloppy" measurements, the bias would be toward finding no association between the factor and breast-feeding. Such a situation might arise from inadequate questionnaires, poor history taking, or reliance on prolonged maternal recall. Of potentially greater import is non-random (differential) misclassification, in which outcome measurements are systematically different in those exposed vs. not exposed to the factor under study. This is particularly likely to happen when study subjects or observers are not "blind" to either the research hypothesis or the subjects' exposure status. Observers who are measuring the outcome (breast-feeding status) might be influenced, even if unconsciously, by knowledge of a mother's prior exposure to the factor under consideration. Similarly, subjects who are aware of their exposure status (especially if they are also aware of the study hypothesis) may alter reporting of their breast-feeding behaviour.

Finally, in selection bias, the exposure-outcome association is biased by the way study subjects are selected (or subsequently lost to follow-up) from the target population of which they are presumably representative. If the relationship between exposure and outcome in those selected for study is different from those not selected, bias will obviously occur. This does not seem to have been a particularly important problem for studies of breast-feeding but is a potential issue in case-control studies, especially if breast-feeding and non-breast-feeding mothers (the cases and controls) are selected from different sources.

B. Statistical Inference

Statistical inference involves an examination of the role of chance (random variation) in explaining a research study's findings. The actual study sample is presumed to be representative (even if not randomly selected) of some larger target population. The observed association between exposure and outcome is compared to the null hypothesis of no such association in the target population. The statistical inference may be erroneous for one of two reasons: (1) the null hypothesis is falsely rejected when, in fact, it is true (Type I error); or (2) the null hypothesis is not rejected when it is actually false (Type II error).

The P value that results from most statistical tests is an expression of the probability of obtaining the sample result if the null hypothesis is in fact true for the target population. The P value thus reflects the probability of a Type I error. In other words, if the P value associated with a given association is .05, such a result would be obtained 1 out of 20 times in samples of the same size randomly selected from a target population in which the null hypothesis is true.

Type I error is not generally a major problem for either breast-feeding studies or other research studies when a single a priori hypothesized association is being tested. Occasionally, however, multiple factors are investigated simultaneously, and many of the associations analyzed arise post hoc, i.e. after the data are examined. In this setting, the measured P values underestimate the true probability of a Type I error (the null hypothesis is more likely to be falsely rejected). This is particularly likely to occur in so-called "fishing expeditions" in which numerous factors are assessed for their effect on breast-feeding initiation or duration. Of course, when several such studies net the same "fish" (find the same factors to be significant), the probability of error is reduced.

An even more important source of Type I error relates to the unit of statistical analysis, i.e. the group vs. the individual. For reasons of feasibility or ethics, many health service interventions are undertaken en bloc on entire groups: wards, hospitals, communities, or regions. Most investigators then analyze their results based on the individuals within these groups as the units of statistical analysis. But this is often inappropriate since individuals within groups tend to be more similar to each other than they are to individuals in other groups, and the extent of within-group dependence will reduce the effective sample size (7,8,9). If the sample size is taken to be the number of individuals, the resulting P value will then be too low (too "significant"), and the null hypothesis may be falsely rejected. If an investigator wishes to study the effect of an intervention in one community and compares breast-feeding rates in the "experimental" community to those in a "control" community without such intervention, the true sample size is not the total number of individuals living in the two communities. In fact, if the communities were perfectly homogenous, it could be as low as two! Investigators need either to demonstrate substantial independence of individuals within groups or to include a sufficient number of groups to ensure adequate statistical power (9).

The second type of erroneous statistical inference, Type II error, can arise from inadequate statistical power whenever small samples are used. In this case, the null hypothesis may be false but is accepted simply because the sample size is inadequate to reject it. The absence of an association in small studies makes it hazardous to infer that such an association does not exist in the target population. This is particularly important in the setting of breast-feeding studies where numerous factors are often investigated, many of which are associated with one another, and each of which may have a relatively small impact independent of the others. Small studies are simply incapable of adequately excluding a true effect of these factors.

External Validity

Many clinicians, researchers, and public health practitioners will be interested in the extent to which the results of a given study, even if internally valid, are generalizable (externally valid) to other populations. External validity may be limited by factors related to the study subjects or study procedures.

Differences in study subjects can arise either because of selective participation in a study, the study of special subgroups, or regional differences between one population and another. Selective participation means that subjects who agree to participate in a study may not be representative even of their own community. If study participants are highly motivated, for example, they may have higher rates of breast-feeding and thus may not experience the same benefit from a given intervention as would the general community. In this kind of scenario, a

study could produce a false negative result; the intervention would appear ineffective, whereas its effectiveness would be much higher in the general population. Other kinds of special subgroups, defined by a variety of clinical or socio-demographic criteria, might be either particularly susceptible or particularly resistant to a given intervention, and generalizability beyond the subgroup studied would be hazardous. Finally, regional differences may exist so that study results in one setting cannot be applied to those in another. This is a crucial limiting factor in attempting to extrapolate results from developed to developing countries or vice versa.

External validity can also be compromised by a study's procedures. This can occur if the intervention is so unusual or special that it is not generally available in other settings. Another potential threat is the Hawthorne effect. Participation in a study may itself improve breast-feeding rates irrespective of treatment, and this improvement may make it difficult to demonstrate any additional benefit of the treatment (so-called "ceiling" effect)(9). Once again, the result will be a false negative one, i.e. the treatment will appear to be ineffective, whereas it may be quite effective in a real world, non-study situation.

PRENATAL FACTORS

1. General Health Information and Education

Most women have probably decided whether or not they will breast-feed before becoming pregnant (10,11), and certainly before any contact with an obstetrician or other health care professional. As mentioned in the Introduction, a great deal has been learned in recent years about the health effects of breast-feeding. In industrialized countries, where literacy rates approach 100% and where general consciousness about health issues is increasingly prominent, most women have been exposed to articles in newspapers and magazines, as well as radio and television programmes, emphasizing the health benefits of breast-feeding. In developed countries, the renaissance in breast-feeding has occurred concomitantly with this increasing knowledge. It seems likely that at least part of the increased initiation and duration of breast-feeding in such settings is attributable to mothers' knowledge of its health benefits.

One study from St. Vincent (12) has attempted to relate maternal exposure to health information and breast-feeding duration. Although no association was found with radio and newspaper use, the specific issue of breast-feeding information was not addressed. A recently published report from Israel (13) indicated a crude association between exposure to reading materials (both pre- and postpartum) and breast-feeding duration, but the association disappeared after controlling for the confounding effect of social class.

Adequate epidemiologic studies of the effects of general health information and education would probably require the experimental introduction of an information-education campaign in selected regions or communities not having such intervention. Given the general access to the media in industrialized countries, however, it would be impossible to isolate women from generally available information, and such a trial is probably not feasible. Nonetheless, it seems highly unlikely that such a dramatic reversal in breast-feeding trends could have occurred over the last 10-15 years totally independently of mothers' information base.

Another aspect of general information and education relates to prenatal classes and counselling. Although several studies have shown a positive association between prenatal course participation or prenatal counselling and breast-feeding

initiation or duration (11,14,15,16,17,18), none has been experimental in design (e.g. randomly assigning mothers to classes or counselling vs. a non-treatment or placebo control group). Observational studies of this factor are extremely prone to confounding bias, since mothers who choose to attend prenatal classes or seek prenatal counselling are more likely to be older primiparas of high socio-economic status, and in developed countries such women are already far more likely to both initiate breast-feeding and to breast-feed for a longer period. In one study controlling for differences in age, level of education, and occupation, Robitaille et al (15) demonstrated a positive effect of prenatal course participation on breast-feeding initiation. The previously cited study (13) of breast-feeding duration, however, found that control for social class eliminated a crude association with prenatal classes.

The problem is, when mothers themselves decide whether to attend prenatal classes or whether to seek prenatal counselling from La Leche League or other breast-feeding support groups, most of them may already be highly committed to breast-feed even before seeking these services. In addition to confounding by motivational factors, this creates a large potential for reverse causality bias; seeking the service may be the effect, rather than the cause, of breast-feeding behaviour.

Although it seems logical that prenatal education and counselling would be beneficial, the size of the impact remains obscure. Since the provision of such services may require a sizeable investment by the health care system, adequate demonstration is necessary that a prenatal support programme has a sufficient impact to justify its cost. Such demonstration will require either randomized clinical trials (or other experimental studies), or measurement and control for pre-pregnancy desire and motivation to breast-feed. Interventions that are assigned by groups (e.g. communities or regions rather than individuals) must be reflected in the unit chosen for statistical analysis.

2. Encouragement by Health Professionals

Although some women cite counselling and encouragement by their obstetrician or other prenatal health care professional as a factor in their decision to initiate breast-feeding (10, 19), most women seem to arrive at their decision before becoming pregnant, or at least before contacting a health professional about their pregnancy. One of the problems may be that physicians themselves may not be adequately informed about the benefits of breast-feeding. In a recent study of obstetricians and pediatricians in a large New York City hospital, Winikoff et al (20) demonstrated considerable misinformation, especially among the obstetricians. Most of the scientific publications about the beneficial effects of breast-feeding have appeared in the pediatric literature, and many obstetricians may not be aware of them.

Before embarking on a large-scale education campaign of physicians, midwives, or (in developing country settings) community primary health care workers, better evidence is required that improved knowledge among prenatal health professionals would indeed improve breast-feeding rates. Once again, because women with greater desire or motivation to breast-feed may be more attracted to physicians or other health professionals who are more knowledgeable about breast-feeding, the potential for confounding and reverse causality bias is enormous. The preferable research design for investigating the importance of this factor would be a randomized trial in which the health care professionals were randomized to either receive or not receive an educational programme concerning breast-feeding and its health benefits. In the absence of such evidence, it is difficult to recommend any large-scale public health effort toward educating health care professionals, especially

since such efforts may be difficult to achieve in practice and may involve considerable expense.

IMMEDIATE POSTPARTUM FACTORS

1. Early Maternal-Infant Contact

Several of the clinical trials of early maternal-infant contact have studied breast-feeding duration as an outcome. In a small (n = 30) well-controlled trial of mothers intending to breast-feed, Thomson et al (21) found that primiparas given 15-20 minutes of skin-to-skin early contact were significantly more likely to be breast-feeding at two months. A Jamaican study by Ali and Lowry (22) found that mothers assigned to early contact were more likely to be breast-feeding exclusively at 6 and 12 weeks postpartum. Similar trends have been obtained in England (23), Sweden (24) and the United States (25), but owing to wide variability in the duration of breast-feeding and small sample sizes, observed differences did not achieve statistical significance.

Thomson and Kramer (26) have recently reviewed the potential problems of information and confounding bias arising from non-blinding of subjects and caregivers in these studies. Did the early contact mothers know that they were receiving some "special treatment"? Were mothers who received the extra early contact treated differently in some other way throughout their hospital stay? Because previous studies have not adequately controlled for these factors, despite their experimental design, no definitive conclusion can be reached about whether or not early contact in itself is sufficient to affect breast-feeding duration. Nonetheless, the evidence does tend to point in that direction. Future research in this domain should attempt to control more rigorously for the various sources of bias inherent in these types of studies.

2. Information and Support by Health Care Professionals

As indicated earlier, most mothers report having chosen their method of infant feeding prior to delivery. Some improvement in breast-feeding initiation rates has been reported as a result of hospital staff encouragement in several studies (19,27), while others have found no such advantage (11). All of these studies have been based on historical controls, however. With the exception of one study (19), breast-feeding rates in the control group were recorded at least one year before that of the experimental group. In an era of rapidly rising breast-feeding rates, this finding becomes difficult to interpret. The one study (19) in which evaluation was done in two brief consecutive time periods noted a significant increase in the proportion of mothers initiating breast-feeding in both experimental and control groups (although breast-feeding duration was not different in the two groups).

In a study comparing different hospitals, Meyer (28) found that hospitals with programmes to encourage breast-feeding were associated with higher breast-feeding initiation rates. The statistical analysis in this study was based on individual women rather than the number of groups, and intra-group dependence was not taken into account. But more importantly, women delivering in different hospitals may differ considerably in such important confounding variables as racial/ethnic origin and socio-economic status, and the type of hospital and geographic region may also differ considerably from one site to another. These results are thus extremely difficult to interpret.

In two studies of breast-feeding duration, women still breast-feeding reported the hospital staff as more helpful than those no longer breast-feeding (29,30). Since this information was collected at the time the outcome was determined (1 and 3 months postpartum in the two studies), the association here too is difficult to interpret. Mothers who encountered breast-feeding problems may in retrospect have wanted more help than those who experienced no problems. Far more convincing evidence comes from a recent controlled trial (31) of in-hospital and post-discharge support by a lactation nurse. At 4 weeks postpartum, the breast-feeding rate was significantly higher among women receiving the support, especially among those in the lower social classes.

If support and encouragement by health care professionals in the immediate postpartum period does affect breast-feeding initiation or duration, the relative importance of the professionals' knowledge, versus application of that knowledge, is not clear. Many obstetricians, pediatricians, and postpartum nursing staff are relatively misinformed about the health benefits of breast-feeding and the proper management of difficulties that arise in mothers who decide to breast-feed (20). Because of the difficulties (confounding bias) in before-and-after studies or comparisons of different hospital settings, adequate demonstration of an effect of these factors probably requires an experimental research design. Future clinical trials in this domain should focus on both stages of the process: (1) education and training of postpartum professional staff; and (2) specific measures of counselling and support by these staff in the immediate postpartum period. To date, firm scientific evidence of the effectiveness of extra information and support rests on a single recent study (31). But it seems unlikely that such a marked increase in the prevalence of breast-feeding in developed countries could have come about totally independently of postpartum professional advice and help.

3. Rooming-In

In general, "rooming-in" refers to the hospital practice of housing mothers and newborns in the same room. But its precise definition varies considerably across hospital settings, especially with respect to the amount of time the mother and infant spend together, e.g. during daytime hours only, more than 12 hours each day, or around-the-clock. Several observational studies have reported a significant association between rooming-in and a longer duration of breast-feeding (3,29,32,33,34). Once again, however, the likelihood of confounding bias makes such an association difficult to interpret. Mothers choosing to care for their babies themselves (rather than by the nursing staff) are likely to differ in many respects, particularly in terms of motivation to breast-feed.

One experimental study reported a highly significant increase in breast-feeding initiation after rooming-in was implemented (35). But it is difficult to attribute changes in rates to one specific intervention when historical controls are used, particularly after an interval of several years.

In summary, then, the evidence concerning the effect of rooming-in is far from conclusive. All previous studies have suffered from important methodologic problems, especially the use of historical controls, inadequate control for other sources of confounding, and statistical analyses based on individual women, rather than en bloc intervention groups. Because rooming-in represents a fairly easily modifiable factor associated with the delivery setting, this is an important area for future research. Ideally, future studies should attempt to randomly assign a sufficient number of different postpartum wards, or different hospitals, to rooming-in vs. traditional hospital procedures.

4. Demand vs. Scheduled Feeding

The type of feeding schedule ("on demand" vs. regularly scheduled feedings) and rooming-in are closely related. Rooming-in is particularly conducive to demand feedings since the baby can be fed whenever it appears hungry. One very well-controlled clinical trial of scheduled vs. demand feeding was carried out by Illingworth et al in 1952 (36). Mothers in the demand group were much more likely to be breast-feeding at 1 month postpartum. Unfortunately, neither the method of treatment assignment nor evidence of the equivalence (i.e. absence of confounding) of the two experimental groups is presented. Even more unfortunately, this trial has never been repeated, and since the length of hospital stay and the type of postpartum care given in 1952 are quite different from the present day setting, it is not clear whether the results are applicable.

In a more recent study, Salariya et al carried out a clinical trial to compare frequent (every two hours) vs. routine (every four hours) feeding schedules (23). Although these authors found no differences in the proportion of mothers breast-feeding at 6 or 12 weeks postpartum, the median length of breast-feeding showed a non-significant trend favouring the frequent feeding schedule. Since the sample size was small and breast-feeding rates were high in both groups, the negative findings may reflect a high probability of Type II error rather than a lack of true effect.

As with rooming-in, frequent on-demand feeding represents a very viable option for intervention in the immediate postpartum period. This factor deserves far more attention in future health services research than it has received previously. Once again, the preferred design would be a randomized controlled clinical trial.

5. In-Hospital Formula Supplementation

It is widely held that breast-fed babies should not be provided routine supplementary formula feedings in the hospital. Three justifications of this position are often stated:

- (1) milk production depends on demand; thus the greater the demand, the greater the production;
- (2) sucking from a bottle may require less physical effort by the baby than sucking from the breast, and the difference may lead to breast-feeding difficulties; and
- (3) a mother's confidence in her milk supply may be eroded by being told that her baby is getting supplemented because she is not yet producing enough milk.

Several observational studies have reported that in-hospital supplementary feedings diminish the duration of breast-feeding (34,37). The findings are likely to be confounded, however, since mothers choosing to supplement their babies may be the same mothers who, independently of supplementation practices, are less likely to continue breast-feeding. In support of this possibility, Samuels found a difference between mothers who did, and those who did not permit their infants to be supplemented in hospital (38). Mothers requesting no supplementation were more likely to be married, white, and over 30 years of age; to have had vaginal deliveries; and to have their infants rooming-in with them. Furthermore, it is often difficult to separate the cart from the horse in these observational studies. Mothers who decide to reduce or stop breast-feeding are likely to request (or permit) supplementation.

Three experimental studies have also been published (19,39,40), all of which used historical controls. The reported increase in breast-feeding rates seen after changing hospital policy toward reduced supplementation may have resulted from other temporal effects since breast-feeding rates were generally rising in the population groups under study. Furthermore, two of the three studies (19,40) involved changes in procedures other than supplementation, and thus any effect of the latter is "contaminated" (confounded) by the multiple manoeuvres involved.

A recently published controlled clinical trial (41) of in-hospital formula supplementation not only demonstrates the absence of an effect, but also explains why previous observational studies consistently showed such an effect. Despite institution of markedly reduced formula supplementation in one of two postpartum well-baby nurseries, the percentage of mothers still breast-feeding at either 4 or 9 weeks was virtually identical in the two groups. When an "observational" analysis was carried out in the traditional supplementation nursery, however, formula supplementation and breast-feeding duration were highly associated. The apparent "conflict" between the experimental and observational findings in the same women is explained by the fact that women who are less highly motivated to breast-feed or who have trouble doing so (e.g. sore nipples) are more likely to supplement. The association is biased both by confounding differences between the mothers and by reverse causality: the conscious or subconscious decision to stop or reduce breast-feeding causes the mother to request or accept supplementation. In other words, in-hospital formula supplementation appears to be a marker, rather than a cause, of breast-feeding difficulty.

LATER POSTPARTUM FACTORS

1. Counselling and Support

Support by lay community groups, e.g. La Leche League, has been reported to be positively related to breast-feeding duration (42). But as in the case of prenatal education and professional encouragement, those mothers most interested in breast-feeding are also those most likely to contact such community groups. This self-selection creates groups that cannot be compared without adequate adjustment for the motivational differences that can confound the treatment effect. Control for this source of confounding requires the development of valid and reproducible measures of motivation for breast-feeding or (preferably) the use of a randomized clinical trial design.

A recent observational study from Israel (13) reported a significantly longer duration of breast-feeding among mothers who later reported having received advice from their obstetrician at a 6-week postpartum visit. It is unclear from this study, however, who initiated the discussion: the (perhaps highly motivated) mother or the obstetrician. Reference has already been made to a recently published clinical trial (31) demonstrating a higher breast-feeding rate 4 weeks postpartum in mothers receiving both in-hospital and home support by a lactation nurse. Since the intervention spanned both the immediate and later postpartum periods, however, it is difficult to know which period of support was more important.

Another source of postnatal support is frequent telephone contact, with referral of mothers with breast-feeding problems. Two similar randomized trials (35,43) suggest that such contact may modestly improve breast-feeding duration. In one of these trials (43) the improvement was not statistically significant, although the small sample size indicates a high likelihood of Type II error.

Some authors have recommended the institution of a telephone "hot-line" that would allow mothers with breast-feeding difficulties or questions to call in to a qualified counsellor at the hospital or in the community. Any attempt to measure the efficacy of this type of programme would also have to deal with the problem of confounding by self-selection.

2. Infant Feeding Schedule

As in the immediate postpartum period, on-demand feeding at home, along with continuation of night-time nursing, has been associated with a longer duration of breast-feeding (44). Frequent, around-the-clock suckling is known to stimulate breast milk production, and such feeding schedules should (at least theoretically) be maximally conducive to continued breast-feeding (5). Similarly, formula (or other non-breast milk) supplementation at home and the introduction of solid foods have been reported to be associated with a shorter breast-feeding duration (30,38).

As with in-hospital supplementation, the two major difficulties in interpreting the results of the above studies are confounding bias due to differential motivation to breast-feed, and reverse causality bias, by which mothers who have already decided to begin weaning discontinue night-time feedings or supplement the child with infant formula or solid foods. But, unlike the situation with in-hospital supplementation, home feeding schedules are not so susceptible to experimental intervention. Maternal feeding practices are subject to profound cultural influences and it is often infeasible to attempt to influence them in any controlled way. Even in the unlikely case that an intervention could be implemented, the real world relevance (external validity) to mothers' own decisions regarding feeding times and formula or solids supplementation would be extremely dubious.

3. Infant Formula Samples and Other Forms of Advertising

There has been considerable concern and controversy about the possible effects of providing free infant formula samples or other forms of infant formula company advertising to breast-feeding mothers. In two descriptive studies from Jamaica, mothers cited receipt of free samples or advertising by milk nurses as reasons for discontinuing breast-feeding (45,46). One report from Papua New Guinea demonstrated higher breast-feeding rates following legislation restricting the sale of infant formula, but the before-and-after design invites confounding by other temporal change (47). A previously cited observational study from St. Vincent found that maternal awareness and purchase of advertised infant foods was associated with earlier introduction of non-breast milk (12). Although several variables were controlled through appropriate multivariate statistical techniques, the association is probably confounded by maternal motivation to breast-feed. Furthermore, even if the association is a causal one, the direction of the causal relationship is unclear since a mother who had already decided to begin weaning may have sought well-known (advertised) brands of infant foods.

In a recently published randomized clinical trial among a well-educated group of Montreal mothers, Bergevin et al (48) reported a trend for lower breast-feeding rates at 1 month among those who had received samples, with statistical significance attained in three potentially vulnerable sub-groups: primiparas, mothers with less formal education, and mothers who reported being ill after leaving the hospital. Because the differences in the overall group did not achieve statistical significance, however, this study bears repeating, especially in developing countries or among high-risk groups in developed countries. A recently published trial from the Philippines (49) found a similar, though

statistically non-significant, trend. Unfortunately, receipt of formula samples was not assigned randomly in the latter study, resulting in substantial differences in numbers of women in the two experimental groups. Moreover, home interviewers were not blind to the mothers' treatment group. Rigorously conducted randomized trials are an important priority for future research in this area.

4. Maternal Employment

The evidence is mixed (50,51) concerning the relationship between a mother's return to work after delivery and breast-feeding duration. One of the major problems in interpreting studies in this area has been the issue of causal direction. If mothers who return to work breast-feed for a shorter duration than those who do not, it may be either because they returned to work after stopping (or at least after beginning weaning) or because the work itself interfered with successful lactation. Another problem is defining what is meant by breast-feeding in these studies, since total and exclusive breast-feeding may indeed be difficult during full-time maternal employment, whereas partial breast-feeding is much more practicable. This is particularly important with respect to lactation amenorrhoea and fertility regulation since the data are quite clear that partial breast-feeding does not have nearly the same contraceptive effect as exclusive breast-feeding with frequent, on-demand suckling (5).

Financial or social demands on women may not permit change in employment practices even if such practices do interfere with exclusive breast-feeding. Thus, in a sense, it may be erroneous to consider maternal employment as a modifiable factor. From the standpoint of possible intervention strategies, however, a feasible research design might be selective (preferably randomized) provision of on-site day care, flexible hours, or "nursing breaks" during the work day.

5. Combined Hormonal Contraceptives

Estrogen-containing combined hormonal contraceptives have been shown to reduce milk flow (4). Although use of such contraceptives might offset the ovulatory effect of breast-feeding in individual women, other health benefits (especially to the infant) would be lost. In two descriptive studies from the Middle East, mothers frequently cited contraceptive pill use as the reason for discontinuing breast-feeding (44,52). Several controlled observational studies from developing countries have reported an association between the use of such contraceptives and a shorter duration of breast-feeding (51), and although one (53) controlled for several potential confounding variables, the problem of reverse causality remains for all observational studies in this area. Mothers planning to stop breast-feeding may begin using contraceptives before stopping so as to maintain adequate contraception. Thus, a decision to stop may precede, and "cause" their use of the contraceptives rather than arise as a consequence of that use.

The ideal study design to investigate this question would be a placebo-controlled randomized trial. Such a trial has not thus far been attempted, nor is it likely to be in the foreseeable future. Considering the well-known biological effects on breast milk output, it seems advisable to recommend that women intending to continue breast-feeding not use combined oral contraceptives. Avoidance of these medications would be indicated for the nutrition of the nursing child, even if there is no effect on the duration of lactation.

CONCLUSION

A mother's decision to initiate or continue breast-feeding depends on a variety of biological, attitudinal, behavioural, and economic considerations that are often difficult to conceptualize and even more difficult to measure. Since the goal of health services research in this area is to identify factors with true causal impacts on the initiation and duration of breast-feeding, the methodologic issues we have discussed are of practical, and not merely theoretical, importance. Although scientific perfection may be an unattainable ideal, gross violation of design and statistical guidelines may result in disillusionment (unfulfilled promises of higher breast-feeding rates) and considerable waste of human and financial resources. The issue is not so much one of scientific "purity" but rather how to effect the desired changes most efficiently.

Future studies in this domain should give greater attention to the internal and external validity of their design, analysis, and interpretation. Better measurement methods need to be devised. Blinding of subjects, caregivers and observers need to be more routinely instituted. Historical controls should be avoided wherever possible. Group interventions should be compared using the group as the unit of statistical analysis unless outcomes in individuals are shown to be independent of group membership. Potentially confounding variables should be measured and controlled for appropriately; where this is not feasible for observational studies, experimental designs (randomized trials) should be used. Randomized trials may also be necessary to eliminate reverse causality bias. In fact, many of the potential factors we have discussed can probably only be satisfactorily addressed using an experimental approach.

Based on the available evidence, those factors that seem most promising to pursue include prenatal information and support, efforts in the immediate postpartum period to maximize maternal-infant physical contact and breast-feeding, and provision of counselling and support for mothers who encounter difficulties with breast-feeding during both the early and later postpartum periods. Efforts to study the effect of restricting infant formula company advertising or the availability of infant formula, especially in developing country settings, are also of high priority given the recent trends in breast-feeding rates seen in such settings. Despite the inadequacy of current knowledge, public health efforts to promote breast-feeding cannot and should not wait for results of "definitive" studies. Rational policy must be based on the best available information. But benefits for fertility regulation, as well as other aspects of maternal and child health, will at least partly depend on the methodologic rigor of future health services research.

TABLE

MODIFIABLE FACTORS WITH POTENTIAL INFLUENCES ON BREAST-FEEDING
INITIATION OR DURATION

PERIOD	FACTOR
PRENATAL	<ol style="list-style-type: none">1. General health information and education2. Encouragement by health professionals
IMMEDIATE POSTPARTUM	<ol style="list-style-type: none">1. Early maternal-infant contact2. Information and support by health care professionals3. Rooming-in4. Demand vs. scheduled feeding5. In-hospital formula supplementation
LATER POSTPARTUM	<ol style="list-style-type: none">1. Counselling and support2. Infant feeding schedule3. Infant formula samples and other forms of advertising4. Maternal employment5. Combined hormonal contraceptives

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