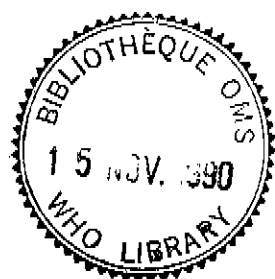


Introduction of new contraceptives into family planning programmes

Guidelines for social science research

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Special Programme of Research,
Development and Research Training
in Human Reproduction

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Foreword

The performance of a new fertility regulation method outside the laboratory environment--i.e., under conditions of actual use--is influenced by factors other than its intrinsic nature. The characteristics of the users of the method, the structure and functioning of the family planning system providing the method, and the general socioeconomic and cultural environment play an equally important, if not greater, part in determining its efficacy and effectiveness. Hence, with proper attention to the perceptions and needs of the users and those of the providers of family planning services, including training of the providers in handling new technology, the performance of new methods can be significantly improved in terms of acceptability, continuation of use, effectiveness and safety.

The Special Programme of Research, Development and Research Training in Human Reproduction maintains the position that the development of a new contraceptive method is not complete until it is carried beyond the "ideal" conditions of clinical trials through a "real life" situation, where the interaction between the technology, the users, and the service providers can be examined in order to get a better picture of the method's performance.

Research experience in the area of field testing of contraceptives is still limited. These Guidelines are being issued by the WHO Special Programme's Task Force on Behavioural and Social Determinants of Fertility Regulation to help investigators in designing and implementing studies in this important area. The Guidelines draw on lessons learned from previous work. It is expected that this publication will help create more awareness about the need and importance of field studies in the development of fertility regulation methods.

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1. Introduction

A major objective of the WHO Special Programme of Research, Development and Research Training in Human Reproduction is to develop new, improved methods of fertility regulation suitable for introduction into national family planning services. The availability of a wide choice of contraceptives for men and women is likely to increase the chance that couples will find a contraceptive option that meets their particular requirements. Thus both adoption and continuation of methods are also likely to be enhanced.

The process of development of a new contraceptive method--or variant of an existing method--and its eventual incorporation into a national family planning service involves a long sequence of biomedical and initial field trials, as is the case with any new drug. Typically the following stages occur in sequence:

Basic research and development. The method is developed in the laboratory and tested for effectiveness and toxicity in suitable animal models.

Clinical trials. The method is assessed for effectiveness, safety and side-effects under closely controlled conditions in a succession of trials involving progressively larger numbers of human subjects.

Introductory trials. The method is assessed under natural or real world conditions for acceptability, continuation, use-effectiveness, side-effects and associated health events. Specific service-related needs, such as staff training, are also evaluated.

Long-term surveillance. Following its widespread introduction, the method continues to be assessed for long-term side-effects and for rare associated health events.

This sequence of research activities draws upon biomedical and epidemiological techniques and its main focus is the evaluation of the performance of the contraceptive method under varying conditions. *Social science research* complements this technological assessment by providing information on the perspective of users, their spouses, and service

providers regarding the method within the users' cultural, social and economic context. The importance of the user perspective stems partly from the consideration that technology should be modified to suit people, rather than people be modified to suit technology (Marshall, 1977). There is also another more practical consideration. The beliefs, values and preferences of potential users and providers largely determine the acceptability and successful use of a method. By providing insights into these human factors, and by assessing their practical implications for the management of family planning services, social science research thus can make an extremely important contribution to the introduction of a method.

The purpose of these guidelines is to assist scientists in the planning and conduct of social science research on the introduction of contraceptive methods into family planning programmes. These guidelines are equally relevant to the introduction of newly developed methods and the introduction of existing methods to new settings. This document is addressed both to those with a formal training in the social sciences and to clinicians and health workers with social science backgrounds or interests. The following sections examine the potential contributions and substantive scope of social science research and describe the major research designs and common problems encountered in the implementation of studies.

2. Social science research: objectives and relationship to biomedical trials

As stated earlier, social science research complements biomedical assessments of the performance of a method by providing information on the perspectives of users and service providers and the sociocultural rationale for their attitudes and behaviour. In this regard the central aim of social science research is to probe beyond the bare statistical results on effectiveness, continuation of use, and side-effects and method abandonment, obtained first from clinical trials and later from introductory trials, by identifying social, cultural, and behavioural determinants of those results. A number of methodological implications further distinguish behavioural and social studies from biomedical research, and in particular from introductory trials of new methods. For instance, in introductory trials data are collected in clinic-based investigations for anywhere between 1000 and 10 000 cases, with usually little emphasis being placed on investigating in depth the socio-behavioural factors affecting the performance of the method in the particular setting where it is being used for the first time on a wide scale. In contrast, social science studies involve intensive investigation of smaller samples and data collection is often community-based. Moreover, a much wider range of data collection methods may be used (see section 5) and many more variables included (see section 3).

Within the broad aim of identifying the determinants of acceptance and successful use of new methods, social science research may serve to answer a variety of specific questions related to the nature of the method, mode of delivery, geographical setting, and practical problems encountered. Examples include:

- + Which characteristics of the methods are the most beneficial and which are least beneficial?
- + What side-effects are perceived and how do these perceptions relate to broader health beliefs?
- + How are known side-effects tolerated and handled?
- + What is the decision-making process by which a new method is accepted or rejected?
- + What social, economic or demographic factors affect the duration of use of the contraceptive method?

* What views do users have of the service delivery system and in what ways do these views influence willingness to continue the use of the method?

* Is the information that potential users receive comprehensible, sufficient and appropriate to their needs?

The timing of social science research in relation to biomedical research or introductory trials depends on the objectives of the overall research strategy. If, for instance, the objective is to assist in the design of a culturally appropriate information and delivery system by assessing the knowledge and attitudes of potential clients, the study has to be conducted prior to the introductory trial. More commonly, studies proceed in parallel with an introductory trial. This arrangement permits early detection of problems and subsequent modification of introductory procedures. It may also assist in overcoming low response rates and selection bias problems of clinic-based studies; home interviewing of clients inevitably achieves higher contact and response rates than those achieved by studies that rely upon return visits to clinics by clients. Social science studies can also follow introductory trials. In such instances, levels of acceptance, continuation and use-effectiveness are already known and the purpose may be to provide explanations which can then be used to refine the strategy for nationwide introduction of the method.

Though the contribution of social science studies to the successful introduction of new methods is easily distinguished from that of biomedical trials, its successful design and implementation ideally requires a multidisciplinary team that includes medical, public health, and statistical as well as social science staff. This constellation of skills required to conduct social science studies reflects the multifaceted nature of the topic. User perceptions do not exist in a vacuum. They are shaped by the intrinsic properties of the method and by the way in which it is presented. A knowledge of the nature of the method, service characteristics, user perspectives and the cultural setting is required for a full understanding of contraceptive use behaviour.

3. The substance of social science research

Social science investigations of contraceptive introduction are guided by no single theory of human behaviour. However, a number of relevant frameworks exist that can be valuable in the design of research projects. Examples include the health beliefs model (e.g., Kirscht, 1974), models of innovation, adoption and diffusion (e.g., Rogers and Shoemaker, 1971), a variety of frameworks for the analysis of reproductive decision-making (e.g., Shedlin and Hollerbach, 1981) and theories of interpersonal communication. However, none of the models or frameworks commands universal respect among scientists, nor does any single model cover adequately the range of topics that may be addressed in the study of contraceptive introduction. The stance taken in these Guidelines is that the contribution of the social sciences to contraceptive method introduction is an applied rather than a theoretical one: the priority is to gain insights into practical barriers and problems that may impede the contribution of new methods to successful birth planning, rather than to set the more ambitious goal of generating and testing theories of human behaviour.

While the substantive content of social science studies of contraceptive introduction cannot be derived from any single theory, the main topics of interest can be specified. As shown in Fig. 1, these fall into three main groups: ultimate outcomes; intermediate outcomes; and determinants of outcomes. These are briefly described below. The main purpose of this section is to assist researchers in the design of studies by enumerating the factors that may merit inclusion and to state the reasons for their potential importance when this is not obvious.

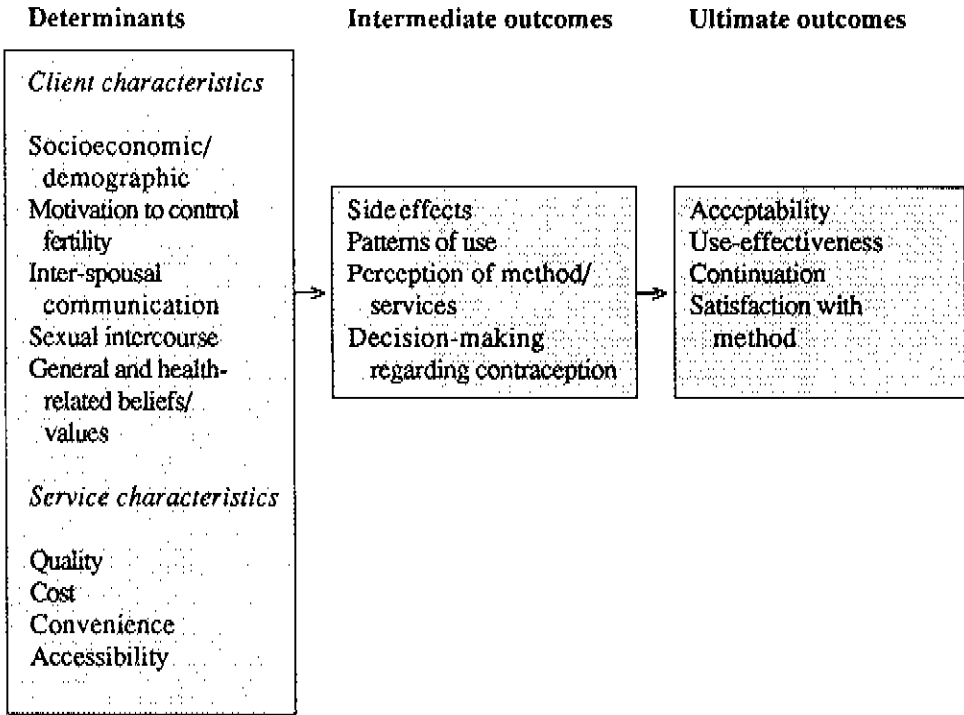
3.1 Ultimate outcomes

While clinical and introductory trials are the main sources of information on ultimate outcomes, measures of outcomes also have to be obtained in most social science investigations in order to elucidate their determinants.

3.1.1 *Acceptability*

This term has a variety of meanings. Three main types of method

Fig. 1. A social science framework for research on introduction of new methods



acceptability may be distinguished. The first, which may be called *hypothetical acceptability*, concerns the verbal assessment of potential users in response to some description or representation of a new method, or even an imaginary method. For instance, is the idea of a sheath to be used by women rather than men, or an oral contraceptive to be taken by men, considered attractive or unattractive (compared to other methods) and for what reasons? This type of acceptability research may not yield results that are highly predictive of subsequent willingness to try the method when it is offered in a clinical setting (Keller, 1979). But it can provide valuable information on the existence and nature of resistance or misconceptions that need to be overcome for the successful introduction of the method, or alternatively, provide indications that the basic concept of the method is seriously flawed.

The second type of method acceptability concerns the willingness of

individuals to try a new method in a fully informed manner. This may be termed *initial acceptability*. Unlike hypothetical acceptability, the criterion here is behavioural rather than attitudinal, and measures are usually derived from clinical data on numbers of acceptors. Though the idea is straightforward, the interpretation of results is difficult because much depends on the manner in which the choice of method is presented to potential users, the range of other methods available, and uncertainties about the total number of potential acceptors.

The third common use of the term acceptability refers to the evaluations and behaviour of individuals who have actually tried the method. This is often referred to as *experiential acceptability*. Acceptability in this sense is simply a generic term for more precise outcomes that are discussed below.

3.1.2 *Use-effectiveness*

Use-effectiveness refers to the incidence of (unintended) conceptions while a method is used under normal or average conditions. It differs from method- or theoretical effectiveness, which expresses the failure of a method under conditions of perfect user (and provider) compliance, by taking into account any shortcomings in the way the method is used. The force of this distinction depends on the method. For instance, the effectiveness of voluntary surgical sterilization or hormonal implants cannot be influenced by the user and any divergence between method and use-effectiveness is attributable to defects in medical provision. However, for methods that demand a behavioural contribution from the user, this distinction is of great practical importance.

Conceptions during use or attempted use of a method are by definition unintended. For certain analytical purposes, it is useful to classify conceptions according to eventual outcome (induced abortion, spontaneous abortion, live-birth) and to motivational status (i.e., whether use was to end childbearing or to delay the next birth).

3.1.3 *Continuation*

In most trials of new methods, the majority of discontinuations are prompted not by a conception or the desire to conceive but by other factors, most of which are derived from dissatisfaction with the method or associated services. Accordingly, duration of use is usually a key indicator of method performance. Perhaps the single most valuable

contribution of social scientists is to augment clinical data on the determinants of discontinuation, which are usually based on simple reporting procedures and/or the interpretations of clinic staff. This augmentation may take the form of direct questioning or it may be achieved inferentially by a careful comparison of the characteristics of continuing users and those who have stopped use.

The collection of additional information on contraceptive behaviour after discontinuation of the new method may also help to elucidate the reasons for stopping. Switching to another method implies a reasonably strong motivation to control fertility; conversely, non-use is likely to indicate weakly held motivations.

3.1.4 *Method satisfaction and information channels*

The length of time during which couples continue to use a contraceptive effectively is a robust and demographically appropriate criterion of success of the method. But even prolonged use does not necessarily imply total satisfaction with the method. Nor can it be used as a valid criterion of success for irreversible methods. Social science evaluations of method performance therefore should include measures of client satisfaction with the method in terms of convenience, perceived safety, lack of undesirable side-effects, willingness to recommend to others and so forth.

A further reason for supplementing behavioural data on continuation with attitudinal data concerns dissemination of information. There is ample evidence that contraceptive behaviour is heavily influenced by communication among peers. The past and present users of the method probably constitute the most influential source of information about new methods; the nature of their messages to relatives, friends and neighbours will be conditioned by their level of satisfaction with the method. *The identification of dissemination channels*, and the messages about contraception that they carry, should always be considered in social science investigations of method continuation.

3.2 Intermediate outcomes

Intermediate outcomes are so called because they are located temporally and causally between the ultimate outcomes and the independent or determinant factors. Typically, biomedical trials collect rather little information on this category of variables. Thus a major potential contri-

bution of social science research is to illuminate this area, particularly by analysing users' reactions to, and experiences of, a new method and its mode of presentation.

3.2.1 *Perceived side-effects*

The toxicological, clinical and epidemiological study of side-effects lies outside the domain of social science research (see WHO, 1987, for guidelines). Rather, the emphasis is on reported, or perceived, side-effects. In terms of the potential effect on continuation, users' beliefs about the side-effects of a new method can be as important as the physiologically verifiable effects. In addition to details of reported side-effects (e.g., duration, frequency, severity of symptoms, effect on ability to work) the user's own evaluation of the importance of each symptom should be sought, because reactions to the same symptom may vary between cultures and individuals. For instance, in a study of vaginal rings, weight gain was considered an advantage in the Dominican Republic but a disadvantage in Brazil (Hardy et al, 1983). Similarly, the significance attached to changes in the characteristics of menstruation are culture-dependent. Reductions in menstrual flow, or amenorrhoea, may be regarded as seriously harmful in some settings, because bad blood is thought to be retained in the body (WHO, 1981). Alternatively, such a side-effect may be viewed as an advantage because time-consuming and inconvenient purification customs, associated with menstruation, are minimized.

Enquiry into the nature of users' behavioural responses to a perceived side-effect (e.g., diet, rest, seeking of health advice) will often provide further insights into perceived seriousness of the effect and its role in determining continuation. A shortcoming of most clinic-based studies is that data on side-effects and their treatment may be available for only a selected minority of users who return to the same clinic where the method was initially prescribed.

Community-based enquiries represent an opportunity to obtain an unbiased sample of users who have experienced side-effects and to elicit a more complete picture of their experiences.

3.2.2 *Patterns of use*

As mentioned earlier, contraceptive methods vary greatly in the demands they make on users for effective use. For oral contraceptives

and coitally-related barrier methods, regularity and consistency of use are the major determinants of use-effectiveness. Thus the extent of user compliance with the recommended regime may be inferred, though not proven, from clinical or survey data on use-effectiveness. The detailed and intensive questioning of continuing and past users, which is possible in community-based surveys, may reveal much information of practical value for the improvement of services and counselling. For instance, to what extent does irregular use of oral pills reflect incorrect knowledge of the mode of action of the method (see Seaton, 1985). Similarly, does irregular use of barrier methods stem from supply, storage or disposal problems, from the varying circumstances and degree of privacy surrounding sexual intercourse, or from the antipathy of partner or spouse? How do successful users overcome these practical difficulties?

A correct understanding of the mode of action of the method may not be a pre-condition for successful use, but a systematic enquiry could provide the explanation for low use-effectiveness and for perceived side-effects or other concerns about the method. The need for user comprehension is obvious in the case of periodic abstinence, and is perhaps as important for effective use of oral contraception. Less predictably, perception of the intra-uterine device as a barrier method or as free-floating in the body may cause problems (MacCormack, 1985).

3.2.3 Perceived characteristics of the method

The rating of a method by users or potential users regarding such dimensions as safety, convenience, effectiveness and interference with sexual pleasure is obviously relevant to method evaluation from the user perspective. Interpretation of this type of data is strengthened when ratings of several different methods can be compared (see Tanfer and Rosenbaum, 1986), and/or the opinions of continuing and discontinued users of a specific method contrasted. The social and moral connotations of methods may also merit investigation. Confusion between vasectomy and castration, or between contraceptives and abortifacients may affect opinions on methods. Similarly, the belief that condoms are most appropriate for use with prostitutes may condition acceptability of this method.

3.2.4 Perception of services

The nature, quality and efficiency of services are probably of equal importance to the physical properties of the method in determining its

acceptability and continued use. Recognition of this fact has given rise to the specialized area of *health systems research*. Many of the central concerns of this genre of research, such as assessment of staff levels and training needs or of the adequacy of referral networks, lie outside the scope of these Guidelines. However, by identifying service-related problems as perceived by the users, community-based social science studies can contribute considerably to health systems research. For example, social science studies can answer questions such as: What information is given to users at the time of initial acceptance or on subsequent visits? Do users consider that this information was accurate and sufficiently detailed? Is the method considered expensive in terms of fees or related travel or time costs? What is the attitude of users towards the schedule of re-visits and physical examinations? Are clinic opening times considered to be convenient? Are delays experienced at clinics an important source of dissatisfaction? For an exceptionally detailed evaluation of health services from the patient's viewpoint the reader is referred to Sung, 1977.

It should be noted however that the record of social science surveys in disclosing user discontent with services is not impressive. In many cultures, it appears that individuals are reluctant to criticize. It is therefore unwise to rely exclusively on the direct testimony of users. Other approaches to the evaluation of user satisfaction with services, such as structured observation and interviews with key informants are discussed later.

3.2.5 *Decision-making*

For most methods successful introduction demands at least two major decisions from users: the initial decision to try the method and the decision to continue using it or to stop its use. Information on the dynamics of decision-making may suggest ways in which the informational and educational aspects of method promotion can be improved. In some settings the role of the mass media should be considered (see for example, Jones et al., 1980a). More commonly, interpersonal communication is far more important. It may be useful to know what types of people were consulted before a decision was made what was the nature of their advice, and how were they perceived with regard to credibility and power to influence (see Porter, 1984). The role of service providers on decision-making may also be assessed.

3.3 Determinants of outcomes

The range of possible influences on intermediate and ultimate outcomes is very wide and selection of factors for inclusion in a study depends on its objectives and scope. For instance, a multicentre study spanning many different communities or even countries may need to examine community characteristics, such as urban-rural character, predominant religion or social acceptance of contraception (as indicated by the overall level of use of existing methods) in order to explain inter-site differences in a new method's performance. Such community factors are irrelevant for a single-site study, where the emphasis has to be on explanation at the level of individuals.

3.3.1 *Socioeconomic characteristics*

Education and literacy are usually found to be more powerful predictors of contraceptive behaviour than characteristics related to economic factors, such as employment, occupation, income, or standard of living. Even when there is no particular interest in analysing socioeconomic differences in acceptability or continuation, the inclusion of some background variables is advisable in order to establish the extent to which the study population is representative of the wider host population. Information on socioeconomic differentials in successful use may also indicate the suitability of the method for nationwide provision.

3.3.2 *Demographic characteristics*

Eligibility for, and the appropriateness of, certain methods of contraception may depend on a person's age, marital status, and fertility history. Furthermore, these factors largely define the strength and nature of motivations for fertility control. For most studies simple measures of prior fertility (such as number of living sons, daughters, and deceased children and recency of last birth) will suffice; for some purposes, a complete history of live births or pregnancies (including dates of each pregnancy termination) may be required.

3.3.3 *Fertility control motivation, prior use, and attitude to fertility regulation*

While motivation to regulate fertility may be inferred imprecisely from demographic characteristics, the nature of motivation (whether for purposes of family size limitation or birth-spacing) and its intensity

should be measured directly. An illustration of the importance of strength of motivation for successful use may be found in Jones et al. (1980b).

Successful prior use of a method is likely to be a powerful predictor of success with a new method, though this finding by itself contains little explanatory insight into the reasons for success. As with prior fertility, a summary of past use (such as methods ever used and details of last method used including reason for discontinuation) typically will be sufficient, though a complete retrospective history of episodes of use may be required in some studies.

One reason for the common finding that past use predicts current or future use is that prior successful experience of contraception signifies both motivation and an acceptance of the morality, social respectability and feasibility of fertility regulation. A deep ambivalence on these matters is probably characteristic of individuals living in societies where contraception is little practised, even when the desire to limit family size is strongly felt. Such ambivalence may act synergistically with side-effects and other use-related problems to produce low acceptability and continuation rates. Measurement of cultural and social attitudes towards the notion of contraception or the belief that reproduction is subject to personal control (such as self-efficacy) is not easy but should be considered when a new method is being introduced in a culture where practice of contraception is low. For instance, the degree of perceived social support for contraception may be ascertained by asking individuals whether they think that different categories of persons (for example, priests, older people) approve or disapprove of contraception. There have also been many attempts to measure self-efficacy: see for example Clifford, 1971, for measurement guidelines.

3.3.4 *Inter-spousal communication*

One great advantage of community-based studies over clinical trials is that it permits investigation of the role of the spouse. The attitudes and beliefs of the spouse may be as important a determinant of adoption and continuation as those of the user. The willingness of husband and wife to talk about sex and contraception may also be an important influence on successful use, particularly of coitally related methods (e.g., Hill et al., 1959; Poffenberger, 1968).

3.3.5 *Frequency and circumstances of sexual intercourse*

For barrier methods, vaginal rings and "morning after" pills, the frequency of sexual intercourse and its circumstances may influence method acceptability, suitability, use-effectiveness and continuation. Of particular relevance may be the nature of the relationship (conjugal or casual) and the privacy of intercourse.

3.3.6 *Service characteristics*

Problems with services from the users' perspective were discussed under Intermediate outcomes (section 3.2). Here, the concern is with the 'objective' characteristics of services such as: types and training of service provider; the attributes of service providers, including their attitudes, personal experience of, and preferences for, particular contraceptive methods; quality, length and methods of counselling; the regime of clinical examination and check-up visits; the characteristics and work routine of outreach staff; treatment of side-effects; and the scale of fees charged. Of special importance is the study of the knowledge and attitude of services providers, which is often a key determinant of success or failure in the introduction of a new method. As mentioned earlier, other features of clinical services may be important determinants of successful introduction of a new method, but it may be difficult to isolate and quantify their impact unless there is deliberate experimental variation or sufficient variety of procedures among clinics participating in the study. It may be noted, however, that, even in single-clinic studies, travelling time to the clinic differs between individuals and thus may be analysed as a determinant of continuation. It is also true that the cost and quality of service may not be the same for all users; it is possible that the poor and least educated receive the most cursory treatment and experience the highest costs in relation to income. Such (unintended) variations in services are amenable to study by social science methods by observing client-provider interactions.

3.3.7 *Health beliefs and values*

Among the various determinants of contraceptive choice and continuation of use discussed in these Guidelines, the topic of general health beliefs and values is perhaps the most neglected in social science studies. Yet health beliefs and values may exert a powerful influence on method acceptability, perception of side-effects and continuation. Beliefs about the functions of menstruation is one example that has already been men-

tioned and has been the focus of extensive study. Similarly, erroneous beliefs about female anatomy may give rise to fears that intra-uterine or barrier devices can get 'lost' in the body (e.g., MacCormack, 1985). Attitudes towards touching and cleaning genital areas may also carry implications for the convenience and use-effectiveness of certain methods. Beliefs concerning efficacy or potency of different types of medication may influence reactions to particular methods. For instance, it is believed in many cultures that injections are more powerful than oral preparations. Investigation of relevant health knowledge and attitudes can greatly assist the appropriateness of counselling procedures and assist in explaining the popularity, or otherwise, of specific methods.

3.3.8 *General values*

There is a long history of attempts to relate contraceptive adoption and successful use to the possession of 'modern' values, such as individualism, a planning and achievement oriented attitude to life, and a sense of mastery over nature (e.g., Smith and Inkeles, 1966; Kahl, 1966; Freedman and Whelpton, 1951). Study of such values is more relevant to the assessment of demand for fertility regulation in general, than to the investigation of specific methods. Moreover, many indicators of modernism can be criticized as being ethnocentric and problems of adapting measurement procedures to different cultures have been experienced. Any researcher wishing to relate general values to contraceptive use should be aware of these difficulties.

4. Research design options

4.1 Relationship of study design to objectives

The first pre-requisite of good research is that its general purpose and specific objectives be clearly defined before its design is finalized. The objectives may be descriptive in nature (e.g., measurement of perceived side-effects and satisfaction among users of a new method); they may be explanatory (e.g., determinants of method continuation); or they may take the form of assessing an intervention (e.g., the effect of domiciliary visiting on method continuation). Many research projects have multiple objectives, including descriptive, explanatory and impact-assessment ones. It is necessary to ensure that a single research design can accomplish all its agreed objectives.

The purpose and specific objectives of the study will determine the nature of the study population, the choice of comparison population (if any), the use of a cross-sectional or prospective design, the information to be collected, the methods of data collection, and the form of data analysis. This section considers the choice of the study and comparison populations and the merits of cross-sectional and prospective designs. Methods of data collection and analysis are discussed in section 5.

4.2 Choice of study population

Choosing a study population may involve three tiers of decisions: (a) issues of geographical coverage; (b) selection of clinics; and (c) selection of individuals. At this juncture it should be noted that not all new methods are supplied through clinics. However, most of the following discussion applies equally to other types of delivery system.

The geographical coverage of the study depends not only on the objectives of research but also on its cost and feasibility. At one extreme are multinational studies which involve parallel research by different teams in different settings. Such a design is essential for the assessment of the performance of the method in very diverse cultures. At the other extreme are studies confined to a single small area or a particular religious or ethnic group. Local studies of this type are attractive because of their

easy feasibility and low cost, but their findings cannot be readily applied to the wider population. In between these two extremes is a range of possibilities including nationwide, regional and single-city or even neighbourhood studies.

The selection of clinics is closely related to decisions about geographical coverage. Purely scientific criteria favour the inclusion of a large number of clinics, selected with equal probability or with probability proportional to actual (or expected) number of acceptors. A large number of clinics increases the representativeness of results. As mentioned earlier, the nature and quality of services are potentially major determinants of method acceptability and successful use, and clinics may vary widely in relevant characteristics such as emphasis placed on particular methods, size, staff-client ratio and opening hours. It is equally true that method performance may depend on community characteristics. Thus investigations based on a small number of clinics or catchment populations may yield results that are atypical or even idiosyncratic. A further advantage of a large sample of clinics is the possibility of introducing experimental inter-clinic variations in counselling or outreach procedures.

Practical constraints on these scientific desiderata are often severe. Apart from considerations of cost and feasibility, the new method under study may be available at only a few clinics. The willingness of clinics to participate may further limit the choice. The purpose and proposed scope of the research project has to be explained fully to clinic staff and agreement negotiated. Institutional agreement, at a higher level, including clearance by ethical committees, also must be obtained, in order to prevent problems that may arise later in the absence of official approval.

Finally, a realistic appraisal should be made of the capacity of each clinic to participate in the study. The extra burden of work on clinic staff depends on the research design of the study. At the very least, most social science studies will require a well maintained clinic register of acceptors, and linked details of re-visits, complications and discontinuations. Unless detailed addresses or locations of all acceptors are available, a community-based follow-up study may encounter serious problems of sample bias. Experience suggests that users with stable and easily identifiable addresses tend to come from relatively higher economic strata. Practical ways of overcoming this are discussed in Annex 3. Many studies will require a much greater commitment in terms of domiciliary visiting, extra record-keeping, filing and report writing. Issues to be

raised at an early stage include the following: does the clinic possess enough trained staff, working space and materials to perform these tasks? Will it be necessary to recruit and train extra staff? What will be the working relationship and division of responsibilities between the permanent clinic staff and research staff? What adjustments will have to be made to enable the clinic to operate in as near to normal fashion as possible?

The final tier of decisions concerns the selection of study individuals. The choice is already constrained by medical and perhaps other criteria of client eligibility and by the consent of clients to try the new method (see section 7). Knowledge of these criteria is particularly important for the choice of an appropriate comparison group, which will be discussed below. Despite these constraints, there are usually a number of options in selecting individuals for study. Samples must be defined in space and time, before details of selection can be considered.

Social science investigations of the use of new methods are typically community based: they involve interviews with individuals or groups in their homes. If clinics have widely scattered catchment populations, this characteristic poses a considerable logistic and financial burden. In many countries fieldwork is expensive as it involves subsistence and travel costs, as well as salaries. There may therefore be strong practical arguments for restricting the study population to individuals living within a certain radius or travelling time of the clinic. But there is a serious drawback to this tactic. Individuals who travel a long distance to a clinic are likely to differ in key characteristics from those who live nearby. For instance, they may be more motivated and better informed. Resolution of this trade-off between expediency and selectivity will depend on the local circumstances. The important point is to make an explicit decision, in full knowledge of the implications.

In defining the study population and the duration of follow-up of subjects, two aspects must be considered. The first concerns investigations in which all, or a sample of, individuals enter the study population as they are enrolled at selected clinics as acceptors of the method. The study population thus accumulates over time, and a decision is required to fix beginning and end dates for entry into the study. This decision depends on the desired sample size and the acceptance rate. The main practical problems arise when this rate diverges from expectations. If the number is greater than expected, the sampling fraction can be reduced and weighting factors introduced at the analysis stage if considered neces-

sary. Alternatively, the closure date can be brought back. When the number of acceptors is lower than expected, the solution is less obvious because extension of the entry period is likely to increase costs. It is also unwise to extend the period for some clinics but not others, because the characteristics of acceptors may change over time and complicate analysis of inter-clinic differences.

The second aspect of the time dimension concerns the length of observation or follow-up period. The incidence of side-effects, reactions to them and discontinuations are all time-dependent variables. Typically, the first few months following acceptance are crucial; in this period the rates of discontinuation and method switching are high. Nevertheless, a study that focuses exclusively on this initial phase provides an incomplete account of user experience and satisfaction, and for most analytic purposes, a longer observation period is required. For instance, adequate investigation of satisfaction among individuals who have undergone sterilization demands a follow-up period of several years (Warren et al, 1988).

Once the study population has been defined in space and time, the investigator may still face a number of options in the detailed sample selection procedures. Except for small exploratory studies, the principles of probability sampling should be followed, whereby each individual eligible for inclusion has a known chance of selection. Simple random sampling from clinic registers, however, may not be the best strategy. Stratified sampling should always be considered because it increases the efficiency of the sample. For instance, strata may be formed in terms of number of children, educational level, prior use of another method, or locality of residence. Over-sampling of certain less common types of acceptor may be desirable, so that sufficient numbers are obtained to permit separate presentation of results for these minorities.

4.3 Use of comparison groups

For exploratory or purely descriptive research projects, a single sample of acceptors of a new method may be acceptable. Many useful social science studies have been of this type. Similarly, an investigation of the determinants of successful use of a contraceptive may be based on a single sample of acceptors. However, this approach has limitations as difficulties may arise in the interpretation of results. Consider the following example:

Suppose that a community based follow-up survey of rural acceptors of a new method gave the following results: percentage of acceptors continuing with the method after six months--65; percentage of continuing users reporting overall satisfaction with the method--73; percentage of discontinuers who cited menstrual irregularities as the main reason for discontinuation--35. How are these results to be evaluated? Are they sufficiently encouraging to recommend national incorporation of the method, or do they suggest that further modifications to the method or services are needed? Does the rather low level of continuation reflect a general lack of commitment to the principle of birth planning in this rural population or method-specific problems?

The main problem in such cases is the lack of a comparative perspective. What is needed in this instance for sound policy-relevant interpretation of results is similar results for rural users of another method (or methods) or comparison with urban users of the same method, so that the performance of the new method can be rated against alternatives. This sub-section concerns the various ways in which comparison can be incorporated into the design of social science investigations. These include: experiments; comparison with users of other methods; and before and after comparisons.

4.3.1 *Experimental comparisons*

In certain circumstances, the classical experimental method of randomized trials, as used for vaccine testing, are appropriate for the assessment of new methods of contraception (e.g., Chi et al., 1987; Sivin et al., 1987). But for obvious ethical and practical reasons, the applicability of this approach is limited. However, it is often feasible and ethical to test the effect of alternative counselling, clinical or outreach procedures on method continuation, use-effectiveness or satisfaction in a truly experimental manner by random allocation of acceptors to different procedures. Examples include experiments to measure the effect of domiciliary visiting on continuation rates (e.g., Chan, 1971) and experiments to measure the effects of IUD insertion by fully qualified doctors and by paramedical staff on subsequent method use and satisfaction (e.g., Eren et al., 1983).

Because of the potentially greater number of factors requiring control, the social sciences have a less developed tradition of experimental research than the biomedical and epidemiological sciences, with the result that opportunities for experimental study of social or educational inputs

in the context of provision of new contraceptive methods remain under-exploited.

True experimentation requires very careful ethical consideration, detailed advance planning and rigorous adherence to agreed allocation procedures. It usually demands a major commitment by clinic staff. Sometimes, however, natural variation in services can be studied in a quasi-experimental manner. For instance, clinics may be staffed by male and female doctors and by paramedical counsellors, some of whom are using the new method. The effect of the sex of the doctor and contraceptive status of the counsellor on method adoption, compliance with the re-visit schedule and method continuation may be studied as if these variations in service characteristics were the subject of a true experiment. The validity of such quasi-experiments depends on how closely the allocation of clients, or potential clients, to different treatments corresponds to random, or chance, allocation. The ability of clients to choose the type of doctor or counsellor clearly vitiates the principles of experimentation and makes it difficult to isolate the effect of the service characteristic on method acceptance or subsequent use from client characteristics.

4.3.2 *Comparison with use of other methods*

The most common way of introducing comparability into studies of a new method is to collect similar or identical data for acceptors of another method (or other methods). In principle, the strategy is straightforward. The comparison method is chosen on substantive or programmatic grounds, and is defined in time and space as for the study population. The two samples are selected and studied in similar ways. The performance of the new method can then be compared to the performance of the other method under similar conditions.

Interpretation of such comparison is not so straightforward. The difficulty arises from the fact that acceptors of the method under study and the comparison method are self-selected and thus may differ in characteristics that can be exerting an independent effect on the outcome variables (e.g., previous contraceptive experience, strength of motivation to control fertility, number of children, education). There may also be different clinical criteria for the use of the two methods. Wherever possible, these confounding factors should be controlled in the research design by matching the comparison sample to the study sample with regard to characteristics that are likely to influence successful use.

However, it is usually impractical to match for more than a couple of characteristics. It is therefore necessary to introduce further controls in the analysis.

Where observation of a proper comparison sample is not possible, less satisfactory types of comparison will have to suffice. The results can be compared to those of similar independent studies of other methods, though possible differences in clinic procedures and population characteristics may complicate interpretation. The new method can also be compared to previous use of other methods by acceptors of the new method. This type of comparison is only feasible in high-use settings where a considerable number of acceptors of a new method have had previous experience of other methods. It also suffers from life-cycle and selectivity effects. Attitudes towards contraception may change as reproductive life progresses. Moreover, individuals willing to try new methods may be drawn disproportionately from those who have found other methods unsatisfactory.

4.3.3 Before and after comparisons

Before and after comparisons serve a different purpose from comparisons with use of other methods. By collecting information on clients both before and after acceptance of a new method, they permit a more penetrating analysis of change. In turn, this helps to overcome one of the inherent problems of studies of users of new methods, namely the difficulty of distinguishing clinical and perceived side-effects or other consequences of method use. Individuals who have discontinued use of the method may exaggerate or invent ill-effects, a tendency that may stem from a desire for congruence between behaviour and beliefs (see, for example, the theory of cognitive dissonance in Festinger, 1957). While misperceptions, or rationalisations, may assume the force of reality for individuals and should be studied because they influence successful use of the method, it is useful nevertheless to be able to distinguish biologically-based and perceived changes.

Repeated measurement of relevant variables before and after use of a new method provides a firmer basis for identifying real changes in health or welfare than does exclusive reliance on post acceptance measures. Before and after comparisons are particularly useful when identification of the determinants of successful use is the major aim of the study. The initial, or baseline, measures are typically taken at the time of method acceptance. Relevant variables might include menstrual characteristics,

coital frequency and measures of marital and sexual satisfaction. The use of standard instruments for the measurement of psychiatric symptoms might be considered (see Goldberg and Hillier, 1979).

4.4 Prospective and cross-sectional designs

A major question for many social science investigators is whether to employ a prospective design, involving repeated measures, or to rely on a single cross-sectional approach. The advantages of the former include: an ability to detect changes in side-effects and attitudes with increasing duration of use; the avoidance of long recall periods; and the opportunity to collect extensive data by distributing topics to several separate interviews. The major disadvantages include: high cost, prolonged data collection phase; problems of sample attrition because of follow-up losses; and the risk that behaviour and attitudes of the study subjects will be modified by repeated interviewing. In addition, processing and analysis of data from prospective studies are relatively complicated. Files have to be matched and merged and the sheer volume of information that may be collected poses problems.

In contrast, single-round surveys are cheaper, logistically and analytically less complex, and quicker to complete. They provide a valid cross-sectional picture but lack the ability to analyse process or change, and are more vulnerable to recall lapse and rationalization than prospective studies. They also suffer from censoring. The elapsed time between initial acceptance of the method and interview varies between individuals; in a typical single-round study, some acceptors will be interviewed only a few months after acceptance, while others will be interviewed more than a year after. This individual variability in observation period, or exposure, generally has to be handled by life-table methods of analysis. It also represents an effective loss of sample size, because only a minority of the sample will have had a prolonged period of use, or potential use, of the new method. For this reason, single-round surveys have to be based on larger sample sizes than prospective surveys.

Prospective and single-round designs are not mutually exclusive. For example, a main sample of acceptors can be interviewed once and a sub-sample selected and followed-up. Such a mix is particularly attractive if it is possible to interview the main sample at some relatively fixed and short period after acceptance, e.g., three months. As noted previously, the early months of use are often critical and it is important to collect data on this phase while the experience is still fresh in respondents' minds.

5. Methods of data collection and analysis

Social scientists have at their disposal a range of data collection methods and related modes of analysis. As noted earlier, the choice of the main method will depend on the aims of the enquiry, but a mix of methods may well be the most rewarding option. All too often, however, social scientists working on introduction of contraceptives rely exclusively on the most familiar method--structured interview surveys--without considering seriously the possible contributions of other approaches, particularly to the investigation of motivations, beliefs and values that may have a major influence on contraceptive behaviour. These other approaches include unstructured or semi-structured individual interviews, focus group discussions and various types of observation. Usually, they complement larger-scale structured surveys. Less commonly, they can constitute alternatives to the survey approach, though this strategy is advisable only for experienced research teams with considerable interpretation skills.

The purpose of this section is to describe briefly the major data collection methods, to discuss their main requirements in terms of staff skills and analysis, and to highlight their main advantages and limitations. Further details about each of the methods described here may be found in the selected bibliography on research methods in Annex 1.

5.1 Unstructured individual interviews

In an unstructured interview, typically the interviewer is prepared with a number of broad topics to be investigated but has no list of precise questions. The interview itself takes the form of a one-sided conversation, in which interviewer encourages the respondent to talk freely and merely guides the discourse towards new topics from time to time. The order in which topics are discussed usually does not matter but, for reasons of comparability, it is important to ensure that all topics of interest are covered. As in a larger survey, it is preferable to start the interview with subjects that are not sensitive and that are likely to be of interest to the respondent. This tactic helps to establish a rapport with the respondent which is vital to the success of unstructured interviewing.

Respondents may be selected on the basis of a number of criteria. Key informants may be chosen for their special importance to the process of contraceptive introduction or for their specialist knowledge of issues of relevance to the enquiry, such as health beliefs. Examples of such key informants include clinic staff, and community-based health workers, midwives and leaders. Alternatively, unstructured interviews may be conducted on a small sub-sample of acceptors of a new method, in which case it is important to ensure that the selected respondents are representative in terms of education, family size and other such characteristics.

Answers of respondents may be tape-recorded, written down in long-hand or short-hand as the interview proceeds, or both methods may be used. The merit of tape-recording interviews is that it allows senior members of the research team to listen to the flow of discussion and the exact vocabulary used by informants. Moreover, no information is lost because of inattention or selective perception of the interviewer. The main analytical method is to listen to recordings and to read transcripts of the interviews, either copied from recordings or written by interviewers on the basis of notes made during the interview. This procedure demands both objectivity and creativity. Objectivity is required to assess the extent to which initial hypotheses are confirmed or rejected. Creativity is needed to detect new ideas and hypotheses. Successful use of this method is therefore very dependent on the skills and insights of the researcher and findings are typically impressionistic rather than numerical and take the form of hypotheses that may or may not be generalizable.

The process of interpretation can be assisted and accelerated by a formal content analysis in which answers on particular topics are extracted clerically from the transcripts and are then grouped together. This may be a cut-and-paste operation or may involve copying by hand. Care should be taken to preserve the respondent identification number for each excerpt.

The main advantages of unstructured interviewing over larger, structured surveys include: (a) respondent determination of the salience of topics and themes; (b) greater depth and detail of information; (c) greater opportunity to share and understand the viewpoints of respondents and how their beliefs and experiences with the contraceptive method under investigation relates to wider issues; and (d) possibility of discovering the unexpected, which is usually precluded in a highly structured approach.

There are, of course, some disadvantages. The successful application of this method requires highly skilled and trained interviewers, who themselves must understand the purposes of the research and indeed must become part of the research team rather than being merely data collection agents. Data interpretation also demands high level skills. Because interpretation is partly subjective, the analyst needs to be constantly on guard against the danger of using evidence selectively to support his or her own preconceptions or prejudices. A further implication of this element of subjectivity is a loss of reliability or repeatability.

Unstructured interviews produce a very large amount of information for each respondent and methods of recording and analyses are very time consuming. Accordingly, sample sizes are usually small, typically in the range of 20-60 respondents. Inevitably, this feature raises doubts about the representativeness of results, and great care should be taken to minimize these by careful selection of respondents.

These drawbacks of enquiries based on small numbers of unstructured interviews--non-quantitative results, low repeatability and dubious representativeness--suggest that the method is best suited for initial exploratory research or as a complement to larger, more statistical enquiries. For instance, small unstructured studies can yield hypotheses, new lines of enquiry, information on respondents' conceptualization of issues and vocabulary, and other invaluable guides for the design of questionnaires for larger and more structured surveys. Alternatively, unstructured interviews may be conducted in parallel with or following a larger enquiry, in which case their main purpose may be to act as a partial check on the validity of the larger enquiry, or to enrich the results of the overall research programme by exploring certain topics in greater depth, or to explain anomalous or unusual statistical relationships.

5.2 Group discussions

Group discussions share many of the features of individual unstructured interviews but, as their name suggests, enquiry takes place within small groups, usually between six and ten respondents. Discussion is guided by a moderator or facilitator and it is useful to have an observer to take notes.

Group discussions have an advantage over individual interviews in that they are quicker and cheaper to conduct for the same number of respondents. They permit exploration of ways in which people interact

in discussion of a topic and of the extent of agreement in opinion and attitude. Most importantly, a group context may be conducive for the expression of embarrassing or socially disapproved attitudes and behaviour. At least one person in a group is often prepared to voice such attitudes or relate such experiences. If this happens, the social reserves that may restrict communication in a one-to-one interview can dissolve, resulting in a discussion of remarkable frankness. For instance, a group discussion may disclose adverse feelings about clinic procedures or staff more effectively than other methods of enquiry. A final possible advantage of group over individual settings is the greater breadth of ideas, opinions and experiences that are likely to be expressed. The content of an individual interview is limited by the experiences, recall, conceptual and verbal abilities of a single person. In a group discussion, there is obviously a bigger pool of experiences and verbal talents.

As a research method, group discussions involve a degree of risk and unpredictability and therefore should not constitute the sole method of enquiry in most studies. While they can be very successful in eliciting a wealth of information at a low cost, they may also be dismal failures. If members of the group remain ill at ease with each other, if discussion is dominated by a single individual, or if the topics evoke limited interest, then little of value will emerge. These risks, however, can be reduced by careful planning and skillful conduct of the discussion.

The choice of venue for the discussion is one important practical consideration. It should be neutral with regard to the substance of the discussion (i.e., not held at a family planning or health centre), informal and congenial. Apparently minor points, such as provision of refreshments or attendants to take care of young children, can be critical to its success. In cultures where punctuality is not customary, special efforts may be needed to ensure that participants arrive at the required time.

The mode of selection of group members also demands careful planning. In general, groups should be as homogeneous as possible in terms of sex, educational background, economic and marital status and other relevant characteristics. This homogeneity will reduce the danger that discussion is inhibited by considerations of status or hierarchy.

In the context of research into the use of a new contraceptive method, it is uncertain how far this need for homogeneity should be taken. If, for instance, a major aim of the enquiry is to elucidate the reasons underlying successful or unsuccessful use of a method, should separate group

discussions be held for those who have discontinued and for those who are still using? In this example, the optimal strategy may be to hold both mixed and unmixed sessions, because their respective merits cannot be predicted in advance. Is it an advantage or disadvantage for participants in a group discussion to know each other? Sometimes participants are selected from among the membership of organizations such as mothers' clubs or from the same community, in which case they will be well known to each other. This familiarity may carry some advantages in reducing initial tension or embarrassment but also has attendant drawbacks. Social alliances or antipathies, of which the research team is unaware, may distort interactions and the presence of members of the same social community may make disclosure of disapproved attitudes more difficult. For these reasons, it may be preferable to hold discussions among people who do not know each other.

The performance of the moderator is vital to the success of a group discussion. The task does not require high academic qualifications but demands considerable communication skills. The first experience of running a discussion may be daunting and much has to be learnt by experience. Thus one additional value of a second researcher--the observer--is to evaluate the performance of the moderator and suggests ways in which it might be improved.

The following points clarify the role of the moderator:

- ✦ Do not convey the impression of being an expert but nevertheless be sufficiently familiar with the subject matter to pose relevant questions.
- ✦ Ensure that you remain the leader of the group, being able to curtail irrelevant discussion and broach new topics.
- ✦ Do not allow your own opinions to become apparent by expressing open agreement or disagreement with opinions of participants or by repeatedly seeking the contribution of particular individuals whose general viewpoint concurs with your own.
- ✦ Encourage all to participate and do not allow one person to dominate the discussion.
- ✦ Avoid a group question and answer format by encouraging discussion between participants.

- ✦ Control the time allocated to each topic.

- ✦ Be alert to pick up new information or perspectives and ensure that these are discussed in depth; conversely, do not allow the discussion to dwell at length on topics that have been explored fully in previous sessions and for which the prospects of fresh insights appear small.

- ✦ In order to avert the danger of an inadequate discussion of a particular topic, have a list of possible questions to rekindle interest; these may take the form of imaginary scenarios, for example, "suppose a woman found that her husband objected to use of the method, what might that woman do? How could she respond?"

Analysis and interpretation of group discussions involve steps that are similar to those already described for unstructured individual interviews, though it is not usually possible to link components to (individual) characteristics of the participants. Their time-consuming nature again implies that the number of discussions will usually be small, typically in the range of 5-20. Tape-recording is rather more important in group discussions than for individual interviews because it is difficult to make comprehensive notes during a group discussion.

5.3 Participant observation

Participant observation is the classical method of social anthropology. To a greater or lesser extent, the observer becomes part of a study community and aspires to see the world through the eyes of its members. The use of this research method requires an anthropological training and a prolonged period of field work. For these reasons, and because the study of contraceptive behaviour is ill-suited to observation, it has rarely been used for research on new contraceptive methods.

However, the observation method can be applied in a narrower and more structured manner to the analysis of specific situations and interactions. Time-use studies and intra-household observations of food preparation or hygienic practices are familiar examples. In the context of contraceptive introduction, such structured observational techniques are most useful for investigation of client-provider interactions at family planning clinics.

The essential requirement for clinic-based observations is unobtrusiveness. The presence of an observer is always likely to cause some

reaction or changes in behaviour and it is important that this "contamination" be minimized. The dangers of altered behaviour are probably greater in the case of the provider rather than the client. The latter is already in an unfamiliar setting and may pay little attention to the presence of third person, nor see anything unusual in the arrangement. Conversely, clinic staff will be far more conscious of the observer and his or her purpose in being there. However, it is not easy to maintain artificial standards of behaviour for prolonged periods and therefore any initial contamination is not likely to persist.

As with interviewing techniques, observation may be structured to differing degrees. When the research issues of interest are well-established and can be clearly specified, a detailed check-list can be prepared and observational data recorded in the form of ticks or checks on the form. For instance, it may be of research interest to measure the precise advice or warnings about side-effects that are given to acceptors of a new method. In such a case, a complete list of possible side-effects is prepared and the observer enters a check against each one mentioned by clinic staff. Similarly, a comprehensive list of possible treatments or responses to each type of side-effect can be prepared and a check entered for each one mentioned. Such highly structured observation yields quantitative data (e.g., percentage of all consultations where increase in menstrual bleeding was mentioned as a possible side-effect) and can be conducted by well trained research assistants.

At the other extreme are more exploratory, less applied types of observation whose objective is to assess the more subtle and qualitative aspects of client-provider interactions. In such a case the focus of interest will be not only on what is said but on non-verbal behaviour of both parties. This type of observation demands experience, considerable skill and powers of interpretation and should only be attempted by senior members of the research team.

5.4 Structured interview surveys

Structured interview surveys involve the questioning of respondents in a highly standardized manner in which the precise sequence and wording of questions and methods of recording answers are specified in advance on an interview schedule or questionnaire. The overall objective is to obtain directly comparable data from each respondent, by minimizing the variability of the interview situation. This objective implies that the questions be asked in exactly the same manner and that

the social and geographical setting of the interview should be similar. For instance, it is likely that interviewing in a clinic will yield different responses on certain topics to home interviewing and it is therefore unwise to mix these two settings in the same survey. This point is of obvious practical relevance to surveys of contraceptive acceptors. Similarly, the degree of privacy may affect response. The presence of clinic staff or spouse within earshot carries obvious possible implications for the willingness of respondents to reply honestly to certain questions. For these reasons, it is highly desirable that all interviews be conducted in privacy.

This objective of standardization also implies that the merit of a survey will depend greatly on meticulous preparation of the instrument. The precise information required to meet objectives must be decided. Measurement issues must be resolved. Questions must be devised that are unambiguous, relevant, and easily comprehensible to respondents. The flow of questions and interviewer instructions must be clearly laid out and must be conducive to creating and maintaining rapport. Careful forethought must be given to the recording of answers, construction of coding categories and their entry onto a computer-readable medium.

The development of a questionnaire may involve the following steps:

- + On the basis of the objectives of the study compile a list of topics, or hypotheses, to be canvassed in the survey.
- + Discuss these with other interested parties and refine as necessary.
- + Conduct exploratory research in the form of unstructured interviews and/or group discussions in order to identify other topics of potential importance and to establish ways of measuring the concepts developed.
- + Prepare a first draft of the questionnaire, translate (and translate back for checking purposes) into local languages, where appropriate, and conduct a small-scale pre-test.
- + Prepare a revised draft with instructions for interviewers' and conduct a pilot survey under field conditions, preferably using interviewers who will also be part of the main survey.
- + Carry out a hand analysis of the pilot survey and, on this

basis and from extensive de-briefing of interviewers, finalize the content of the questionnaire.

✦ Consult with data processing personnel regarding the final design of the questionnaire in order to minimize the risk of problems at data entry and editing stages.

There is a huge amount literature on the design of questions and questionnaires. Some of the essential points are summarized below as a check-list of things to consider with regard to each question:

✦ Can the question be shortened by eliminating of unnecessary words or by disaggregation into several different questions? Similarly, does the question contain several different themes or concepts that might confuse the respondent?

✦ Is the question neutral or does it mention only one of the possible answers, thereby increasing the chance that this answer will be chosen?

✦ Does the question contain an implicit assumption that may not be valid? For instance, the question "What side-effects did you experience?" assumes that some side-effects do occur. Similarly "For how long did you breastfeed your child?" carries the assumption that weaning has occurred.

✦ Does the question define, where necessary, what is meant by certain terms? For instance, the phrase 'family planning' can have a variety of different meanings. Past experience suggests that in order to obtain reliable information on knowledge or use of methods, it is necessary to ask method-specific questions. Similarly, the question "Do you work?" is irredeemably vague.

✦ Does the question use local terms and words that are familiar to the respondent?

✦ Does the question pose an unnecessary burden on the respondent to recall several different elements simultaneously before attempting a response? For instance, the question "How much did your last visit to the clinic cost?" requires the respondent to recall the occasion of her last visit, travel costs and clinic costs. In this instance, it is preferable to ask a series of more simple questions. For example, "When did you last visit the clinic? How did you travel to the clinic? How much did you pay for

the transport? Did you have to pay any money to the clinic?" etc. Such disaggregation assists the respondent to recall relevant details and should yield data of higher reliability than a single global question.

✦ Does the question elicit answers that are sufficiently precise to meet analytic objectives? This point is particularly important in the investigation of side-effects. Answers such as "irregular bleeding" or "backache" are too vague to assess objective or subjective importance for overall method satisfaction. Irregular bleeding may refer to variability in duration of menstruation or to spotting between menstrual periods. Similarly, backaches may range from minor discomfort to severe functional incapacity. A series of very detailed questions is required for adequate investigation of both types of side-effect.

✦ For questions where the need for probing is anticipated, are illustrative probes printed on the questionnaire? Similarly, where verbatim recording of all answers to a question is required, is this requirement made clear to the interviewer by a written instruction?

✦ When answers are pre-printed on the questionnaire, are they comprehensive and mutually exclusive? Is it made clear to the interviewer whether they should read them out or not?

✦ Do questions follow a logical and natural sequence? Are skip and filter instructions clearly displayed?

The above check-list may assist researchers in avoiding some of the more obvious pitfalls but practical experience is also extremely important. Above all else, a well-constructed questionnaire demands a firm and detailed grasp of analytical requirements--which determine content--and the imagination to see questions, and their possible difficulties, from the viewpoint of the average respondent--which determine the precise wording of questions.

In the excitement of developing a questionnaire, training interviewers and organization of fieldwork, it is easy to overlook data processing and analysis requirements. Yet it is precisely at these later stages of survey implementation that prolonged delays most frequently occur, resulting in delayed publication of results. In reality, data processing starts at the beginning of fieldwork, when all completed questionnaires should be checked for completeness, legibility and consistency. Errors detected at this stage by interviewers themselves or supervisors can be corrected,

if necessary, by a revisit to the respondent. Unless errors are detected immediately, it may become extremely expensive or impractical to conduct re-interviews. Seriously flawed questionnaires may have to be discarded.

Even when a rigorous field checking system has been implemented, it may still be advisable to conduct a manual re-edit at the survey headquarters. Experience suggests, however, that the efficiency of such editing is low. The task is extremely boring and repetitive and thus it is difficult to maintain the concentration required to spot errors. At the very least, some incentive or reward system should be considered to increase the attraction of the work and hence the motivation of staff.

The extent of coding--the conversion of answers to numerical form--depends on the design of the questionnaire. Open-ended questions--those requiring the recording of verbatim answers--always require coding and this aspect of survey processing requires considerable skill and supervision. Closed questions, however, may need no coding at all, provided that the questionnaire is designed appropriately. Annex 2 shows two typical but alternative layouts. In the first example, answers are recorded in a separate column by circling numbers and the data can thus be entered straight onto diskette or tape without any intermediary preparation. This arrangement avoids the introduction of additional human errors via the coding process. In the second example, answers are recorded amidst the main text of the questionnaire, thus making it difficult for direct computer entry. For questionnaires of the second type, answers (in numerical form) may have to be transcribed onto a separate coding sheet or to a separate data entry column printed on the questionnaire.

The next step in the processing of survey data is to enter the edited and coded questionnaires onto a computer-readable medium. Recent developments in computer hardware and software have made it possible to combine entry with computer editing. Range, structure and consistency checks can be pre-programmed so that the entry of any erroneous value is immediately flagged on the screen. This interactive entry-edit method has the benefit that a 'clean' data file is produced at the outset. However, there are disadvantages. The detection of errors slows down the rate of data entry and requires the presence of more senior and experienced staff to resolve them. Depending on local circumstances, it may be preferable, therefore, to enter data without checking or to restrict checking activities at this juncture to simple edits (such as range checks) that should have a

low error rate and can be resolved in a straightforward manner. Under this strategy, the main editing will be performed on the whole data file or in batches. Error lists will need to be produced, with the file being subsequently updated, and checks re-run until no further errors are detected.

It should be stressed that the editing of lengthy and complex questionnaires, particularly those that collect information about logically related dates and durations such as birth or contraceptive histories, can be an extremely demanding and time-consuming task. Advance planning is essential and precise rules have to be specified to resolve errors that arise from missing, partially complete or inconsistent data.

Once the data file is clean, the final step before the main analysis is to derive from the raw data those variables that are required as direct inputs to tabulations and other analytic data classifications. Variables may be derived from the raw data by combining answers from several different questions, by forming aggregate scores from lists of opinion items, by simple mathematical manipulations (e.g., calculation of durations from calendar dates of successive events), and, in a multitude of other ways, re-arranging items for analytic convenience. These derived variables may be physically added to the raw data file or may form a new analysis file. Alternatively, they may merely be constructed in programming code and have no physical presence on the data file.

The analysis itself will typically progress from straightforward tabulations to more advanced techniques. For time-dependent variables, such as use-continuation rates, life-table techniques will be required. A full exploitation of the data may well require regression techniques and perhaps finally the application of hazards models (estimation of life tables with co-variates).

5.5 The use of clinic records

The role of clinic records in social science investigations will depend very much on the scope and purposes of the investigation. In some studies, these records will provide only a sampling frame of acceptors. In other studies, information collected by clinic staff on medical and personal characteristics, compliance with the schedule of re-visits, occurrence and treatment of side-effects may form an important part of the study.

In general, it is advisable to confine recording of information by clinic staff to simple, factual information and to design correspondingly clear and simple recording forms. Questions requiring verbatim recording of answers and attitudinal questions should be minimized.

These restrictions on the data collection contribution from clinic staff stem from practical considerations. Clinic staff have other duties and priorities that take precedence over research, and therefore it is inappropriate to burden them with an extensive additional task. Moreover, it is not a good idea to combine the roles of counsellor and research investigator. Very different skills and outlooks are needed for these two tasks and it is therefore unlikely that both can be performed simultaneously with success.

6. Practical aspects of research planning and implementation

6.1 Preparation of a research proposal

Every protocol should include a well articulated and realistic timetable. Such a timetable is essential for the formulation and evaluation of budgetary allocations and for planning the project.

The best way of presenting the timetable is to list (vertically) every step of the study (e.g., testing of questionnaire, training of interviewers, supervision, reports, recruitment of cases, and beginning of home visits), and the months (horizontally) during which the study will take place (see Fig. 2). For each step an entry should be made in the cell(s) corresponding to the month(s) when it will be carried out. Overlapping of steps should be checked to ensure that they follow a logical sequence. For example, staff cannot be trained to fill out forms before the forms and the manual are finalized.

Fig. 2. An example of timetable for project activities

Item	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
Preliminary, exploratory field work	=====											
Design of questionnaire	=====											
Pre-test of questionnaire			=====									
Training of interviewers				=====								
Collection of data						=====						
Coding of data									=====			

When the study starts, a copy of the timetable should be exhibited at the clinic and research headquarters, so that staff can ensure that the right steps have been completed, and are being carried out on schedule. Sometimes it will be necessary to make adjustments, based on field experience, such as allowing enrolment to continue for a longer period than originally planned.

A detailed presentation of the budget is a critical step in the preparation of a research project (see Table 1). To prepare a budget there must be a detailed study design and the major steps in the timetable must be reflected in budget entries. The study design should provide information on the number of respondents, estimated number of home visits, number of clinic visits, forms and other materials to be printed, computer supplies, etc.

6.2 Supervisory systems

Supervision provides opportunities to continue training, to correct mistakes and to reinforce standards. Frequent supervision is needed, especially during the first months. The responsibilities of the supervisors should be defined in detail. How often will they visit each clinic? Will there be non-scheduled visits? What will be checked each time?

Table 1. A sample budget presentation

Personnel	Number of persons	Duration in months	Number of persons-months	Cost per person-month	Total cost
Supervisor	1	24	24	1,000	24,000
Pre-test interviewers	10	1	10	500	5,000
Main survey interviewers	30	5	150	500	75,000
Data entry/editing staff, etc	5	10	50	400	20,000

The number of clinics involved in a study will determine the supervisory structure. In a single-clinic study, it may be sufficient to have one responsible clinic-based person, with the principal investigator in overall charge. If more than one clinic or more than one country (in a comparative study) participates, more elaborate supervisory measures must be considered. For instance, it may be necessary to have a regional supervisor in addition to a clinic-based supervisor. In the case of a study involving many clinics in different parts of a country, several regional supervisors may be needed. In multi-national studies, one principle investigator will be responsible for each national component. Multi-site studies may require a technical co-ordinator who will act as the main link between the research institute, or sponsor of the study, and the participating organizations or clinics. The co-ordinator should be an experienced professional with some knowledge of the language spoken in the country to be visited if possible, or of the common language used in a multilingual region. This person should have research experience and must have a good knowledge of the different contraceptive methods provided. A timetable for visits should be agreed upon early in the study, and a check-list prepared that defines the purpose and scope of visits.

Reports on such visits will include information on all items in the check-list, and on any other aspect of the study that may seem important. The development of the study, according to the timetable, should be examined during the visit. The co-ordinator will discuss and suggest solutions for problems encountered. Participating clinics must be visited in order to obtain a first-hand feeling of the difficulties in the field. Un-scheduled visits should be made occasionally, especially to clinics where the performance is below average or recruitment is behind schedule. Finally, some time must be set aside for discussing the reports and problems encountered by other supervisory staff.

6.3 The role of clinic staff

Social science studies of new contraceptive methods are carried out mainly by specially trained research staff. However, the role of clinic staff is also crucial. They provide the contraceptive methods and collect the baseline information that will be used as part of the research. Their attitude towards the study may influence the quality of clinic-based data. However, these workers rarely have any training in research methodology and it is often difficult for them to understand the potential contribution of social research or its procedures.

One potential danger of studies that involve comparison of a new method with an existing one is that clinic staff may pay special attention to users of the new method. This tendency can distort results of the trial. To the greatest possible extent, it is important to ensure that study and comparison groups receive similar quality of clinical care.

To address these problems, it is essential that clinic staff involved in the study be provided with a full briefing and relevant training. They should be told of the study's purpose, and should receive some information on research methodology, techniques of interviewing, and instructions for completing the forms. Staff should also be well acquainted with the time-table, and know the procedures to be observed at each follow-up visit. Information on the new method should also be provided and staff should understand why they are involved and what they may gain through their involvement.

Training must be a continuous process, as people tend to forget the study procedures, and also because new staff need briefing. This continuous training is also important in order to avoid mistakes that may jeopardize the study.

To ensure that similar training will be applied in all centres and that trainees can discuss their doubts concerning what to do in special situations, it is necessary that written instructions, in the local language, be given to each participating group. Instructions should include what to do at each follow-up visit.

During training, the importance of following agreed clinic protocols should be emphasized, as well as the need to fill in the forms correctly, to provide the client with adequate information and support, and to register the users' addresses as completely as possible to facilitate finding them later on, if needed. Further suggestions on ways in which loss to follow-up can be minimized are given in Annex 3.

In training clinic staff, it is important to ensure that the staff are able to obtain reliable information from the clients. When questioning clients, it will often be necessary to probe further into vague or irrelevant answers, so as to clarify inconsistent replies. When and how to probe is a skill that is acquired with practice. An important point to stress is that the staff must never suggest an answer.

It is vitally important that clinic staff remain motivated throughout the

study. This can be accomplished by periodic meetings, where partial results and problems are discussed. If new routines are introduced in the clinic to help accomplish the study's purposes, they should be clearly defined in terms of which workers do what, when, and the different steps to be followed by clients when they come to initiate a method, or for follow-up. Changes should be kept to a minimum, however, and special care should be taken to avoid overburdening the staff with long working hours, or with activities for which they are not prepared or remunerated. The purpose of a field study is to assess the contraceptive under "normal" programme or clinic conditions. Therefore, "normal" routines must be preserved and respected.

6.4 Recruitment of subjects

Once staff training has been completed and all necessary supplies are available, subject recruitment may begin following pre-arranged ethical standards (discussed in Section 7 below). Before offering the new method to a client a screening form should be completed, in which all the factors defining eligibility are recorded. This will avoid problems related to contraindications for admission to the study. If the person fulfils the requisites for participating in the study, her/his signature (or thumb impression) must be obtained on a consent statement.

Success in attaining the number of admissions required to reach the desired sample size depends not only on the method's performance, but also on the motivation of clients. It is assumed that subjects participating in the programme are motivated to use contraceptives for spacing their pregnancies or for limiting the size of their family. Information given by health personnel from maternal and child health clinics, friends, relatives, mass media or others can transform motivation into action.

Compensation should not be provided to users of the new method unless a system exists to compensate all users in a particular clinic or context. Any compensation should be only to defray extra costs or loss of benefits, such as transportation, returning to the clinic and being examined more often than regular users, medication for side-effects, time lost from work or from family responsibilities, and must be reasonably related in amount to these types of expense.

Special care must be taken to ensure that compensation is not used as a way of recruiting study subjects to meet sample sizes, or as a way of keeping them in the study. Patients should volunteer freely for the study

and should be free to leave it at any time. *Compensation should not be interpreted or used as an incentive* for participating in the study.

Information, education, politeness, and kindness will probably be very good incentives for users to return to the clinic. Short waiting periods, the assurance that complaints will be taken into account and treated, and that clients can discontinue the method when they wish to, will also act as incentives. Such compensation is, without exception, preferable to monetary incentives.

6.5 The role of research staff

In most social science studies of contraceptive introduction, the main task of research staff will be to gather information by various types of home interviewing. This community-based data collection effort may be supplemented by clinic-based research activities.

Regardless of precise arrangements, it is vital that a good working relationship between clinic and research staff be established and that a clear demarcation of duties be specified. It is also important to avoid the impression that the research team in some sense is assessing the quality of clinical work, because this may lead to suspicion and lack of co-operation. As described in the previous section, thorough briefing of clinic staff and training, where relevant, should minimize the risk.

The main practical considerations of project implementation as they relate directly to research staff are the following: recruitment, training, logistics of fieldwork, and supervisory and quality control procedures in the field. Such is the variation of local circumstances and possible study designs that it is difficult to offer precise recommendations. Instead, some of the major options are described below.

The field staff recruited for the study should be of the same sex as the respondents, should speak the same language/dialect, must be available for the entire duration of fieldwork, and must be literate and reasonably numerate. Subsistence costs can be minimized by the recruitment of local residents, though delicate issues of confidentiality are raised when subjects and field staff know each other personally. It is an advantage if staff are married but experience in many surveys suggests that mature single persons are capable of interviewing respondents on matters of reproduction and contraception. Prior research experience is usually an advantage but in practice is difficult to find.

Recruitment may be effected by advertisement. Or, it may be possible to employ an available pool of people, such as school teachers during vacation time. All applications should be thoroughly screened and a slight surplus to requirements be recruited to offset drop-outs during the course of the study.

Sound training, proper field supervision and some type of quality control checks are important determinants of data quality. The length of training itself may vary between a few days and several weeks, depending on prior experience of the trainees and complexity of the task. Regardless of its duration, the main emphasis should be on practical work. Classroom teaching will be essential for explaining the aims and techniques, but the skills of investigation can only be learnt by experience.

The major functions of field supervisors are: (a) to liaise with community authorities, where necessary; (b) to solve unexpected problems; (c) to check completed work; and (d) to implement quality control procedures. In the case of large surveys, the latter may involve re-visiting a small proportion of respondents to ensure that the correct person was indeed interviewed and to re-check answers to a few key questions. Knowledge by interviewers that their work is subject to such checking acts as a powerful disincentive for dishonest or shoddy work.

Precise fieldwork logistics will depend on the geographical clustering of respondents, on the sample size, the required timing of data collection in relation to date of initial acceptance, and on whether the study is cross-sectional or prospective. The greatest practical difficulties are likely to be encountered in surveys where respondents, or clients selected from a clinic register, are small in number but widely scattered, and repeated home-visits are required. In this instance, it may be inefficient and expensive to retain full-time field staff. Instead a system of part-time employment may need to be devised, and considerable responsibility for the scheduling of interviews delegated to the field investigator.

6.6 Report writing, publication, and dissemination of results

The central purpose of research on the introduction of new methods is to provide practical guidance. Dissemination of results to people and institutions involved in the planning, policy-making and management of family planning services is thus a vital part of the entire research endeavour. However, researchers often fail to ensure proper feed-back of their results, because they do not understand sufficiently the priorities,

constraints and needs of policy-makers. Above all else, policy-makers must be provided with the main findings of the study in a succinct, clear, easily understandable form, along with practical recommendations. It is often easier to achieve these features in a presentation, with audio-visual aids, rather than by a written document. The communication between researchers and policy or programme staff should be a dialogue, wherein both sides explore the complications of the study for future action. During this dialogue, researchers are more likely to exert influence if they demonstrate an understanding of the financial, political and managerial constraints under which family planning services are provided and new policies set.

Policy and programme staff should be involved in the design of the study, and should be kept informed about its progress. This will facilitate the wide dissemination of the main results. Accordingly, progress reports, including information on what was done, the problems encountered, and how these situations were resolved, should be presented not only to the sponsoring institution but to other relevant agencies. Usually reports are expected at the end of the third, sixth and twelfth month of the study. Information on every step that should be underway or completed, according to the timetable, must be reported. Problems encountered and the modification of future activities should also be mentioned.

The purpose of the final report is to provide a full description of the study, its objectives, process of implementation, and results obtained. Therefore, it should be comprehensive, and all items included in the progress reports should be covered again, in a systematic manner. All alterations of the original protocol which occurred during the study's development should be mentioned. The reasons for changes should be explained, as well as any effect they may have on the results and/or the comparability of the data.

The central part of the report should present, in detail, the main analyses and conclusions. The relevance of the study results for the clinic, region and/or country, as well as for future studies, should be discussed. The report should end with recommendations (based on the conclusions of the study) and the next steps to be taken with relation to the method evaluated, regarding, for example, clinic routines, informational needs, and other service policies if the method is to be used throughout the programme, or special guidelines if the method is to be used at all. Recommendations can be based on any particular aspect or knowledge gained during the study, so that future research may be

improved in such aspects as training of personnel, midway evaluation, motivation of users to return for follow-up, counselling to improve continuation, revision of questionnaires, selection of personnel, and so forth.

The final report to be presented to the sponsoring institution(s) has objectives that differ from those of a publication or a paper for a scientific audience. Usually, it contains more details or information than the articles published in scientific journals.

If the study results show that side-effects from the method are unacceptable and use-effectiveness is too low in a particular population, every effort should be made to make these conclusions known in order to avoid a situation in which a programme may be making efforts to introduce a method that may not be suitable to the local clientele. Conversely, if the results show that early discontinuation is caused by poor understanding of the method's mode of action (e.g., alteration of menstrual cycles during the initial months of use followed by a return to regular patterns), counselling procedures would need to be modified.

The study's results should also be disseminated among the appropriate participating staff. After having devoted many hours of work to the project, gaining an insight into some problems from their own perspective, they deserve to be informed of the project's outcome.

A policy oriented discussion with health planners and programme managers should take place once the report has been completed in order to ensure that the results are widely known by the competent national authorities and agencies.

Finally, publication of key findings in a scientific journal is highly desirable. This step requires tactful negotiation about authorship and choice of a suitable journal.

7. Ethical issues

The major ethical issues involved in the introduction of new contraceptive methods concern clinic staff and are not the direct responsibility of researchers. Nevertheless, research staff need to be aware of the ethical standards that must be followed in the recruitment of users of new methods. Great care must be taken to ensure that persons being recruited in an introductory study voluntarily consent to participate in it. The informed consent form is an essential aspect of the protocol for any field study and it should be prepared in a way such that it is appropriate for local conditions and that the user is able to understand. Sometimes consent can be obtained verbally but even in those cases a form must be completed and the user must sign it or endorse it with a thumb print. In multicentre studies, the form will be taken as a minimum requirement, to which additions may be made as dictated by local requirements.

The consent form should include: (a) a statement describing the study and the nature of the subject's involvement in it; and (b) a certificate of consent attesting to the subject's consent.

The statement describing the study should:

(a) explain in the subject's mother tongue, and in terms the subject can understand, why the study is being done and why the subject has been asked to take part in it;

(b) describe, in sequence, and some detail what will happen in the course of the study;

(c) explain the nature, likelihood and treatment of anticipated discomfort or adverse effects;

(d) explain whether or not the study procedure offers any benefits to the subject or to others;

(e) state that all records are confidential and that each subject has the right to withdraw at any time without prejudice to her/his further medical treatment.

The certificate of consent should begin with a description of what was explained to the patient and end with a paragraph such as the following:

“I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent to participate as a subject in this study and understand that I have the right to withdraw at any time”.

The document should be signed by the subject and by the staff member or members who provide the information, ascertaining that it was understood and confirming that consent was freely given.

Investigators should also clearly indicate the benefits the subjects may receive for participation, such as compensation for travel expenses or lost earnings, medical treatment and follow-up. When financial reimbursement is involved, amounts, the manner and timing of payments should be specified. Ethical questions may also arise in the course of community-based studies of users of new or well established methods of contraception. Respondents may assume that research investigators are experts and ask for advice about side-effects or other health problems. In responding to such requests, there are two simple rules. First, delay any advice until the interview is complete. Second, refer the client to the nearest appropriate clinic or health centre for treatment of reported side-effects or other health complaints.

References

- Chan, K C (1971) Hong Kong: report of an IUD reassurance project. *Studies in family planning*, 3: 225-232.
- Chi, I, Smith, S C, Borko, E, Sun, T H, Begum, S F, Hunt, W L & Wilkins, L R (1987) Clinical acceptability, use-patterns and use-effectiveness of the vaginal contraceptive sponge and neo sampooon tablet--an international multi-centre randomized clinical trial. *Contraception*, 36: 499-514.
- Clifford, W B (1971) Modern and traditional value orientations and fertility behaviour: a social demographic study. *Demography*, 8: 37-48.
- Eren N, Ramos R & Gray, R J (1983) Physicians vs auxiliary nurse. Midwives as providers of 100 services. A study in Turkey and Philippines. *Studies in family planning*, 14: 43-47.
- Festinger, L (1957) *A theory of cognitive dissonance*. Stanford, CA, Californian University Press.
- Freedman, R & Whelpton, P K (1951) The relationship of general planning to fertility planning and fertility rates. In: P K Whelpton & C V Viser (eds.) *Social and psychological factors affecting fertility*. New York Milbank Memorial Fund.
- Goldberg, D P & Hillier, V F A (1979) A scaled version of the General Health Questionnaire. *Psychological medicine*, 9: 139-145.
- Hardy, E A Reyes, Q, Gomez, F, Portes-Carrasco, R & Faundes, A (1983) Users' perception of the contraceptive vaginal ring: a field study in Brazil and the Dominican Republic. *Studies in family planning*. 14: 284-290.
- Hill, R, Stycos, J M & Back, K W (1959) *The family and population control, a Puerto Rican experiment in social change*. Chapel Hill, University of North Carolina Press.
- Jones, E F, Beniger, J R & Westoff, C F (1980a) Pill and IUD

discontinuation in the United States, 1970-1975: the influence of the media. *Studies in family planning*, 12: 293-299

Jones, E F Paul, L. & Westoff, C F (1980b) Contraceptive efficacy: the significance of method and motive. *Studies in family planning*, 11: 39-50.

Kahl, J A (1966) *The measurement of modernism: a study of values in Brazil and Mexico*. Austen, University of Texas Press.

Keller, A (1979) Contraceptive acceptability research: utility and limitations. *Studies in family planning*, 10 (8/9): 230-237.

Kirscht, J P (1974) Research related total modification of health beliefs. *Health education monographs*, 2: 455-69.

MacCormack, C P (1985) Lay concepts affecting utilization of family planning services in Jamaica. *Journal of tropical medicine and hygiene*, 88: 281-285.

Marshall, J F (1977) Acceptability of fertility regulating methods: designing technology to fit people. *Preventive medicine*, 6: 65-73.

Poffenberger, T (1968) Motivational aspects of resistance to family planning in an Indian village. *Demography*, 5: 757-766.

Porter, E G (1984) Birth control discontinuance as a diffusion process. *Studies in family planning*, 15: 20-29.

Rogers, E M, & Shoemaker, F (1971) *Communication of innovations: a cross-cultural approach*. New York, The Free Press.

Seaton, B (1985) Non-compliance among oral contraceptive acceptors in rural Bangladesh. *Studies in family planning*, 16: 52-58

Shedlin, M G & Hollerbach, P E (1981) Modern and traditional fertility regulation in a Mexican community: the process of decision-making. *Studies in family planning*, 12: 278-296.

Sivin, I et al. (1987) Two years of intra-uterine contraception with levonorgestrel and with copper: a randomized comparison of the TCu Ag and Levonorgestrel 20 mg/day devices. *Contraception*, 35: 245-256.

Smith, D H & Inkeles, A (1966) The OM Scale: a comparative socio-psychological measure of individual modernity. *Sociometry*, 29: 353-377.

Sung, Kyn-taik (1977) Patients' evaluation of family planning services: the case of inner-city clinics. *Studies in family planning*, 5: 130-197.

Tanfer, K & Rosenbaum, E (1986) Contraceptive perceptions and method choice among young single women in the United States. *Studies in family planning*, 17: 269-277.

Warren, C W, Monteith, R S Johnson, T & Oberle, M W (1988) Tubal sterilization: questioning the decision. *Population studies*, 42: 407-418.

World Health Organization Task Force on Psychosocial Research in Family Planning (1981) A cross-cultural study of menstruation: implications for contraceptive development and use. *Studies in family planning*, 12: 3-16.

World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction (1987) *Guidelines for the toxicological and clinical assessment and post-registration surveillance of steroidal contraceptive drugs*. Geneva World Health Organization (Unpublished document No. WHO/HRP/SP.REP/87.1).

*Annex 1***Selected bibliography on
research methods****A. General**

Bongaarts, J & Potter, R G (1983) *Fertility, biology and behaviour: an analysis of the proximate determinants*. New York, Academic Press, (Studies in Population).

Campbell, D T & Stanley, J C (1963) *Experimental and quasi-experimental designs for research*. Chicago, Rand McNally and Co.

Cuca, R & Pierce, C S (1977) *Experiments in family planning: lessons from the developing world*. Baltimore, The Johns Hopkins University Press.

Fisher, A J Laing & Stoeckel, J (1983) *Handbook for family planning operations research design*. New York, The Population Council.

Jones, R A (1985) *Research methods in the social and behavioural sciences* Massachusetts, Senauer Associates Inc.

Lin, N, Burt, & R S Vaughn, J C (1976) *Conducting social research*. New York, McGraw Hill Inc.

McKinnell, A C (1977) Attitude scale construction. In: C A O'Muircheartaigh & C Fayne (eds.) *The Analysis of survey data*. London, John Wiley.

Mosser, C A & Kalton, G (1971) *Survey methods in social investigation*. London, Heinemann.

Oppenheim, A N (1964) *Questionnaire design and attitude measurement*. London, Heinemann.

United Nations (1985) *Studies to enhance the evaluation of family planning programmes*. New York, Department of Economic and Social

Affairs (Population Studies, No 87).

United Nations (1978) *Methods of measuring the impact of family planning programmes on fertility: problems and issues*. New York, Department of Economic and Social Affairs (Population Studies, No. 61).

Warwick, D P & Osherson, S (eds.) (1973) *Comparative research methods*. New Jersey, Prentice-Hall Inc.

B. Data processing

Banister, J (1980) Use and abuse of census editing and imputation. *Asia and Pacific census forum*, 6: 3 (East-West Population Institute).

Fellegi, I P & Holt, D (1976) A systematic approach to automatic edit and imputation. *Journal of the American Statistical Association*, 71: 17-35.

Montgomery, A C & Crittenden, K S (1977) Improving coding reliability for open-ended questions. *Public opinion quarterly*, 41: 235-43

Rowe, B & Croft, T (1987) Construction of analysis files. In: J Cleland & C Scott (eds.) *The World Fertility Survey: an assessment*. Oxford, Oxford University Press.

Sande, I G (1982) Imputation in surveys: coping with reality. *American statistician*, 36: 145-52.

Trussell, J (1987) Date imputation. In: J Cleland and C Scott (eds.) *The World Fertility Survey: an assessment*. Oxford, Oxford University Press.

Woodward, J L & De Lott, J (1952) Field coding versus office coding. *Public opinion quarterly*, 16: 432-6.

World Fertility Survey (1976) *Editing and coding manual*. Voorburg, Netherlands, International Statistical Institute (Basic Document 7).

World Fertility Survey (1980) *Data processing guidelines*. Voorburg, Netherlands, International Statistical Institute (Basic Documentation II).

C. Statistical analysis

Phillips, J F (1982) A logit regression method for the multivariate analysis of contraceptive attrition. In: A I Hermalin & B Entwistle (eds.) *The role of surveys in the analysis of family planning programs*. Liège, Ordina.

Schirm, A Trussell, T J Menken, J & Grady, W (1982) Contraceptive failure in the United States: the impact of social, economic and demographic factors. *Family planning perspectives*, 14, 68-75.

Tietze, C & Lewit, S (1974) Recommended procedures for the statistical evaluation of intra-uterine contraception. *Studies in family planning*, 4: 35-42.

Trussell, T J & Hammerslough, C (1983) A hazards model analysis of the co-variables of infant and child mortality in Sri Lanka. *Demography*, 20: 1-26.

Trussell, T J & Kost, K (1987) Contraceptive failure in the United States: a critical review of the literature. *Studies in family planning*, 18: 237-283.

D. Unstructured interviewing and group discussions

Fern, E F (1982) The use of focus groups for idea generation: the effects of group size, acquaintanceship and moderation on response quantity and quality. *Journal of marketing research*, XIX: 1-13.

Hoinville, G & Jowell, R (1977) *Survey research practice*. London, Heinemann (Chapter 2, Unstructured design work).

Jones, S (1985) The analysis of depth interviews. In: R Walker (ed.) *Applied qualitative research*. Aldershot (UK), Gower.

Program for the Introduction and Adaptation of Contraceptive Technology (1987) *Use of focus group discussion research: looking at the acceptability of NORPLANT implants in four countries to improve product introduction efforts*. Washington, DC, PIACT.

Schearer, S B (1981) The value of focus group research for social action programs. *Studies in family planning*, 12: 409-432.

Annex 2

Examples of questionnaires

This Annex illustrates two types of questionnaire, one that requires coding and one that does not. The examples are *not* complete questionnaires.

A. An example of a questionnaire that requires coding

1. Have you become pregnant at any time since ____ (date of starting use)?

Yes

No
(Skip to Q4)

Not sure
(Skip to Q4)

2. When did you become pregnant?

_____ month _____ year

3. Were you using _____ (method) at the time you became pregnant or had you stopped using?

Using
(Skip to Q6)

Not using
(Skip to Q6)

4. Since the day you started using _____ (method), have you or your husband used any other method?

Yes

No
(Skip to Q6)

5. What was the (first) method you or your husband used?

_____ (method)

B. Example of questionnaire that does not require coding

- | | <i>Answer codes</i> | <i>Skip to</i> |
|--|---|----------------|
| 1. Have you become pregnant at any time since _____ (date of starting use)? | <i>Yes</i> <input type="checkbox"/> 1
<i>No</i> <input type="checkbox"/> 2 → Q4
<i>Not sure</i> <input type="checkbox"/> 9 → Q4 | |
| 2. When did you become pregnant? | <i>Month</i> _____
<i>Year</i> _____ | |
| 3. Were you using _____ (method) at the time you became pregnant or had you stopped using it? | <i>Using</i> <input type="checkbox"/> 1 → Q6
<i>Stopped using</i> <input type="checkbox"/> 2 | |
| 4. Since the day you started using _____ (method), have you or your husband used any other method? | <i>Yes.</i> <input type="checkbox"/> 1
<i>No</i> <input type="checkbox"/> 2 → Q6 | |
| 5. What was the (first) method you or your husband used? | <i>Pill</i> <input type="checkbox"/> 1
<i>IUD</i> <input type="checkbox"/> 2
<i>Condom</i> <input type="checkbox"/> 3
<i>Injection</i> <input type="checkbox"/> 4
<i>Withdrawal</i> <input type="checkbox"/> 5
<i>Safe period</i> <input type="checkbox"/> 6
<i>Other</i> _____ | |

Annex 3

Suggestions for minimizing losses to follow-up

At admission

Once individuals have volunteered to participate and have been enrolled in a study, they must be told of the importance of follow-up. This may enhance compliance with scheduled visits to the clinic. It also may help prevent the subjects being surprised about the type and detail of information asked of them, e.g., regarding their address.

In rural areas with compact villages, problems of subsequent location of clients are usually not severe, provided that full details of all names (including, in some cultures, spouse's or father's name) are fully recorded. In urban or peri-urban localities, much greater care is needed. Registering the subject's name and address (street, number, locality, city) is not enough. There are several reasons for carefully registering other helpful information, for example:

- + street names and dwelling numbers may not exist;
- + sometimes, the person may not know the formally correct address or be embarrassed to report this (in both cases it might be made up);
- + the street or the area reported by the subject may not appear on the map of the town or city;
- + or, the address is correct but nobody seems to know the person.

Therefore, it is important to collect information such as:

- + landmarks to their home;
- + how are the subjects known in the neighbourhood: by name or nickname; by the work they do (seamstress); by spouse's name (John's wife), etc?

+ do subjects have a telephone at home, or is there a number nearby where messages can be left?

+ with whom does the subject live (husband, mother)?

+ names of these persons.

Does the subject live in a low-income or shanty-town area? If so, probe for more information as there may be no street names but only block and house numbers. Ensure that you get the correct number of the house (if available), as sometimes all houses share a number that identifies the area and also have their own number (e.g., 45-23, in which 45 is the number of that particular area). Find out where the neighbourhood is (points of reference).

Does the subject work away from home? Where? What are the working hours? Is there a telephone available? If she/he is a housemaid or worker, record the name of the employer, and, if possible, the address.

How do the subjects get home? What bus(es) do they take? Where do they get on and off the bus? Points of reference should be recorded such as Rosario Park, Sweet Bakery, Mary's Drug Store, large white house, shoe factory.

Every time a user returns to the clinic, ask for the current address and record any change. Do not ask "Do you still live at the same address?"; the user may remember that she/he moved since her/his last visit to the clinic, and simply answer positively.

Before going to the field

Several steps can be taken to increase the possibility of locating the person. Unless the interviewer or health workers know exactly where to go and how to get there, it is useful to take some precautions before going to the field: consult a map of the city and/or region and/or consult the "guide" or city map for instructions on how to get to the area or street.

If a visitor cannot find the area or the street she/he is looking for in the map and/or guide, other solutions should be sought. Depending on the local conditions, it may be possible to get information from telephone books, local transportation bureaux, post offices, etc.

A small map of the area surrounding the street where the person lives should be drawn on a piece of paper. Include local markers or reference points that assist in defining the area. Field visitors should take this map with them.

Once in the field

If field interviewers seem to be in the right area, but cannot find the street, they can ask knowledgeable people such as a taxi driver or a postman. Inquiries may also be made in local shops. It is best to ask again, every couple of blocks, as the information obtained is often not very clear, or may be insufficient or wrong.

If the street and the number have been found, but the study subject is not known there, the visitor should ask in several houses nearby. The user may have given the wrong number, or the house has no number and she gave that of her neighbour. It must be remembered that 'neighbour' may mean not necessarily the person next door, but in the whole surrounding area.

In low-income areas, shanty houses may have different numbering systems determined by social welfare or public health programmes that may have taken place. Houses may have a number given by the malaria control programme, and another by the water supply system. It is also possible that the owner has written a number that existed before any 'improvements'. Consequently, houses may have two or more numbers, alone or in pairs (e.g., 176, 17-153, 4-52), and written in different places (e.g., light post, electricity meter box, wall).

Sometimes there is more than one house on the same piece of land with one behind the other in alleys that cannot be seen from the street. The house at the back may follow the numbers on the street or lane (e.g., 27-37 on the front house, and 27-39 on the one at the back). This gives the impression that the houses facing the street have alternate numbers, or that there are missing numbers. It is important in a high-density area to probe behind the house in front of the street as the core of the block may be fully occupied by a variety of housing arrangements.

When field interviewers start making inquiries about study subjects close to where they live, some explanation of why the visitor is looking for the client should be given. If this precaution is not taken the visitor may be considered as a tax or bill collector and people will not give

information. Clients may pretend to be someone else. Similarly, interviewers must be careful not to break confidentiality assurances given to subjects when she/he was admitted to the study.

When explaining why persons are being sought, the contraceptive or the drug they are using, and the family planning clinic must not be mentioned. This is confidential information and should be talked about only when the client has been found and the visitor is alone with her. The explanation given to others will be, more or less, that the client has consulted a hospital, or has had a baby, and the visitor wants to know how she is getting along.

In rural areas in general, information on how to find a house is different from that in the city, e.g., near the two mango trees; a yellow hut; on the other side of the hill. The visitor should try to find out how far the house is in distance and/or time. "Near" for the informant does not always correspond to the visitor's idea of nearness. Can she/he walk that far and back?

In rural areas it is useful to ask information from anyone encountered. People tend to know each other. Subjects or their relatives may be known by the person being asked, or they may have an idea of how to proceed or where to go to obtain the information needed.