CREATING COMMON GROUND

Women's Perspectives on the Selection and Introduction of Fertility Regulation Technologies

Report of a meeting between women's health advocates and scientists
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TABLE OF CONTENTS

FOREWORD

Since 1960 we have both watched and participated in the evolution of values, ideas and strategies to address the twin problems of population pressures and the health and welfare of women. We have observed this evolution from different perspectives, from different vantage points and from different hemispheres. As we jointly planned the meeting described in this volume, it seemed to us that the last thirty years produced several generations of ideas.

In the late 1950s, policy-makers and those concerned with social and economic development asked themselves the question: *"Is population growth a problem?"*

When the answer to that question appeared to be in the affirmative, the question for the 1960s was: *"How can technologies be developed and distributed to solve this problem?"*

A partial answer was found in the invention of modern birth control technologies.

In the 1970s, the international community focused on the production and distribution of these technologies and on persuading governments to recognize the urgency of controlling population growth.

In the 1980s, and into the next century, this generation is asking: *"How can the technologies be adapted and adopted to best serve both the individual women – the consumer – as well as the community? How can we balance the scales of public policy?"*

We are also asking: *"How can we encourage and engage a broad and deep political will to improve the quality of the technologies, to enhance their use and to ensure free and fully informed choices for the consumer?"*

The Special Programme of Research, Development and Research Training in Human Reproduction of the World Health Organization and the International Women's Health Coalition have come together with a shared commitment to build on the values and ideas that have evolved over the past thirty years. We want to create understanding and strategies that will enhance scientific exploration, improve the quality of technology and encourage advocacy on behalf of women's health and well-being.

The meeting described here represents the beginning of a process. We are on the threshold of collaboration between the users of technology and the creators of it. This requires development of trust through honest and straightforward dialogue between groups which conventional wisdom said could not talk to one another. The meeting described here defied that conventional wisdom, proving that scientists and women's health advocates can hear each other and respect each others' views even when they differ.

This is the first in a series of discussions which we plan with our colleagues and friends from all walks of life.

Mahmoud Fathalla
Director, Special Programme of Research, Development and ResearchTraining in Human Reproduction

Joan Dunlop
President, International Women's Health Coalition

INTRODUCTION

Over the past three decades, women around the world have increasingly sought to space and limit their childbearing, and millions are now using modern methods of fertility regulation. Although women pioneered the family planning movement and make up the majority of contraceptive users, they have had little or no hand in the design and introduction of modern fertility regulation methods. Nor have they been significantly involved in establishing policies relating to fertility regulation methods. Many women have encountered problems with these methods and the systems used to provide them. Lack of accessible information about how methods work, experience with and fears about method safety and side effects, along with documented cases of coercion, have led some women to question the appropriateness of particular fertility regulation technologies and to distrust family planning programmes.

As a result, over the past 15-20 years, women in different parts of the world have taken up issues of reproductive health. Their concern has been to empower women to control their own fertility and sexuality with maximum choice and minimum health problems by providing information and alternative services, and by campaigning for women's right to make informed choices about their fertility, for improved services and for more appropriate technologies. Such activities, among others, have become known as "women's health advocacy".

Recognizing the importance of these concerns and of consumers' views, researchers, policy-makers and service providers have recently begun to seek dialogue and collaboration with women's health advocates. In 1990, an external evaluation of the Special Programme of Research, Development and Research Training in Human Reproduction of the World Health Organization (WHO) recommended that the Special Programme consult with women's groups about its work. As a first step, the Special Programme and the International Women's Health Coalition (IWHC) jointly organized a meeting between scientists and women's health advocates to define how women's needs and perspectives can be brought to bear on the work of the Special Programme and of other organizations concerned with fertility regulation. The International Women's Health Coalition, committed to engaging women's health advocates in the design and development of public policy on reproductive health, saw the meeting as an opportunity to narrow the distance between institutions that formulate policy and the consumers affected by policy.

It was agreed that the meeting should focus on only one aspect of fertility regulation – the selection and introduction of fertility regulation technologies – because the field is vast and complex and because it was thought that the selection and introduction process offers significant opportunities for collaboration between scientists and women's health advocates.

The specific objectives of the meeting were to:

- Establish a dialogue between the scientists and scientific collaborators of the Special Programme, and those involved in women's health advocacy;

- Identify means by which women can influence and be involved in both the choice and introduction of methods of fertility regulation, and find ways in which the Special Programme and other research programmes can work with women's health advocates on a continuing basis;

- Recommend specific actions to involve women's groups in the selection and introduction of fertility regulation technologies at national, regional, and international levels.

To ensure a balance of perspectives, similar numbers of scientists and women's health advocates were invited to participate. Eight international scientists (one from Africa, three from Latin America, two from Asia, and two from Western countries) who collaborate with the Special Programme, and eight staff of the Special Programme attended. Most of the scientists are physicians, working in a range of disciplines including epidemiology, reproductive biology, obstetrics and gynaecology, biochemistry, and social science. The six women and ten men were selected for their expertise on contraceptive safety and efficacy, sexually transmitted diseases, provider-dependent methods such as implants and intrauterine devices (IUDs), and the introduction of new methods.

The fourteen women's health advocates included three women from Africa, four from Latin America, three from Asia, and four from international women's health advocacy organizations. They were chosen on the basis of their long experience in working with women and their ability to represent a broad range of women's views. Some are physicians who work in clinic or other service settings; others are involved in counselling and referral, information exchange and networking. Most work closely with low income women in both urban and rural settings. (Page 43 gives the list of participants.)

The overall theme was addressed in four parts – selection of fertility regulation methods, method introduction, the research process, and women's participation – on which both women's health advocates and scientists were invited to prepare formal comments. Following plenary discussion of these issues, the participants worked in groups to develop recommendations, which were then discussed and agreed upon in a final plenary session. Debate was spirited and rich as participants candidly related their experiences and views, which were often quite divergent. Many questions which participants brought to Geneva were answered, but some remained unresolved and important new questions emerged.

This report is a synthesis of the presentations and discussion at the meeting. It aims to clarify key issues and encourage continued discussion and action at local, national and international levels. It is addressed to all those involved in fertility regulation who wish to make their policies and programmes more responsive to women's needs.

SUMMARY OF SUGGESTED ACTIONS

- Deepen and extend dialogue between women's health advocates and scientists on both the ethical and practical dimensions of fertility regulation technologies, programmes and policies.
- Bring women and women's perspectives into the work of the Special Programme and of other organizations and institutions that develop fertility regulation technologies and services.
- Re-examine the basic concepts of safety, efficacy, acceptability and availability to incorporate women's perceptions and experiences in the definition of each and to define an appropriate balance among them as criteria for method selection and introduction.
- Review and modify criteria used by national governments and donors in the selection of fertility regulation methods.
- Promote health and family planning systems that emphasize high quality care.
- Undertake further research on women's and men's attitudes, beliefs and practices about sexuality and fertility regulation in particular settings.
- Increase investment in male contraceptive methods and involve men in taking personal responsibility for reproductive health and fertility regulation.
- Support collaboration between scientists and women's health advocates on initiatives to eliminate unsafe abortion.
- Develop guidelines collaboratively to specify under what circumstances particular methods should be introduced and to clarify the criteria by which introductory trials determine whether a method is appropriate for widespread introduction.
- Include women's groups and women's health advocates in all parts of the introductory trial process, including ethical and scientific committees that design, monitor and evaluate introductory trials.
- Broaden the evaluation team to include service providers, social scientists, and representatives of women's groups, women's health advocacy groups and community groups.
- Disseminate the results of evaluation widely.
- Provide for long-term follow-up studies.
- Before selecting and introducing fertility regulation methods, undertake studies on: clients' needs and perspectives; knowledge, attitudes and practices of scientists, managers and providers; and the health and family planning infrastructure in each country.

- Foster research on the effectiveness and acceptability of barrier methods and withdrawal.
- Involve women and women's health advocates in all stages of research, including elaboration of ethical guidelines and standards for research, definition of priorities, research design and implementation, and analysis of findings.
- Develop and include innovative research techniques that are participatory, multidisciplinary and sensitive to the clients' situation.
- Train women in both biomedical and social sciences, and train scientists and policy-makers in women's perspectives on reproductive health.
- Disseminate scientific information in a more accessible form and language to women's and other non governmental groups, and provide the results of women's research and experience to scientists.
- Generate financial resources to support collaboration between women's health advocates and scientists.

SETTING THE STAGE FOR DIALOGUE

Different perspectives, different language

Both scientists and women's health advocates emphasized that there is neither one monolithic "scientists' perspective" nor one "women's perspective", but rather a broad spectrum of opinions within each community. They recognized as well that both groups are sometimes constrained from acting fully and consistently according to their perspectives. Women's health advocates often face lack of information, poor funding and various kinds of opposition or exclusion, while scientists face pressure from colleagues, donors or other agencies that have their own views on what research should be funded and carried out.

For instance, scientists working in the field of family planning have different approaches. Some might be termed "hardware enthusiasts" who believe that fertility regulation can be achieved through development of a wider range of effective, safe and acceptable contraceptive technologies. Some are "software advocates" who stress the importance of social and cultural variables and service delivery systems as factors determining fertility regulation. However, there are many who recognize that both hardware and software are needed. While some research agencies, like the Special Programme, have adopted the combined approach, many scientists have concentrated on the hardware, pursuing technological innovations.

From a biomedical scientist's point of view, the process of developing a fertility regulation method from toxicological testing to final clinical assessment is the accumulation of information on safety and efficacy. This process is in part dictated by drug regulatory agencies that require specific tests to establish the safety and efficacy of new products. Once through these stages, biomedical and social scientists, along with family planning programme managers continue to test safety and efficacy, as well as acceptability, through introductory trials. These trials can also help assess the appropriateness of the service delivery system, and develop an understanding of the concerns of users and the needs of the service providers. One of the problems some scientists encounter in this process is with communication and understanding among themselves. For example, social scientists are an essential interface between the community and biomedical scientists, because they study the qualitative aspects of users' and providers' needs. However, most biomedical scientists work with quantitative data and find it difficult to make use of qualitative data generated by social scientists.

Women's health advocates often conceptualize the issues in a completely different way. They see their bodies and their autonomy as the central concern. Women's health advocates thus start with women, not technology, and act according to at least three fundamental assumptions. First, they assume that women have the right to control not only their fertility but also their sexuality. Second, they believe that the exercise of this right requires not only improved methods of fertility regulation and health delivery systems, but also broader improvements in women's circumstances. Third, they know that women can and will make their own rational decisions about

their fertility and sexuality if they have access to appropriate information and appropriate services. The basic objective for women's health advocates is thus to maximize women's choices and control over their fertility, their sexuality, their health and their lives as citizens.

Some scientists sympathize with this view, but women's health advocates feel that many scientists, along with policy-makers, see fertility regulation primarily as a means to limit population growth and speed development, not to empower women. The relative weight assigned to population control compared to women's empowerment has profound effects on the criteria each group uses to set research and policy priorities. Scientists at the meeting agreed that modern methods of contraception have often been associated with the political dimensions of population control. They felt, however, that many scientists involved in this field have undertaken development of fertility regulation methods with the intention of broadening choices for users and protecting their health.

Scientists' concern is to establish safety of methods according to specific, measurable parameters. They assess toxicity, first in animals and then in carefully controlled studies in human volunteers. Subsequent studies address efficacy and short- to medium-term safety. Scientists are able to assess the long-term safety of a drug or device by epidemiological studies only after a product has been in use for many years. Women's health advocates tend to define safety in different terms. They give more priority to methods that have fewer side effects and that protect against sexually transmitted diseases and their consequences such as infertility. While scientists have tended to give priority to methods which minimize users' control, women's health advocates prefer methods controlled by the user.

> *"On the question of side effects, there is always a tendency to over-emphasize the benefits and underplay the risks...Most of the time it is we women who undergo the risks and the benefits are taken by the pharmaceutical companies or by population control experts or governments of Third World countries".*
> – Rani Bang

Women's health advocates and scientists may often use different language or assign different meanings to some words. For instance, scientific language is notoriously incomprehensible to laypersons, and feminist terminology can be off-putting to those who hold different views. Participants gave several examples of the ways in which language can inhibit communication and understanding.

Scientists pointed out that women have used the term "high tech" to refer to certain fertility regulation methods because they are provider-dependent (such as implants, injectable contraceptives or IUD's), while for scientists, these methods are technologically simple. In another example, women's health advocates explained that the scientific community's use of the word "couples" is inappropriately restrictive. While fertility regulation should concern two people, the word "couple" implies established or married people, which excludes adolescents, the unmarried, and commercial sex workers.

Further, scientists and programme planners conventionally define the "unmet need for family planning" in terms of "non-users at risk of unwanted or untimely pregnancy". A women's health advocates' definition would add to non-users, unsatisfied users, incorrect users, users of inappropriate methods, users and non-users with special needs (such as adolescents and sex workers), and most men. Other fundamental differences in the use of terms, such as "safety," "acceptability" and "efficacy" are explored in depth in later sections of this report.

Both scientists and women's health advocates at the meeting recognized that differences in perspectives and language have led to polarization between the two groups, which in turn has fostered distrust and criticism rather than creative collaboration and a search for shared values. Excluded from decision-making and the research process, many women have reacted negatively to decisions by researchers and policy-makers. This negative reaction has often resulted from anecdotal evidence of misuse of contraceptive methods in family planning programmes that do not offer women free and informed choice of fertility regulation methods, and that do not adequately protect women's health.

Scientists, if they have heard women's perspectives at all, have often heard only the extreme views, and many have concluded that it is best to ignore women's groups and the questions they raise. Scientists in general have not attempted to communicate with such groups. They have considered their primary concern to be to generate and publish objective information in the scientific literature. Very few scientists have considered how to convey their findings to women in a form that might allay their fears. It is thus not surprising that women's health advocates currently find that the realities of women's sexual and reproductive lives have had relatively little impact on the setting of research priorities in fertility regulation, or on population programmes and policies.

> *"It is our task as women's health advocates to assist scientists in the tremendous challenge of creating fertility regulation methods that take into account the welfare, sexuality, mental and physical health of women...Male researchers can themselves become more receptive, empathizing with women's biological experience, and open to qualities which have been socially attributed to women such as receptivity, sensitivity, intuition...".*
> – Amparo Claro

Now however, scientists are realizing that involving women and women's health advocacy groups in their work may enhance the appropriateness and acceptability of the technologies they develop. They are seeking dialogue both in order to broaden the scope of their own work and to enable women's groups to better understand the process, the limitations and the results of scientific research. Women's health advocates, similarly, are seeking opportunities to understand scientists and programme managers, and to lend their experience and knowledge to the scientific process.

Who speaks for women? For whom do scientists speak?

While there was consensus about the need to bring women's perspectives and experiences to bear on the development, selection, and introduction of fertility regulation technologies, the participants debated the question of who can legitimately and effectively articulate those perspectives. A number of scientists questioned whether, for instance, women's health advocates, such as those at the meeting, represent the views of poor and rural women. Some participants pointed out that, although women's health advocates may be relatively well educated, most work directly with rural as well as urban women, including low income women. They are thus a legitimate source of information about both the content and the value of the variety of women's perspectives that exist. Each brings a point of view based on her own experiences, having listened to and worked with a wide range of women in her own country and internationally.

"I think a central characteristic [of women's health advocates] is that we are able not to just speak for ourselves as an individual woman, but we are able to say, "I might think this but I know other women think differently."
– Judy Norsigian

Although some scientists remained skeptical that women's health advocates can represent the views of the majority of women, others recognized that they themselves have had little personal contact with the women who should benefit from the technologies they help develop. Ultimately, most participants agreed that women's health advocates and other women's groups can act as a bridge between women and scientists, helping to interpret scientists' findings to other women, and bringing women's concerns to the attention of the scientific community.

"On the [assertion] that urban women activists cannot really represent the views of rural women, I think that, while this can be true in some cases...you have a big gap between so-called "experts" and very poor women, rural and urban. Sometimes it is necessary to have a buffer zone which is what women's activists constitute. [Ideally,] you should have sensitive experts both male and female, then the question of who is representing [women] becomes irrelevant".
– Adetoun Ilumoka

Moral dilemmas

The participants recognized that dialogue is urgently needed to resolve, or at least clarify, a fundamental dilemma in the population field that is present in other fields as well. Societal goals and strategies, as defined by policy-makers, do not necessarily coincide with the goals and needs of individuals. Those who focus on the societal level, emphasize providing services to the largest number of people and have often sacrificed both service quality and choices among technologies. Those who focus on individual health and rights make service quality and choices among technologies paramount.

Women's health advocates raised a number of ethical questions during the course of the meeting that stem from this tension. Is it ethical, for example, to introduce fertility regulation methods without at the same time addressing other equally critical aspects of women's reproductive health, such as pregnancy care, sexuality or reproductive tract infection? Another question raised was whether it is morally acceptable to restrict access to safe abortion services and simply promote contraception, when contraceptive technologies are imperfect, failure rates and abortion rates are high, and the consequences of unsafe abortion are catastrophic for women.

Is it ethical and responsible to introduce contraceptive methods that are heavily dependent on skilled health personnel in countries where health services are generally poor? Is it ethical that developing and developed countries use different criteria and standards for the regulation and monitoring of technologies and services? Do precarious health conditions in resource-poor settings place women at higher risk of side effects from certain contraceptives and, if so, is it ethical to introduce those methods where general health is poor? Do the developers of fertility regulation technologies have an obligation to consider these contextual factors when first initiating work on a new method and throughout the process? Are they or should they be concerned about the ways in which their technologies are likely to be used or abused by the state, service providers or women themselves?

Many of these questions pose profound dilemmas not easily resolved, and some of them may not be resolvable at all. But discussing them openly helped identify some areas (described below) where resolutions might be sought through collaboration between scientists and women's health advocates. In general, the participants recognized that, in any setting, factors such as the particular experiences of a people, their culture, and their behaviour, the quality of the existing health care system, social norms and values about sexuality, fertility and gender roles, and the political and economic climate will all play critical roles in how a method is perceived and used and with what consequences for women. Participants agreed that every effort should be made to consider these factors when a decision is being made about the appropriateness of a particular method of fertility regulation.

Suggested actions

- Deepen and extend dialogue between women's health advocates and scientists on both the ethical and practical dimensions of fertility regulation technologies, programmes and policies.

- Bring women and women's perspectives into the work of the Special Programme and of other organizations and institutions that develop fertility regulation technologies and services.

SELECTING FERTILITY REGULATION METHODS FOR INTRODUCTION

Existing contraceptive methods are of five types – hormonal, intrauterine devices, sterilization, barrier, and natural or traditional methods. Both surgical and medical techniques exist for inducing abortion.

Each method has intrinsic characteristics which must be considered when governments or agencies choose a method for particular countries or programmes. Women's health advocates emphasized, however, that the selection process must also take into account the sexual, reproductive, social and economic realities of women's lives; their health; and the quality of family planning and health services in particular settings. That is, the technologies should not be selected in isolation from the conditions in which they are to be used.

Women are concerned that, in many instances, this principle has not been followed. As a result, methods that should, in women's view, be provided only by well-trained personnel in settings with strong health infrastructure that can ensure informed choice have been misused or abused. Scientists usually consider that they are contributing to knowledge about a particular technology and that they rarely have the possibility of influencing how and where a method is used.

Participants discussed at length the standards that should be set for selection and use of contraceptives, and the efforts needed to encourage adoption of these standards. It was agreed that women's health advocates and scientists, working together, might design more appropriate standards and also monitor selection and use, at least in some settings.

The participants agreed that a woman's selection of a method of fertility regulation is affected by many considerations. These include such personal circumstances as her health, sexual relationship(s) and point in her reproductive life cycle; the societal conditions that affect her sexuality such as her status in society, risk of violence, and possible exposure to infected partners; her prior experience with fertility regulation methods; and her access to information. Her choice will also be affected by the availability of health and family planning services, their quality and accessibility, the mix of methods offered as well as the availability of safe abortion.

> *"Access is not only a question of how distant her home is, or how much the transportation costs, or who will take care of the baby if she goes to the clinic. We have to ask what is the attitude of the husband, what is the attitude of the mother-in-law, what is the attitude of the neighbourhood, of the family, of the city, of the society at large with respect to that woman using that method? What are the sources of information? ...Much more emphasis should be put on this field".*
> – Aníbal Faúndes

It was also agreed that no one method can work for all women at all times in their lives, and that therefore, the broadest possible number of fertility regulation methods should be offered. Some scientists see greater hope for improving choice through development of highly effective, reversible, long-acting methods. Many women's health advocates see a greater need for the promotion of already existing methods that have mini-

mal side effects, are user-controlled, and are protective against infection, such as barrier methods. Behind these preferences lie differences in the definitions and relative weight assigned to four fundamental characteristics of fertility regulation technologies: safety, efficacy, acceptability and availability.

Safety, efficacy, acceptability and availability

Safety

Scientists want to ensure that a method they develop causes no dangerous or permanent side effects. Through toxicological and clinical studies they assess whether a method might be carcinogenic, or might have severe effects on physiological functions such as those of the heart, the kidneys or the reproductive organs, or might have other potentially severe outcomes. The women who use methods that have passed these tests are also concerned about how these methods might affect their overall health, including their sexual interest, physical stamina, or emotional well-being – aspects of health that generally have been given lower priority by researchers and service providers. Side effects such as menstrual bleeding disturbances, which scientists consider unimportant medically, can be of extreme concern to women, and may affect how they perceive the safety of any method. For a woman, safety of use of a method during lactation, and the long-term effects of method use, are of particular concern, and her concept of safety may also require that the method is immediately reversible. Because safety is impossible to measure in absolute terms, and accurate technical information is still insufficient, a broad spectrum of society, certainly women, should participate in the process of weighing risks and benefits of technologies to be introduced.

Some women feel that certain natural substances, such as herbs and plants used as contraceptives may be safer than modern methods and some women's health advocates felt that more emphasis should be put on researching traditional herbs and plants. Scientists pointed out that the Special Programme had funded a

major international research programme in this area, albeit restricted to plants alleged to have properties preventing implantation of a fertilized egg in the uterus or to inhibit male fertility. No new chemical entities suitable for method development were identified. However, this area of research has by no means been exhausted.*

"Natural" is not always simple and safe. On the other hand, there are many traditional methods which I'm sure haven't been adequately explored and could very well turn out to have the advantage of simplicity and safety".
– Henry Gabelnick

Women's health advocates felt that attention needs to be given to the safety of particular methods in settings where disease and malnutrition are very substantial. They emphasized the need to examine interactions between fertility regulation methods and sexually transmitted diseases, especially AIDS. They suggested, for example, that a community with endemic reproductive tract infections, especially where they are undiagnosed and untreated, is an inappropriate environment in which to introduce IUDs.

Scientists pointed out that some agencies do carry out studies on the wider health implications of method use. The SpecialProgramme, for example, is conducting cross-cultural research in more than 20 countries to examine the effect of various contraceptives on a range of problems including HIV transmission, neoplasia, infant development, anaemia, hepatitis B and cardiovascular diseases. It was recognized, however, that more needs to be done, and that the results of such studies need to be made available much more widely than is presently the case.

Scientists indicated that they need to know more about how clients perceive and define safety. However, they also urged that what is known medically about safety should be more adequately conveyed to women. For instance, a once-a-month injectable contraceptive sold over the counter in Latin American countries has been very popular among women because bleeding remains regular. However, the drug contains a high dose of estrogen which increases the risk of metabolic and cardiovascular diseases – a long-term problem which is not noticed on a daily basis by the user. This example underlines the essential need for communication between scientists and users. As a result of this situation the Special Programme has supported the development of an alternative, once-a-month injectable with a lower dose of estrogen, which is currently being introduced into six countries.

Both scientists and women's health advocates agreed that cultural and service delivery factors influence the actual safety of any method. The safety of sterilization or IUDs, for instance, depends largely on the care with which they are delivered. Furthermore, for certain methods, the service provider determines a dimension of safety critical to most women: immediate and effective reversibility on demand.

* A two-volume monograph on the WHO multicentre study on plants, the research operation and findings, is in preparation for publication in 1993. A brief off-print summarizing the findings is available from the Special Programme.

A fundamental difference in perspectives on the relative safety of methods remains. Scientists tend to argue that the health risks of any method should be measured against the risks of a clandestine abortion or of a full-term pregnancy (wanted or unwanted). Their priority is to develop the most effective contraceptive methods to reduce the likelihood that women will resort to dangerous abortions or go through a high-risk pregnancy. Women's health advocates, on the other hand, often see the risks of some methods, whether inherent or caused by poor services, to be too high. Many argue for the provision of methods that have minimal side effects, along with safe abortion as a back-up. They also point out that emphasis on family planning services should not detract from efforts to improve pregnancy and delivery care.

Efficacy

Scientists measure the efficacy of a contraceptive method by quantifying how often it fails to prevent pregnancy. The measures applied are rates of "method failure" and of "user failure". Women, however, may define efficacy by how well a method "works for them in their lives". Their measures include not only pregnancy prevention but also "satisfaction". The latter may encompass the effects the method has on the woman's sexual relationship, her sense of control over the method, the freedom to use it when she pleases, and its efficacy in preventing infection. For many women, these aspects of effectiveness, along with safety as defined above, may be as or more important than contraceptive efficacy. Women's health advocates felt that the scientific community tends to give too much weight to contraceptive efficacy. Scientists stressed that safety is their first concern and indicated that women's perception of their priorities in this regard is incorrect. Scientists and women's health advocates agreed that this is evidence of a serious communication gap that should be closed through continuing dialogue.

Women's health advocates questioned scientists' bias toward systemic or provider-dependent methods that have less likelihood of user failure. They suggested that this emphasis has led researchers to overlook low user acceptability or significant dissatisfaction with the method which may be masked by high continuation rates when assessing the efficacy of methods such as the IUD or subdermal implants. At the same time, what appears to be the lower effectiveness of barrier methods may be due not so much to the methods themselves as to failure to provide adequate information and support to women who use them. Furthermore, service providers have often simply asserted that the diaphragm is inappropriate for low-income women who do not have privacy, water, education or other resources. It has been assumed, rightly or wrongly, that instruction in the proper use of barrier methods places undue demands on understaffed, overworked clinics. The meeting participants agreed that such assumptions need to be tested and the use-effectiveness of barrier methods further studied. They also agreed that clinical studies of effectiveness are not sufficient, since efficacy also depends on the social and health environment,

on service providers, and on users, not just on the method itself. Women's health advocates also suggested that the safety-efficacy balance of barrier methods, backed up by safe abortion facilities, should be compared to the safety-efficacy balance of systemic, provider-dependent methods.

Acceptability

This concept permeated discussions throughout the meeting. The measures commonly used by scientists and policy-makers are rates of acceptance (agreeing to start using a contraceptive method) and rates of continuing a method. Women's health advocates argued for indicators of acceptability that also measure informed choice and user satisfaction. Research on the reasons not only for acceptance, but also for satisfaction and dissatisfaction, could help to increase understanding of what acceptability really means to women. Scientists pointed out that the Special Programme carries out research on these and other aspects of acceptability, particularly on reasons for discontinuation.

It was agreed that acceptance and acceptability are influenced by many factors. For example, if health service providers judge one method better than another, then the counselling and information they provide is likely to reflect that bias and affect acceptance and use of that method. Similarly, policy-makers and providers may make incorrect assumptions about what is acceptable to women and men. A common assumption is that women will not touch their genitals. In Thailand, a clinical trial of a vaginal ring run by clinicians was unsuccessful because of this assumption on the part of the male clinicians, whereas a trial of a similar ring run by midwives met with considerable success, because they spent time demonstrating how the method works. A similar experience occurred in the Dominican Republic. In Brazil, donors, health authorities and gynaecologists have regarded the diaphragm as ineffective and unusable, particularly for low-income women. Yet, a feminist health centre in Sao Paulo has shown that, if women are given information and counselling about a range of methods including the diaphragm, many of them, regardless of income level, choose the diaphragm and find it easy to use. In another instance, in Turkey, family planning officials assumed that women were their primary clients, even though the main method used up to that time was withdrawal. Early family planning efforts failed because men, who control contraceptive practice in Turkey, were not fully involved.

Women's health advocates indicated that women's definitions of acceptability change over time with changes in their circumstances. As women become more concerned with their rights and have more knowledge of their bodies, for example, they may be less willing to accept methods that can adversely affect their health. Many of the participants felt strongly that not only risks but also more responsibility for fertility regulation should be shared by men and that resources for the development of male methods should be increased. Some participants nonetheless expressed concern

that even women in stable relationships may not trust their partners to use contraceptives effectively and, therefore, female methods should continue to have priority.

Finally, acceptability is also conditioned by the availability of methods. The participants agreed that if only one or two methods are available, it is not meaningful to speak of acceptability because there is no choice.

Availability

For a method to be truly "available", a number of conditions must be met, including easily accessible distribution points (clinics, commercial outlets, etc.), where the supplies are consistent, staff are properly trained, and opening hours are convenient for clients. A key aspect of availability discussed at length is affordability, both for the service provider (e.g., a national government programme) and for the consumer. Participants expressed considerable concern that some recently developed methods, such as implants, are costly. This also raised the question of manufacture. Participants from Africa and Asia in particular, stressed that many countries in their regions have no control over manufacture and supply of fertility regulation products, and that this affects availability.

Other critical factors in selection of methods

Health and family planning infrastructure

Women's health advocates and scientists agreed that, in an ideal world, women and men should have the freedom to choose any method, the right to change methods, and the ability to afford any method. This requires properly staffed and maintained health and family planning services and the provision of safe abortion services. In reality, health and family planning services tend to be overworked, understaffed and underfinanced. Adding fertility regulation methods, especially those that require sophisticated delivery and follow-up, may simply compound existing service weaknesses.

> *"We get the feeling now and then that the method gets the blame whilst it is the services that should be the target of complaints".*
> – Olav Meirik

There was general agreement that the health and family planning infrastructure has a very significant impact on the safety and efficacy of fertility regulation methods. Those responsible for selecting methods therefore must determine whether the infrastructure is well enough staffed and equipped to ensure safety and efficacy. Are necessary supplies available consistently, along with trained staff who have both the skills and the time required to deliver the various methods safely? Can the staff ensure informed choice, provide counselling and follow up clients? Are services readily available to deal adequately with method complications, method removal, side effects or unwanted pregnancy?

There were different views on the criteria that might be used in answering these questions. Some participants argued that certain methods should simply not be selected by countries with very weak infrastructure. Others suggested that methods dependent on sophisticated facilities should perhaps be provided first (or only) at higher levels of the health system or in urban areas. Clearly, this is an area of ongoing debate which may be best resolved in particular countries through dialogue among policy makers, service providers and women's health advocates.

Quality of services

Women's health advocates suggested that qualitative aspects of existing health and family planning programmes should be taken into account in selecting fertility regulation methods to introduce into those systems. A service that emphasizes quantitative targets is unlikely to provide or reward counselling, may have coercive elements (e.g., denies women abortions unless they agree to accept a particular method of contraception or sterilization), and may not maintain privacy or treat clients with respect.

"Any type of new technology that we introduce in any country of the world will fail if you don't have good service delivery and good counselling".
– Kerstin Hagenfeld

Such systems will not provide any method appropriately, but especially those that are not reversible (sterilization), are reversible only with the cooperation of the service provider (IUDs, implants) or are not immediately reversible (e.g. long-acting injectables).

Many of these aspects of quality of care could be improved at little or no cost by adjusting objectives to emphasize choice among methods and respect for the client. Others, like counselling, demand time from already over-worked staff – a demand that will increase with the introduction of each additional method. One way to address this problem is to broaden personnel to include non-physicians in the delivery of services – an approach that has proved to be very successful in a number of countries. Participants generally agreed that, regardless of the method to be selected or introduced, family planning services must do more to ensure respect for the user and for her or his cultural, sexual and religious values.

Government and donor criteria for method selection

Women's health advocates expressed a need for more information on the definition and application of criteria for method selection at national levels. Since many countries are dependent upon supplies from donors, the criteria used by the donors are especially important. For example, a recent attempt to manufacture diaphragms in Brazil has been thwarted by lack of donor support, while in Bangladesh, until very recently, only high-dose contraceptive pills have been available.

Government policies can also be very restrictive. Natural methods of fertility regulation are often not included in the official

list of contraceptive methods and thus services are not provided. Health ministries sometimes set supply quotas for certain methods such as condoms, and this can result in serious shortages. Although some public sector agencies are beginning to accept the need for barrier methods, a general prejudice still exists among donors and government programmes against providing methods that require spermicides because of the difficulty of maintaining supplies of spermicides in developing countries.

Unwanted pregnancy and abortion

The primary purpose of very large investments in contraceptive technologies and services to date has been to prevent unwanted, ill-timed or otherwise inappropriate pregnancies. In some countries, nonetheless, induced abortions equal or surpass the number of live births. Worldwide, it is estimated that between 36 and 53 million induced abortions occur every year, and as many as 200,000 women may die each year due to unsafe abortion. Clearly, as yet contraceptive technologies and services neither meet the needs of, nor are accessible to, millions of women who want to control their fertility.

> *"Abortion has to be seen as an important integral aspect of reproductive rights which cannot be neglected. In my two years as coordinator of the women's health programme in Sao Paulo, I have been involved in research in 25 municipal hospitals in poor areas and have seen the increase in abortion and abortion complications as a great issue. The total number of complicated abortions presented at the hospital in 1989 exceeded the number of births. It is therefore impossible for researchers not to involve themselves publicly in the abortion issue in their countries".*
>
> – Maria José Araujo

Recognizing that it will be some time before all women's contraceptive needs can be met, and that some women will always need safe abortion services, most participants felt strongly that women's groups and scientists should actively collaborate to encourage understanding of unwanted pregnancy and to prevent and eliminate unsafe abortion.

A limited number of institutions and organizations (such as the Special Programme) currently support research activities on particular aspects of abortion, including the very serious health effects of unsafe abortion, the factors that lead to unwanted pregnancy and unsafe abortion, and assessment of new technologies for safe induced abortion. These and other aspects of abortion urgently need more research, on which scientists and women's health advocates should collaborate.

Women's health advocates also emphasized that public education and advocacy are needed to decriminalize abortion. Women's health advocacy groups usually work for safe and accessible abortion services, but initiatives are needed from others as well. In a number of countries, physicians and other health professionals have taken the lead, sometimes in alliance with women's organizations. It was suggested that researchers could provide an additional strong and effective voice in national and international efforts to ensure women's access to safe services in all countries.

It was pointed out that the World Health Organization, as an inter-governmental organization, serves the needs of its Member States, who have divergent policies on the issue of abortion. In accordance with the recommendation of the 1984 International Conference on Population, WHO does not promote abortion as a method of family planning, but is concerned with the health aspects, particularly of unsafe abortion.

Suggested actions

- Re-examine the basic concepts of safety, efficacy, acceptability and availability to incorporate women's perceptions and experiences in the definition of each and to define an appropriate balance among them as criteria for method selection and introduction

- Review criteria used by national governments and donors in the selection of fertility regulation methods and, where appropriate, recommend modifications.

- Promote health and family planning systems that emphasize high quality care.

- Undertake further research on women's and men's attitudes, beliefs and practices about sexuality and fertility regulation in particular settings.

- Increase investment in male contraceptive methods and involve men in taking personal responsibility for reproductive health and fertility regulation.

- Support collaboration between scientists and women's health advocates on initiatives to eliminate unsafe abortion.

The availability of methods and the reality of choice: Bangladesh and Brazil

In theory, a wide range of fertility regulation methods is available in Bangladesh but, at most, one third of reproductive age couples use a contraceptive method, and many women resort to abortion. The methods available through governmental and non-governmental channels include high-dose oral contraceptives, condoms, vaginal foam tablets, IUDs (copper T380A), two- and three-month injectables, Norplant subdermal implants, tubal ligation and vasectomy, and menstrual regulation. Other methods used include natural family planning, breastfeeding, withdrawal, ayurvedic and homeopathic methods.

Most women in Bangladesh do not have the wide choices that this list implies. The majority have no access to information about methods and only limited access to services, which are of poor quality. Many women are compelled to obey their husbands and in-laws, and, as a result, practice fertility regulation in secret, if at all. Consequently, methods requiring male cooperation are difficult or impossible for many women to adopt. Injectable contraceptives have become increasingly popular, in part because women can obtain them under the guise of taking their children to a clinic for immunization. Methods which cause menstrual disruption are problematic, however, because bleeding interferes with praying, fasting, sexual intercourse, and a woman's feeling of health and well-being. Women also want to avoid methods believed to cause cancer and methods which might cause infections such as an IUD inserted under unsterile conditions.

Given all these limitations, along with problems of service delivery, it is estimated that every year 750,000 women in Bangladesh have an abortion. Perhaps one-fifth of these have access to safe menstrual regulation through Government clinics; the rest risk their lives in clandestine procedures. For many women, a vasectomy for their partner is the ideal choice, but most men reject it. Most sterilization in Bangladesh is therefore undertaken by women, even though vasectomy is easier, safer and less expensive than tubal ligation.

In Brazil, though the range of legal fertility regulation methods is extremely narrow, about two-thirds of women in marital or consensual unions use some method of contraception or are sterilized. Although the government has adopted an integrated women's health programme which mandates the provision of a wide range of contraceptive methods, in fact, the only fertility regulation methods accessible to most women are oral contraceptives provided through the private sector, clandestine abortion (legal abortion is severely restricted), and tubal ligation. The lack of choice of contraceptive methods and the legal restrictions on abortion mean that women pay a very high price for fertility regulation.

For low-income women, the recurring cost of pills, along with costs of obtaining them, such as transportation, loss of earnings, and child care are deterrents to oral contraceptive use. Side effects of oral contraceptives, such as menstrual disturbances, weight gain, headaches, or loss of libido are reported often, and these kinds of effects frequently result in

incorrect use, discontinuation of the method and, ultimately, unwanted pregnancy.

It is estimated that three million abortions occur each year in the country, compared to four million births. In a survey of low-income women in the state of Santa Catarina, 18 methods to induce abortion were reported, including catheters and knitting needles. In 1989, the number of cases with complications from induced abortion in the municipal hospital of Sao Paulo exceeded the number of deliveries.

With no temporary means of contraception available to them, many women undergo tubal ligation. Not surprisingly, studies show that up to 50 percent of Brazilian women sterilized before 25 years of age regret it. Tubal ligation is not officially provided in the public sector, but it is frequently done clandestinely at the time of Caesarean section. This helps explain the extremely high rate of "unnecessary" Caesarean sections and associated complications in Brazil.

Given the negative experience many Brazilian women have had with hormonal methods and with the service system, the greatest weight should perhaps now be given to methods that have minimal health risks or side effects, are reversible, inexpensive and easy to use. Careful introduction of barrier methods and the IUD may be more appropriate than the introduction of new methods which have systemic effects, require a physician's involvement, and therefore are not under the user's control.

By comparison, an ideal contraceptive in Bangladesh would be one that is easy to use with privacy, is inexpensive, and is not connected with sexual intercourse. It would not require leaving the home, would have minimal side effects and would be socially and culturally acceptable. But the issue in Bangladesh may be less selection of additional methods than improvement in service quality and availability along with broader changes in women's lives that would enable them to make choices for themselves.

This text is based on presentations by Sandra Kabir and Maria José Araujo.

CONSIDERATIONS FOR INTRODUCTORY TRIALS

Ethical issues

The first, systematic approach to public sector introduction of a contraceptive method was undertaken by the Population Council with the introduction of Norplant subdermal implants. No contraceptive method until that time had undergone so many years of safety and efficacy research prior to introduction. Introductory trials of Norplant began in 1983 following 15 years of clinical research on safety and efficacy. Norplant has been approved in 18 countries. More than 55,000 women have used it in 46 developed and developing countries. The objective of the introductory trials has been to establish adequate clinical conditions, including training in insertion and removal, counselling, and clinical follow-up, in addition to post-introductory surveillance. The Council made this substantial investment for several reasons. Previous experience with IUDs had often been very negative, partly because neither providers nor users were adequately informed and trained. Norplant requires minor surgery for insertion and removal and has side effects for which women and providers need to be prepared. As a high-technology, provider-dependent method, Norplant can potentially be abused and a careful introduction process is one way to reduce that risk.

Drawing on the experience with Norplant, the presentations and discussions on introductory trials considered ethical issues, the process of introduction, evaluation of such trials, and cost.

It was agreed that there have been and can be a number of ethical problems with the introduction of fertility regulation methods. It is therefore essential to formulate and follow clear ethical principles at each stage of the process.

Informed consent

Although guidelines exist for research on human subjects (the Special Programme uses them in all of its clinical research), these guidelines are often not followed completely or meaningfully at either national or clinic levels. For example, participants in the trial may sign informed consent forms without fully understanding that the fertility regulation method is under development, or that the method may have as yet undetermined risks or side effects. Scientists, at both national and international levels, in collaboration with women's health advocates, could, it was agreed, undertake to improve approaches to and standards for informed consent as well as to ensure consistent and effective use of the procedure.

Freedom of choice

Freedom to participate or not in a trial depends on the client's access to alternative methods. For instance, if the clinic has only the trial method, an oral contraceptive and surgical sterilization, many clients who are tired of the pill and do not want to be surgically sterilized may accept the trial method. This acceptance would not, however, reflect freedom of choice. Poor, illiterate women especially may often have little or no choice among clinics

or methods and therefore no real freedom to decide whether to participate in a trial. While participants in the meeting agreed in principle that availability of alternative methods and services is important and that trials should not be conducted only with poor women, they did not discuss how to achieve these standards.

Quality of care

Participants generally agreed that methods should not be selected for introduction unless minimum standards of quality of care can be assured, but those minimum standards remain to be defined.

"Method introduction requires that as much attention be paid to the service delivery requirements of the method as to the characteristics and properties of the method itself. Methods are not introduced in isolation of existing service conditions; if conditions are not appropriate, it must be determined whether they can be strengthened, or whether it would be better not to offer the method in that locale but instead use referral mechanisms to another centre".

– Joanne Spicehandler

Full and accurate information, sympathetic and respectful provider-client interaction, continuity of care, and availability of other basic reproductive health services, are essential for informed consent and freedom of choice.

These qualities are not very often present, and it was suggested that the introduction process can be used to stimulate improvements in quality of care, at least in clinics or programmes where the trials are undertaken.

Women's health advocates were skeptical, however, and pointed out that improvements in the few sites used for introductory trials could not ensure improvements throughout a national programme. They questioned whether the experience with an introductory trial would be generalizable to a national programme. There was some discussion on how to achieve a reasonable balance between optimal and realistic conditions for introductory trials, and it was agreed that progress could best be made through collaboration and dialogue between scientists, women's health advocates and programme managers at national and local levels.

The process of introduction

The basic purpose of an introductory trial, whether of a new fertility regulation method or of an existing one not used previously in the particular place, is to evaluate the method in an actual service delivery setting. In the past, the focus has been on **how** best to deliver the method. How should staff be trained? What are the logistical challenges? What changes need to be made in the delivery system? More recently, partly as a result of concerns raised by women's health groups, it has been recognized that introductory trials should be used to determine **whether** a method should be introduced. Women's health advocates, therefore, made a number of suggestions about the design of introductory trials. It was agreed that the design of a trial should allow for the possibility of deciding not to proceed with full scale introduction if the method seems unacceptable or inappropriate to many women.

Preparation for the trial

Women's health advocates suggested that ethnographic studies should be done to help ensure that method selection and trial design are appropriate to local patterns of sexuality, reproductive health, and other considerations. Ethnoanatomy (how people view their own bodies) and ethnoterminology (the language people use to describe various organs, functions and symptoms) are important tools which can be used to design trials and to educate providers and users. Scientists agreed that such studies could be very useful not only for the design of introductory trials but also for their basic work on method development.

Some participants also pointed out that community participation and sensitivity to community needs will be key factors in the success of an introductory trial. Informing and involving various segments of the community, including the media, should help create a positive environment for a trial and for later expansion.

Size of the trial and relationship to the health care system

Women's health advocates from India and Indonesia who have had direct experience with contraceptive introduction urged that introductory trials be done on a small scale and be carried out only in areas where there are adequate health personnel, training, and equipment. Most participants agreed that introductory trials should begin on a small scale and should test whether facilities and personnel are adequate, after which they could be expanded to get a broader base of information to understand the needs of both urban and rural populations. However, women's health advocates felt that such phasing has not usually been done and that, while it should be possible to design trials for rural areas, this may be appropriate for some methods and not others.

All agreed that the weaknesses of an existing health or family planning system can be magnified by introductory trials. Scientists and women's health activists with experience of introductory trials stressed that a trial must therefore include assessment of the limitations of the health service, and identification of means to improve the system and the quality of care offered.

"Even introduction of one item like Norplant means that a clinic which previously did not need to use local anaesthesia has to find local anaesthetics. So you are dealing with introduction of consequences to the health care system and there should always be provision for this in introduction".

– Joseph Kasonde

In particular, women's health advocates suggested that providers taking part in a trial should receive training in counselling, be taught how to discuss sexuality and gender issues, and be trained in the diagnosis and treatment of gynaecological diseases such as reproductive tract infections. The risk of pregnancy should be explained clearly to the women taking part in the trial, and where allowed, providers should be prepared to provide safe abortion services as a back-up.

Monitoring

Women's health advocates suggested that monitoring be concerned not only with the number of women who accept and continue the method but also with the recruitment process itself – how women are recruited, whether they are aware that they are taking part in a trial, whether their partners know about it, in what language information is provided, whether they understand it, who signs the consent form (woman or partner), whether she or he understands what she or he is signing, and what other choices of contraception women are given. Provider-client interaction should be documented to determine whether risks, side effects and benefits were properly explained, whether an examination was performed, whether follow-up instructions were given, whether guidelines for use were followed and whether women were aware of their right to stop participating in the trial if they so wished. It was suggested that women's groups can play a major role in collecting data on all of these, through direct and indirect observation, and through interviewing users on their experiences, including those who discontinue.

An example of such collaboration has occurred in Peru. The Peruvian Ministry of Health consulted with women's groups and scientists on whether to begin an introductory trial of Norplant. Women's groups were then invited to participate in an advisory role for the duration of the study. One example of their contribution in this role is that they advised that illiterate women should be excluded from the study since the educational materials had been prepared for a literate population. The main constraint for the women's groups was a lack of funds for broader participation in the trial. It was agreed that women's groups should be encouraged to develop and submit research projects for funding on issues related to introduction that could be coordinated with the introductory trial.

Follow-up

Participants agreed that follow-up is a complex issue which requires much more attention and investment, particularly with provider-dependent methods such as IUDs and implants, both of which should be removed after a recom-

mended period. Many women may not return for routine follow-up visits and special outreach efforts will be needed. But, very often, clients do not have addresses, or they may move frequently. Can women be found five years later for removal of the implants? Will those who remember that removal is necessary be able to find a properly trained and experienced provider to remove it? What constitutes an acceptable percentage of loss-to-follow-up in such a case?

The discussion focused on the divergence of views regarding the overall goals of trials. If the goal is to find out how best to make a method widely available, on the assumption that the method should be made available, then evaluators will be primarily concerned with operational issues. If the goal is to determine whether a method should be more widely distributed in a country, then the evaluation must assess the acceptability and appropriateness of the method for that country.

> *"Introductory trials have provided us with the opportunity to establish dialogue between health providers, scientists and user's groups and women's health activists. However, it seems to me for the future it will be extremely important to establish this dialogue at an earlier point...".*
> – Gregorio Perez-Palacios

Concern was expressed that introductory trials to date have focused on how a method can be introduced and have had a built-in momentum that made nationwide introduction inevitable. Women's health advocates argued strongly for a "pause" in the introduction process to allow for analysis of data and lessons learned from the introductory trials.

For example, it was argued that the trial period for a long-acting method like Norplant, which requires removal at the end of five years, should be the full duration of efficacy of the method, so that all stages of use of the method can be assessed before a decision is taken to expand provision. Otherwise, large numbers of new users may begin the

method, generally under less controlled conditions, before major lessons can be learned from the introductory trial.

A number of scientists responded that the appropriate time for a pause is not after introductory trials but rather after toxicology testing and clinical trials. Dialogue and collaboration with women's health advocates and other concerned groups at these earlier stages would prevent costly mistakes in later selection of methods for introduction. They were concerned that a "pause" following the introductory trial would be extremely expensive and would cause the service providers and the women taking part in the trial to unduly conclude that the trial had produced negative findings. It was agreed, that, if women are fully informed about the nature of the research at the outset and are kept informed as the trial proceeds, their fears of being used as guinea-pigs will be reduced.

"There was a political pause in the case of Norplant in Brazil. As uncomfortable, bad-mannered, and controversial as this episode has been, I think...that, in the historical process of contraceptive research, it might have been a landmark that makes us now think about pausing in the process of introduction".
– Sonia Correa

It was suggested that the need for a pause could be satisfied if introductory trials were started on a small scale and expanded very gradually. Some methods, such as surgical sterilization, implants and IUDs for instance, might be provided at levels of a health care system where more sophisticated facilities exist, while diaphragms, pills and condoms might be introduced at the community level.

While the meeting came to no clear position on the need for a "pause" at the conclusion of an introductory trial prior to wide-scale expansion, there emerged from the discussion an understanding that an introductory trial is a trial as well as an introduction process. Its results must therefore be carefully evaluated. The trial should include time for reflection and consultation at every stage of the process and should allow for decisions that might curtail country-wide introduction of a fertility regulation method.

Whatever the results of a trial might be, it was suggested that full, impartial information on benefits and side effects, obtained from clients (both users and discontinuers) as well as from medical records, should be made rapidly and widely available. This information should be published in national and international journals and presented in such a way that it is accessible to the general public as well as to the scientific community.

Cost of method introduction

The cost of some modern methods may be prohibitive for countries burdened by international debt and multiple demands on their meagre foreign exchange earnings. In these same countries, the costs of service delivery by highly skilled personnel may also be prohibitive. Scientists and women's health advocates urged that every effort be made to estimate the likely costs of introducing a method before a trial starts. Estimates should include not only the costs of services and supplies, but also the costs of changes needed in existing health infrastructure and of technology transfer for local production.

One participant noted that, even at a late stage in the method development process, it is not always possible to estimate with any accuracy the cost of introducing some methods, particularly those which depend on drug delivery systems. However, methods such as pills, injections, condoms and other lower-technology methods can be adequately costed. Continuing efforts are being made by the Special Programme and others to negotiate lower public sector prices with pharmaceutical companies.

Given these issues, participants recommended that all parties involved, including policy-makers, industry and donors, should be better informed on women's and scientists' views, and should work towards an approach which would cover all the concerns expressed in this section.

Suggested actions

- Develop guidelines collaboratively to specify under what circumstances particular methods should be introduced and to clarify the criteria by which introductory trials determine whether a method is appropriate for widespread introduction.

- Include women's groups and women's health advocates in all parts of the introductory trial process, including ethical and scientific committees that design, monitor and evaluate introductory trials.

- Broaden the evaluation team to include service providers, social scientists, and representatives of women's groups, women's health advocacy groups and community groups.

- Disseminate the results of evaluation widely.

- Provide for long-term follow-up studies.

RESEARCH NEEDS

Women's health advocates were of the view that research on fertility regulation is not neutral, but is influenced by political factors such as the policies of population funding agencies, the search for markets by pharmaceutical companies, and political restrictions on the development of safer abortifacients. Priority has been given to: laboratory and clinical research to generate information about pharmacology and to satisfy requirements for registration of methods by drug regulation agencies; development of new fertility control methods (especially provider-controlled methods); and demographic research (especially fertility trends, marriage patterns and contraceptive prevalence). Only recently, has attention been paid to health service delivery systems or to users' needs.

"I don't know of a time that the development of a new contraceptive was started by saying, what women need is this, so let's try to study a method that responds to this need. What really happens is that there is an opportunity of developing a new contraceptive method because of a new discovery in the biological sciences. And it has been very difficult to reconcile the women's needs or the clients' needs with the opportunities of developing a method. I think the only example that I have is the new studies directed to the needs of women who are breastfeeding, which is not led by demographic interests, but by women's interests".

– Aníbal Faúndes

It was agreed that new discoveries in the biological sciences, rather than women's needs, have most often stimulated the development of new contraceptive methods. However, two recent examples were given of fertility regulation methods which have been developed to reduce side effects that the women are worried about: the low-dose once-a-month injectable which was developed because bleeding problems frequently occurred with two- or three-monthly injectables; and hormone-releasing IUDs developed with a view to reducing menstrual blood loss associated with ordinary IUDs. While acknowledging the importance of such efforts, women's health advocates pointed out that responding to women's criticisms of existing methods was not sufficient. They suggested that research should begin by studying the needs of a particular population and the existing delivery system, as the basis for selecting a mix of methods, both old and new, for introduction.

Clients' needs and preferences

Currently, research on sexual activity, reproductive health, and fertility desires is inadequate. Many more studies are needed to find out what women think about various methods, how they understand them to work, what are their fears, why they discontinue methods, what they find acceptable (both in terms of methods and services received), and what are their views on the financial and social costs of methods. Much more also needs to be learned about women's sexual experiences, their experiences with and attitudes towards reproductive morbidity such as reproductive tract infections, and indigenous fertility control practices and preferences.

The Special Programme supports research on the dynamics of contraceptive use which aims to determine what happens to a woman once she starts practicing contraception, how she chooses among the options available, and how she manages the complexities of contraceptive use, pregnancy, delivery, and post-partum family planning.

"When we talk about selection and introduction of methods, not only biomedical research...is important, but along with it...study of women's attitudes and relationships, their way of life, their religion...".

– Ninuk Widyantoro

Health and family planning delivery systems

The extent to which clients' needs can be met depends fundamentally on health and family planning infrastructure, including, among others, supply and logistics systems, service delivery points, staff skills, regulations and management capacity. Participants gave particular emphasis to the need to assess the skills, knowledge, attitudes, and practices of providers, including not simply medical skill and provision of technologies to clients, but also their ability to provide information and counselling. Several participants pointed out that service providers often have very little information about new methods and that provider bias can certainly affect method use.

It was suggested that KAP (knowledge, attitudes and practice) surveys which are normally carried out on the general public, should also be carried out among scientists, programme managers and providers in order to determine the extent to which they are likely to enable clients to make fully informed choices and provide technically competent services. The participants recognized that such research may be particularly challenging as health systems and personnel are medically-oriented and may find it difficult to think and work in terms of broader social needs. In addition, most health and family planning systems give priority to services and will need to be persuaded of the importance of research and their participation in it.

Fertility regulation methods

The objective of methods research should be to develop a range of methods to suit a wide variety of clients. Women's health advocates pointed out that very little research has been done on withdrawal as a method and that barrier methods are given far less priority than hormonal or provider-dependent methods. Scientists suggested that because of AIDS there is a renewed interest, including in the Special Programme, in barrier methods, especially condoms. Some interest also exists in traditional methods such as withdrawal, although this work focuses on why couples choose these methods rather than on their use effectiveness. Participants urged that more emphasis be placed on research into male methods.

Women's health advocates felt that research is needed on the interaction of fertility regulation methods with common disease conditions such as recurrent diarrhoea, parasitic infestation, anaemia and recurrent reproductive tract infections. Staff from the Special Programme reported that considerable research on such issues is being supported by the Special Programme.

Who should do the research and how

Most researchers – laboratory and clinical scientists, demographers, and social scientists – tend to be men. Service managers and physicians who are or should be involved in introduction research also tend to be men, while non-physician providers such as midwives and village health workers are generally women and are lower in the programme hierarchy. This results in a severe gender imbalance in research that influences both the questions that are asked and the interpretation of the findings.

> *"...there can be different interpretations of the same results of scientific studies, and different conclusions drawn from different interpretations. Finding ways of discussing those differences is really important..."*.
> – Anita Hardon

Two ways were suggested to broaden and balance current research activities: first, to add women to the research team; and second, to draw on the expertise of groups who work closely with women and are likely to represent clients' and women's perspectives. It was agreed that it is vital to include women's perspectives at the very earliest stages of research and throughout the process including the final interpretation of results.

The scientists in the meeting pointed out that laboratory and clinical research must be carried out according to certain scientific norms and standards and expressed some doubt whether non-scientists could be fruitfully involved in these processes. In this regard, the women's health advocates felt that scientific

expertise needed to be broadened and informed by the skills and experience of other professionals who work closely with women.

Participants agreed that many different approaches can be used in research on health systems and on clients. In recent years, for example, several techniques have been used – participatory research, focus groups, and "action-oriented" research – to learn about clients' perspectives while assessing delivery systems. A women's health advocacy group in Brazil, for instance, involved women from the barrios in designing and carrying out research on women's attitudes to sterilization, contraception, and local health services. The women then used the results to educate other women and to take action where needed. Research of this kind can empower women as well as generate important and reliable information.

Participants agreed that women and women's health advocates must be included on ethical committees and should participate in the elaboration and revision of research guidelines, both nationally and internationally. Research and trial protocols could include an instruction to scientists to consult with women's groups and guidelines for protocols could include information about how to encourage the participation of women, especially at local levels.

Suggested actions

- Before selecting and introducing fertility regulation methods, undertake studies on: clients' needs and perspectives; knowledge, attitudes and practices of scientists, managers and providers; and the health and family planning infrastructure in each country.

- Foster research on the effectiveness and acceptability of barrier methods and withdrawal, and increase research on male methods.

- Involve women and women's health advocates in all stages of research, including elaboration of ethical guidelines and standards for research, definition of priorities, research design and implementation, and analysis of findings.

- Develop and include innovative research techniques that are participatory, multidisciplinary and sensitive to the clients' situation.

COLLABORATION BETWEEN SCIENTISTS AND WOMEN'S HEALTH ADVOCATES

CREATING COMMON GROUND

Participants acknowledged that dialogue and collaboration between scientists and women's health advocates, as well as other groups concerned about women's health, requires the development of trust, respect, and mutual confidence, as well as willingness to listen and learn. It was agreed that this meeting was an important first step in the process. Many collaborative activities have been suggested throughout this report that should take place at both international and national levels. It was agreed that the international women's health movement now has sufficient maturity, organizational capacity, networks and direct experience to recommend qualified women to participate in the various activities and to join the staffs of key agencies and programmes. Such women, it was agreed, would have fluent communication skills, a commitment to building communication with scientists, and an ability to foster confidence and mutual respect in such a dialogue, along with required technical and professional qualifications.

"...the important thing is we must enter into a dialogue. Women's health advocates groups should be utilized by policy planners and the activist groups should really force policy planners to bring more human aspects to the programme".
– Badri Saxena

Participants cautioned that it will not be sufficient simply to increase the numbers of women in decision making positions, on staff, in meetings or on committees. Women scientists may or may not approach their work from a woman's perspective. The participation of women's health advocates (both men and women) is important to ensure that women's needs, based on broad exposure to women's experiences, are effectively articulated and pursued. Participants also agreed that, where appropriate, research should be carried out by multidisciplinary teams that include women health professionals as well as women's health advocates. This will require establishing protocols that are understandable to women's groups and encouraging dialogue on such protocols.

Enablement

In order for true collaboration to take place, a two-way communication between peers has to be fostered. It was suggested that most established scientific and policy committees, for instance, have a certain power structure which is not easy to penetrate or change, and that it will usually not be effective to add one or two token women to a particular structure. Rather, a critical mass is needed, along with leadership and commitment from the top. It was suggested that collaboration will require, on the one hand, training "lay" women in both the biomedical and social sciences at national as well as international levels, and on the other hand, promoting the training of scientists and policy-makers in feminist health analysis. Both efforts will require substantial commitment and innovative action from scientists and from women. It was suggested that, as a start, scientists and policy-makers could participate more in women's health meetings and visit women's health projects at local, national and regional levels, to become more familiar with women's reproductive health issues as women define them.

Information exchange

A necessary tool to create and sustain collaboration is exchange and dissemination of appropriate information. Many women's health groups already carry out their own research, but the results are often not available to or promoted in the scientific community. Scientific research institutions could actively help to disseminate this kind of information. Similarly, information about research programmes and the results of scientific research, including that supported by the Special Programme, are usually published in specialized journals. While efforts are being made to spread relevant information more widely, results of research still remain largely inaccessible to non-technical audiences. Articles appropriate to lay audiences could be disseminated through the extensive national, regional and international communication networks developed by the women's health movement over the past two decades.

> *"I believe strongly that women's groups can interact productively with scientists and physicians in [the] area [of incorporating women's testimonies and experiences]. I also believe strongly that cooperation would be enhanced if each party acknowledged the importance of the other while recognizing its own limitations".*
> – Adeyemi Adekunle

Funding and staffing

Most of the hundreds of women's health groups in Southern countries operate on shoestring budgets. Their national and international collaboration in the selection and introduction of fertility regulation methods will only be possible with special support. Even well established research institutes will probably find that they need earmarked staff time, or special staff, to ensure that communication and collaboration take place and to manage specialized activities (such as consultative meetings). These institutions as well as donors will need to allocate funds for collaboration. It was suggested that, in some cases, budgets for research and introduction of fertility regulation methods could include specific allocations for collaboration of women's health advocates and other women's groups.

Suggested actions

- Train women in both biomedical and social sciences, and train scientists and policy-makers in women's perspectives on reproductive health.
- Disseminate scientific information in a more accessible form and language to women's and other non-governmental groups, and provide the results of women's research and experience to scientists.
- Generate financial resources to support collaboration between women's health advocates and scientists.

RECOMMENDATIONS FOR ACTION

Consensus was reached on the following recommendations, many of which are addressed specifically to the Special Programme. The essence of the recommendations has been preserved here, but they have been condensed and expressed in a broadly applicable form. In this form they are addressed to all agencies that undertake and/or fund research on fertility regulation methods, method introduction, and service delivery.

Participation by women

- Ensure that women's health advocates are incorporated into policy and programmatic activities.

- Promote national and regional exchanges between scientists and women's groups, in order to help the scientific community, international agencies and national governments to incorporate women's perspectives into their health and family planning priorities.

- Convene special meetings for scientists and women's health advocates, along the lines of this meeting, to discuss key topics, including:
  - the development of new methods;
  - the development of contraceptive vaccines;
  - the use and further development of barrier methods;
  - induced abortion.

- Involve women, and include women's perspectives, in the identification of research needs and priorities and in the implementation of research on reproductive health at country and regional levels.

Research

- Revise technical, methodological, and ethical guidelines for research, in line with women's perspectives and experiences; promote widespread awareness of these guidelines; and foster their implementation at the country level.

- Promote the institutionalization of ethics committees at country level, with the participation of women's health advocates.

- Establish minimum standards for the quality of care in clinical and introductory trials, and mechanisms for promoting and monitoring quality of care.

- Discuss and revise, incorporating women's perspectives, the definitions of and relative weight to be assigned to safety, efficacy, affordability and acceptability in selecting and introducing fertility regulation methods.

- Encourage the formation of multidisciplinary research teams which include women's health advocates, and the use of participatory research methods at national, regional, and international levels.

Support research on:

- women's and men's views on and experiences with existing methods, and the attributes they most like or dislike;

- the comparative effects on women's health of fertility regulation methods, with attention to both pregnancy prevention and pregnancy termination;
- the use-effectiveness and acceptability of the withdrawal method;
- the safety and appropriateness of RU486 compared to surgical or vacuum aspiration abortion;
- the balance among safety, efficacy, affordability and acceptability for particular methods, in relation to other methods, in particular settings.

Training

- Promote training in reproductive health issues including family planning, in medical, midwifery and nursing schools and other key institutions. Such training should pay attention to women's perspectives and to the "human" as well as technical dimensions of fertility regulation and reproductive health.
- Increase the number of women scientists; incorporate women's perspectives into scientific curricula and programmes; and train women's health advocates to participate in research on fertility regulation.

Introduction of fertility regulation methods

- Encourage the introduction of safer, more user-controlled methods.
- Involve women's health advocates in all phases of introductory trials including design, provider training, management, implementation, monitoring and evaluation.
- Review approaches to method introduction to encourage use of integrated health services, other aspects of quality of care, and more participatory approaches.
- Develop criteria and methods to evaluate the settings into which particular fertility regulation methods might be introduced, including the characteristics of health care infrastructure, the recurring costs of providing the method on a national scale, the quality and quantity of existing family planning services, and the status and roles of women.
- Encourage governments to do everything possible to prevent and eliminate unsafe abortion.

Information dissemination

- Disseminate results of research as widely as possible, in particular to women's health advocates and women's groups worldwide, in appropriate languages.
- Support existing women's health advocacy networks and publications, and promote dissemination of their information widely among the scientific community.

LIST OF PARTICIPANTS

Dr. Adeyemi O. Adekunle
Department of Obstetrics and Gynaecology
College of Medicine
University College Hospital
Ibadan, Nigeria

Dr. Maria José Araujo
Coletivo Feminista Sexualidade e Saude
Bartolomeo Rua Zunega 49
CEP 05426
Sao Paolo, Brazil

Dr. Catherine d'Arcangues
Task Force on Long Acting Systemic Agents for Fertility Regulation
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Dr. Rani Bang
SEARCH
Gadchiroli (Maharashtra)
PIN 442 605, India

Dr. Heli Bathija
Task Force on Safety and Efficacy of Fertility Regulating Methods
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Ms. Frescia Carrasco
(Movimiento Manuela Ramos, Peru)
Smalle Jade, 36B 3TV
2000 Svereskberh
Copenhagen, Denmark

Ms. Amparo Claro
Latin America and Caribbean Women's Health Network
Isis International
Casilla 2067, Correo Central
Santiago, Chile

Ms. Sonia Correa
SOS Corpo
Rua do Hospicio 859/4o andar
Boa Vista, Recife PE, 50050 Brazil

Ms. Jane Cottingham
6 Places des Charmettes
1227 Carouge/GE, Switzerland

Dr. Banoo J. Coyaji
Department of Obstetrics and Gynaecology
KEM Hospital Research Centre
Sardar Moodliar Road
Rasta Peth
Pune 411011, India

Dr. Mahmoud Fathalla
Director
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Dr. Aníbal Faúndes
The Population Council and Universidade Estadual de Campinas
Caixa Postal 6181
13081 Campinas SP, Brazil

Dr. Henry Gabelnick
Director
CONRAD
Suite 806
1611 North Kent Street
Arlington, VA 22209, USA

Ms. Adrienne Germain
International Women's Health Coalition
24 East 21st Street, 5th Floor
New York, NY 10010, USA

Dr. Kerstin Hagenfelt
Department of Obstetrics and Gynaecology
Karolinska Hospital
P.O. Box 60500
10401 Stockholm, Sweden

Mr. Peter Hall
Task Force on Introduction and Transfer of Technology
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Dr. Anita Hardon
WEMOS
Minahassastraat 1
P.O. Box 4263
1009 AG Amsterdam, Netherlands

Ms. Adetoun Ilumoka
25 Reverend William Euba Street
Oyadiran Estate
Sabo, Yaba
Lagos, Nigeria

Ms. Sandra Kabir
Bangladesh Women's Health Coalition
House 46A, Road 6A
Dhanmondi RA
Dhaka 1209, Bangladesh

Dr. Joseph Kasonde
Resources for Research
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Dr. Olav Meirik
Task Force on Safety and Efficacy of Fertility Regulating Methods
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Ms. Catherine Mulholland
Office of the Director General
World Health Organization

Ms. Judy Norsigian
The Boston Women's Health Book Collective
240A Elm Street
Somerville MA 02144, USA

Dr. Maria-Coletta de Oliveira
Nucleo de Estudios de Populacao
Universidade Estradual de Campinas
Caixa Postal 1170
13100 Campinas SP, Brazil

Dr. Gregorio Perez-Palacios
Department of Reproductive Biology
Instituto Nacional de la Nutricion
Salvador Zubiran
Calle Vasco de Quiroga 15
14000 Mexico DF, Mexico

Ms. Deborah Rogow
International Women's Health Coalition
24 East 21st Street, 5th Floor
New York, NY 10010, USA

Dr. Patrick Rowe
Task Force on Prevention and Management of Infertility
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Dr. Badri Saxena
Indian Council of Medical Research
Ansari Nagar
New Delhi 110029, India

Ms. Joanne Spicehandler
Task Force on Introduction and Transfer of Technology
Special Programme of Research, Development and Research Training in Human Reproduction
World Health Organization

Dr. Nahid Toubia
The Population Council
1 Dag Hammarskjold Plaza
New York, NY 10017, USA

Dr. Eka Williams
Department of Biological Sciences
University of Calabar
PMB 1115, Rm 223
Calabar, Nigeria

Dr. Rita Thapa
Women, Health and Development
Division of Family Health
World Health Organization

Ms. Ninuk Widyantoro
Indonesian Planned Parenthood Association
Wisma Pancawarga
Jalan Dr Kusuma
Atmaja SH 85
Jakarta, Indonesia