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EXPANDING FAMILY PLANNING OPTIONS

Research on the Introduction and Transfer of Technologies for Fertility Regulation

CONTRACEPTIVE INTRODUCTION RECONSIDERED: A REVIEW AND CONCEPTUAL FRAMEWORK

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CONTRACEPTIVE INTRODUCTION RECONSIDERED: A REVIEW AND CONCEPTUAL FRAMEWORK

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on behalf of the
Task Force on
Research on the Introduction and
Transfer of Technologies
for Fertility Regulation

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The current priorities of the Special Programme include research into new methods of fertility regulation for both women and men, the introduction of methods to family planning programmes, the long-term safety of already existing methods and other aspects of epidemiological research in reproductive health, social and behavioural aspects of reproductive health, and into methods of controlling the spread of sexually transmitted diseases which can cause infertility. The Special Programme also carries out activities to strengthen the research capabilities of developing countries to enable them to meet their own research needs and participate in the global effort in human reproduction research.

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Table of Contents

Foreword

In 1991, the Special Programme of Research, Development and Research Training in Human Reproduction, on the advice of its Scientific and Technical Advisory Group, established a new Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation. The Task Force subsequently addressed the lessons learned by public sector agencies in introducing contraceptive technologies into family planning programmes.

This paper provides the background and rationale for rethinking past approaches and argues that too much attention has been focussed on how to manage the entry of new methods into programmes without carefully assessing beforehand the needs of potential users and the service delivery system's capability for providing the methods appropriately. A new three-stage framework has been developed by the Task Force to assist programmes in developing countries with decisionmaking on when, whether, and how to introduce new methods. In addition, it proposes that the same framework can be applied to the reintroduction, and improved utilization, of currently available methods. This approach is firmly anchored within the concept of improving the quality of care of reproductive health services, particularly at the primary health care level. It describes the necessity for a participatory process which includes all involved constituencies at the country level.

This document is the first of a series from the Task Force, and will be followed by reports on assessments of the need for contraceptive introduction in various countries, as well as on other topics pertinent to this issue.

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Introduction

By the early 1960s major breakthroughs in the development of fertility regulation technologies signalled the beginning of the so-called "contraceptive revolution" (Atkinson et al., 1986, Mauldin and Ross, 1984). The pill, introduced in 1960, was the first of the "modern" reversible methods, followed by inert intrauterine devices (IUDs) such as the Lippes Loop (Djerassi, 1979). Within a decade, the injectable preparations, Depo-provera (depot medroxy-progesterone acetate, DMPA) and Noristerat (norethisterone enanthate, NET-EN) entered the market, and contraceptive subdermal implants began widescale introduction in 1983. Yet despite the availability of such varied technology - including major improvements in many of these methods to increase efficacy and lessen side effects - contraceptive practice still remains limited in many parts of the world (Bongaarts et al. 1990; Bruce and Schearer, 1983).

Introduction of new technologies has long been seen as one important way of expanding contraceptive utilization and addressing unmet need. More recently the introduction of new technologies has also been regarded as a mechanism for improving quality of care by making available a wider choice of contraceptive options to potential users. Recent public sector introduction efforts, however, suggest that the availability of new contraceptives alone will do little to expand utilization or increase choice, if the existing constraints faced by programmes in delivering adequate services are left unaddressed (Ward et al, 1990; Lubis et al., 1994; Simmons et al., 1990; Simmons et al., 1994).

In general, there has been considerable reliance placed on technology as a solution - a "technological fix" (Djerassi, 1979). Scientists have continued to seek longer-acting, more effective methods, that are easy to use, easy to deliver, and have fewer side effects. The hope being that these technological innovations will create more convenient and "user-friendly" methods, as well as ease the burden on the service system. In reality, however, this is frequently not the case. Despite significant advances in biomedical research, none of the more recently available technologies like NORPLANT® implants, or those currently under development - vaccines and vaginal rings, among others - hold promise of fulfilling all of these "user-friendly" characteristics. In fact, with each new technology, both users and providers are instead presented with another trade-off. Every method has a different side effect pattern, and places a different potential burden on the service delivery setting (Atkinson et al., 1986; Bruce, 1987; Simmons et al., 1990).

The focus on newer methods as a solution to the problems faced by services has also diverted attention from a more thorough examination of the underlying causes of low levels of acceptance and continuation of available methods. Adequate information on the delivery of existing methods is vital to an understanding of how well a new method will function in the service setting. Such information is also essential to

strengthen planning for the better utilization of the full range of family planning services.

Although the development of new and improved technologies continues to be important, seeking an appropriate balance between the method and the service should not be overlooked. Until a decade ago, however, little attention was focused on research to examine the service delivery context surrounding the introduction of new contraceptive technology.

Two public sector introduction efforts undertaken in the past ten years - NORPLANT® implants and the once-a-month injectable, Cyclofem™ - have significantly informed our understanding of the need to balance contraceptive technology with appropriate management capability. These experiences have also raised our awareness of the need to question whether service systems can readily adapt to the demands of new methods, and determine if the cost-benefit to the user and programme outweigh the investment required for adequate training, counselling, supervision, and logistics management. In this paper, we argue that technology should be assessed with greater emphasis on the ability of the service environment to provide it appropriately to the user community. Introduction can play an important role in that it provides a window of opportunity for strategic decision-making.

Whether programme managers are considering expansion of the range of methods, or improvements in the utilization of currently available methods, the introduction process, as described below, can provide a framework for a more appropriate assessment of the method mix.

We draw upon past public sector introduction efforts in order to provide a rationale for a more balanced and systematic analysis of the processes contributing to effective decision-making on when, whether and how to introduce new methods into family planning programmes. The paper reviews the factors that have shaped and defined past approaches to introduction and presents a new strategy for a systematic approach to the introduction of new methods or the improved utilization of existing methods.

The ideas presented here are the outcome of a strategic planning process undertaken in December 1991 by the Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation of WHO's Special Programme of Research, Development and Research Training in Human Reproduction. Concerns about service delivery problems encountered when new methods were incorporated into large-scale programmes prompted the Task Force to convene a special consultation on how to address these issues[1]. The experts who participated in that meeting contributed to a revised conceptualization of introduction that veers away from a focus on specific methods and instead advocates an examination of the bigger picture - what do we know and what can we learn about services and users that will better inform the decision-making process on selection of methods to expand the

[1]The participants in this meeting of experts group were Ian Askew, Jeremiah Banda, Ellen Hardy, Firman Lubis, Barbara Mensch, Indra Pathmanathan, Jay Satia, Ruth Simmons, and for the WHO Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation, Peter Hall and Joanne Spicehandler.

method mix? The revised framework suggests that the same approaches for considering new methods are also of great value in developing strategies for underutilized methods.

It is hoped that the ideas expressed here can be used as a frame of reference by national programmes, large scale private programmes and international agencies in reconsidering approaches to expansion of the method mix at both national and global levels. This paper presents new theoretical perspectives for which the specific research methodologies must be tested and further refined. WHO's Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation has made a commitment to undertaking this endeavour and sharing the results with the broader international community.

Past Approaches to Contraceptive Introduction: the Single Method Focus

Introduction, as defined by industry, has traditionally been the point at which a product was "launched" onto the market. Products developed by pharmaceutical companies were managed through sales-oriented marketing campaigns; those developed by non-profit research institutions were licensed to pharmaceutical manufacturers and distributors and handled through the standard commercial channels (Sherris and Perkin, 1989). The training and service delivery requirements of methods and the consequences of adding methods to the programme were only evaluated years after their availability on the market.

In this paper, the definition of introduction derives from the strategic plan for NORPLANT® implant introduction, the first comprehensive public sector introduction effort undertaken by a non-profit international agency, the Population Council (Brown and Greenslade, 1983; Spicehandler, 1989). Introduction as presented in this paper has been expanded to encompass the overall process of managing, implementing and evaluating activities leading to decisions about expansion of the method mix. The introduction process is an interdisciplinary exercise that draws from the medical, social and management sciences, and the operational expertise of service providers and programme managers.

The Population Council originally conceptualized introduction as an interim step or bridge between the research and development phase of a method and its broader use in family planning programmes. Until 1983, when NORPLANT® introduction began, there was no "bridging step." The Council therefore translated introduction into an opportunity to assist family planning programmes with meeting the managerial and programmatic requirements essential to the appropriate delivery of this new technology (Brown and Greenslade, 1983; Spicehandler, 1989).

The Council's introduction approach was largely influenced by its three decades of experience working with family planning programmes in developing countries (IDRC and The Population Council, 1990). The rationale for the Council's involvement in NORPLANT® implant introduction was based on the lessons learned from the troubled entry of the Lippes Loop IUD into the Indian family planning programme in the 1960s. There is surprisingly little documentation of what occurred in the published literature although there are many anecdotal references to the problems encountered. According to Soni (1984), the IUD was

> "...enthusiastically introduced as the vital missing link in the [Indian] programme. Within two years of its introduction 1.7 million IUDs were inserted. But the success and optimism were short-lived as inadequate pre-insertion checks, poor follow-up, genuine side effects and grossly exaggerated rumours led to high termination rates and a 7-year slump in annual insertions. The

programme had, quite simply, been rushed through without organizational preparedness to cope with the known side effects."

After almost three decades of availability of the IUD in India the percentage of couples using the IUD remains low, at 2% (Ross et al., 1992).

The strategy developed for NORPLANT® introduction followed a single method focus. It was designed primarily to facilitate this contraceptive's entry into programmes, and attempted to identify the management and technical issues that would impact on the appropriate delivery of this method in country-specific situations (Brown and Greenslade, 1983). The objectives of that effort, which began in 1983, were to provide data for national level regulatory approvals, develop national training centres, offer firsthand experience to leading health care providers, and identify the management and programme parameters required to integrate this new method appropriately into the service delivery system. Evaluation techniques were employed to gather feedback from service providers and users that could be channelled into the preparation of technical and counselling guidelines, training and evaluation activities (Spicehandler, 1989).

By 1987, additional studies were designed to look more specifically at counselling, training and clinic management issues. This later effort was designed in response to service related concerns drawn to the Council's attention during the earlier phase of introduction (IDRC and the Population Council, 1990). It documented such important areas as the need for careful planning on the scale-up of service delivery and led to important programmatic recommendations regarding access to removal (Ward et al. 1990). The introduction by WHO of the once-a-month injectable, Cyclofem™, to which this paper will also refer, followed a similar model to that for NORPLANT® (Hall et al., 1992; Hall et al., 1994).

Although the introduction effort focused on a specific method it nevertheless offered opportunities for addressing quality of care issues in the participating clinics (Beattie et al., 1990). As NORPLANT® implants or Cyclofem™ were introduced into the routine service delivery setting, the strengths and weaknesses of existing services came under observation in the research. Thus introduction became a vehicle for identifying service-related problems affecting other methods in the mix as well as the method being introduced. It also allowed for the development of interventions that could have a positive impact on all methods - particularly, improvements in counselling. The training curricula developed for both NORPLANT® and Cyclofem™ introduction reinforced provider knowledge on the risks and benefits of all available methods, and offered a communications skills component to which few clinicians had been exposed in earlier training. It is important to keep in mind, however, that these improvements were still by-products of a decision aimed at incorporating a given method into the system.

The method-specific information generated by introduction research was important to the development of guidelines, standards, counselling materials, and training programmes for the clinical management of NORPLANT® implants and Cyclofem™. However, the strategy for introduction of these methods had several shortcomings.

First, the strategy did not evaluate whether the service system had the appropriate capability to offer these methods prior to their introduction. Since the principal objective was to manage the method's entry into programmes, an important component of the NORPLANT® introduction effort was to undertake activities in clinics that could be developed into national training centres. Considerable emphasis was therefore placed on the structural support required to enable these health facilities to serve as nuclei for the extension of training after product registration. Yet the ability to sustain an effort in a given country can vary considerably depending upon the existing health infrastructure.

In Colombia, for example, a service delivery study conducted with both the private IPPF affiliate and the government sponsored programme showed significant differences in the ability of these programmes to ensure that service providers were adequately trained in the techniques for NORPLANT® implant insertion, removal and counselling (Ward et al., 1989). The IPPF affiliate, which has a strong family planning services infrastructure, was able to sustain adequate quality of care because of a well developed capacity for training and staffing. The government programme, on the other hand, experienced greater difficulty with ensuring access to implant removal, because of an inability to meet the training demands caused by frequent staff turnover.

The introduction strategy also did not help programmes to explore whether or not the method had a place within a given service system. In Indonesia it was thought that the introduction of Cyclofem™, the monthly injectable, would increase contraceptive options by offering users an injectable with a more regular bleeding pattern than the progestogen-only methods already available, Depo-Provera (a three monthly injectable) and Noristerat (a two monthly injectable). Based on this assumption, the National Family Planning Coordinating Board of Indonesia (BKKBN), with support from WHO, initiated introductory studies in several district health centres in four Indonesian provinces.

In this study, and in a related study of Cyclofem™ service delivery, researchers observed the use of Cyclofem™ as a substitute for exhausted supplies of DMPA or NET-EN (Lubis et al. 1994, Simmons et al., 1994). Depending upon the frequency of its occurrence, this practice should raise questions about the niche for a third injectable in the family planning programme. If programme managers display a preference for the longer term injectables and Cyclofem™ is offered primarily as a substitute, then potential users are not gaining an additional contraceptive option and choice is not expanded. Additionally, if logistics management is already a problem in the distribution of currently available injectables, Cyclofem™ supply will also be affected, once it is introduced.

Past introduction experience also challenges the widely held assumption that broad distribution to the largest number of service delivery points assures wide availability. Some methods are not suitable for distribution through health posts and primary health care settings with limited facilities. Such is the case where special training or the need to ensure high levels of asepsis are required. Certain methods may have to be restricted to settings with specific

facilities and trained staff. The NORPLANT® experience illustrates this point clearly. Referral networks to a limited number of facilities may be more appropriate for NORPLANT®, surgical sterilization and IUDs, while pills, injectables and condoms could be distributed through a less restrictive network if systems for resupply are in place and functioning.

The NORPLANT® implant and Cyclofem™ introduction efforts have been instrumental in drawing attention to both the user perspective and service environment considerations that affect the introduction of new methods. Considerable gains have been made in terms of our understanding of the managerial dimensions of method utilization. However, past experience indicates that introduction must in the future move toward a more critical evaluation of the need and the niche for additions to the existing method mix prior to a method's entry into the system.

A Broadened Perspective on Introduction: Focus on Method Mix and Programme Capabilities

In contrast with earlier efforts, the new strategy for introduction proposed by WHO emphasizes introduction as an instrument for strategic decision-making on method mix. It provides a logical structure for assessing the suitability of methods given the social and service context of method delivery in a given setting. In addition, the WHO strategy advocates that the introduction process also be applied to addressing problems with the delivery of currently available methods. The revised conceptual framework for this new approach to introduction has six essential elements. The framework is:

Method mix oriented. The focus is on analysis and assessment of the existing method mix within a given programme - not on a single method. All methods are viewed as having distinct advantages and disadvantages and trade-offs to the programme and the user must be carefully evaluated. Potential additions to the mix must be assessed in the context of the constraints within the given service system.

Quality of care focused. The framework establishes two principal criteria as the basis for decision-making on introduction: (1) Will the addition or expanded utilization of a method contribute to maintaining or improving the existing levels of quality of care offered to clients? (2) Will the method indeed expand the range of options for fertility regulation available to the public served by the programme? The first question recognizes that including an additional method without specific adaptations in the system has potential for overburdening existing facilities, and may in fact have a negative impact on the current level of quality of care. The second, as suggested by the earlier example of an additional injectable in the Indonesian programme, reminds us that expanding contraceptive options in the family planning programme does not always increase contraceptive choice to the user.

Driven by management capability. The framework advocates matching methods with the appropriate management capability to ensure that they are used appropriately in programmes. Services must be able to offer adequate standards of technical care and an interpersonal dynamic between user and provider that will inspire user confidence in the programme. Technology driven approaches fail to consider that technologies function within the strengths and weaknesses of the existing service delivery system.

Geared for decision-making. Various steps in the decision-making process are identified. The opportunity to pause and reassess the potential role of the method within the programme exists at each stage of the introduction process. It is understood that preliminary assessment may lead to various possibilities including the decision that introduction of a method originally thought to be a useful addition should not proceed.

Based on participation. Collaborative research and decision-making are

encouraged in order to increase the range of experiences reflected as well as to ensure commitment to the outcome. The framework therefore advocates bringing together Ministry of Health officials, family planning programme managers, health management and social science researchers, grass roots level service providers, women's health advocates and consumer groups. Those with a vested interest in the process will have a vested interest in the implementation of the outcome.

Country owned. Although country level ownership appears obvious, decision-making is often strongly influenced by donor priorities. Working partnerships with donors, international agencies and non-governmental organizations (NGOs) should be encouraged because of the resources and technical know-how that these agencies can provide, but decision-making and implementation should nevertheless remain the responsibility of the participants specified above.

In order to implement the introduction process in a way that maintains the integrity of these elements, a three-stage framework is proposed, which is described in the following section.

A Three-Stage Framework for Contraceptive Introduction

A three stage framework is proposed that places policy choice and research needs on whether, when, and how to introduce fertility regulation technologies in the context of the service environment and user demand. Stage I is a preliminary assessment of user and service delivery needs, programme policies, and potential programme constraints aimed at identification of which method or methods - if introduction is deemed advisable at the time - should be the focus of attention in the given context. Stage II entails the design and implementation of research to look at both the issues affecting services and users as these methods enter the system. Stage III focuses on the utilization of research results for decision-making, policy and planning. The basic structure of the framework is illustrated in
Figure 1.

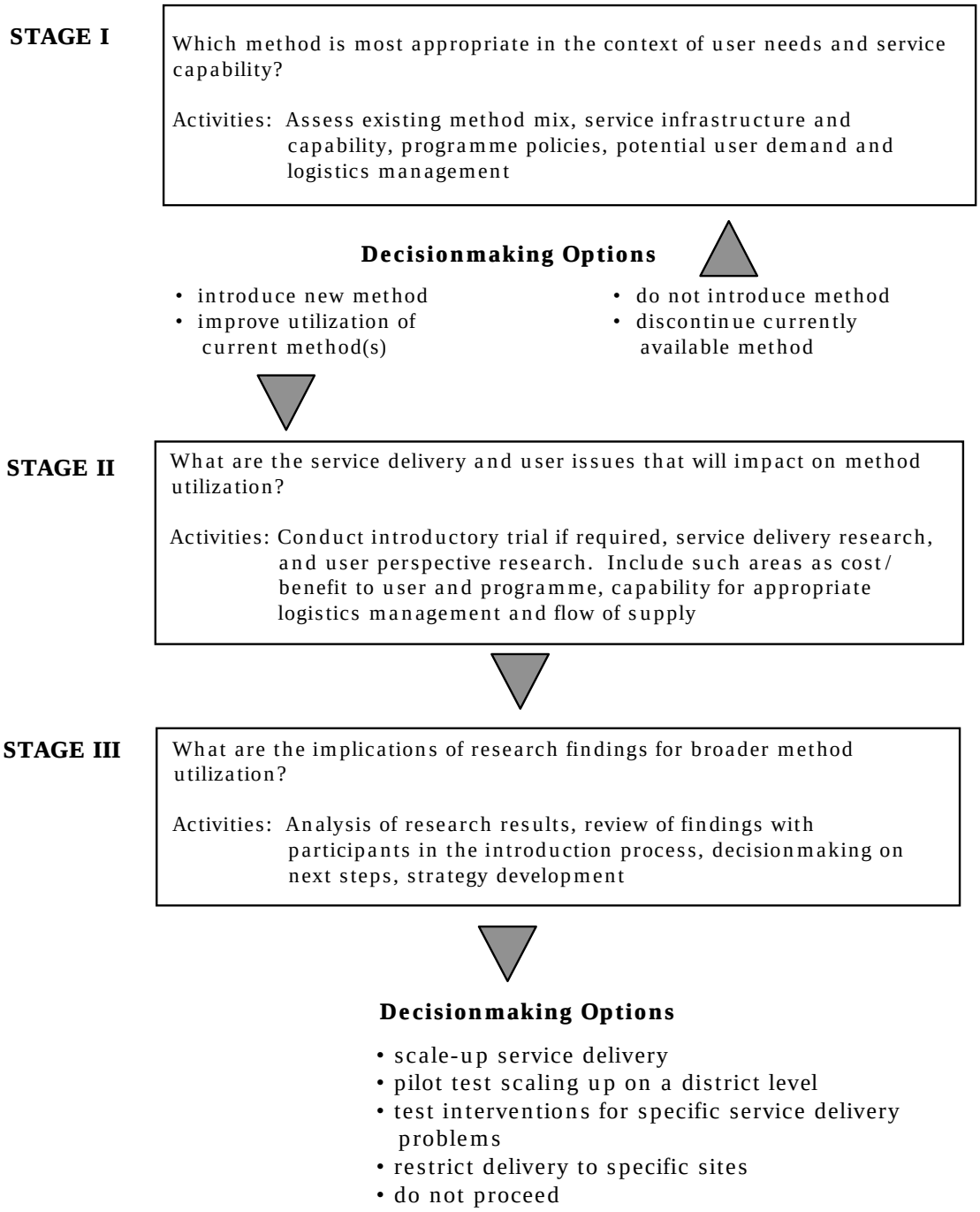
This three-stage framework suggests a line of inquiry that Ministry officials and programme managers should follow at the country level. It is not intended to be used as a rigid formula but rather as an adaptable model. The framework recognizes the diversity of service delivery systems within a country as well as across the borders of a region - a point overlooked in earlier introductory efforts. Since patterns of service infrastructure differ so greatly, the suggestion of one concrete model becomes misleading. Programmes find themselves trying to adapt to an often unattainable hypothetical model rather than focusing on the realities of their system as it currently functions. Snow and Chen (1991) caution that matching supply and demand factors to technology is not as cut and dry as it seems but "...a laborious process, with unpredictable outcomes" both for the method mix and for policy. They encourage experimentation, intervention and "solid field assessment" in order to arrive at an appropriate method mix in a given setting. Thus the key to the framework's application is flexibility in what is examined and how the approach will be used to shape decision-making.

Stage I: Assessment

The principal objective of the Stage I assessment is to make a reasonable judgement about additions to the method mix or possible improvements in the utilization of existing methods. This assessment is only the preliminary step in a larger process. It is not envisaged as a period for extensive in-depth analysis or baseline research. Existing secondary data, a limited number of key informant interviews with policy-makers, service providers, logistics managers, users, and women's health advocates, and some limited observations of clinic settings would constitute the inputs into this initial decision-making stage. The validity of the course of action pursued would be tested during Stage II research.

Stage I addresses the question of the need for additional technology. Prior to a considerable programmatic investment in expansion of the method mix, both

Figure 1. A Three-stage Framework for Decision-making on Contraceptive Introduction



The introductory trial

The primary purpose of the introductory trial[2] is to offer clinicians a firsthand experience with the technology in order to develop confidence with the method in their own country setting. It is generally conducted in a limited set of facilities under monitored conditions. Such research examines method use in clinic settings and is necessary in such cases as NORPLANT® introduction where the clinical norms and guidelines need clarification prior to broad-scale use. An introductory trial might also be appropriate to improve the credibility of a method in which the provider community has little confidence, such as the contraceptive diaphragm.

The introductory trial utilizes a research protocol resembling a simplified clinical trial. The clinic case record form collects data principally on reasons for dis-

[2]The introductory trial should not be confused with a Phase III clinical trial. It is only undertaken after safety and efficacy data meeting international standards have been obtained through clinical trials. Data from clinical trials up to Phase III are the data submitted for registration of the product with regulatory authorities. An introductory trial is sometimes referred to as "post-phase III" or 'phase IV'.

continuation and complaints about side effects. Analysis of continuation rates and efficacy from these studies makes it possible to assess the extent to which use in a more realistic setting produces different results from those seen in clinical phase III trials. Preliminary analysis of available data from Cyclofem™ introductory trials, for example, shows higher rates of discontinuation for service or convenience related reasons than was apparent in phase III trials. The continuation rate in Indonesia during the multicentre clinical trial was 91% after one year of follow-up in one research centre and 66.4% after one year of follow-up in six district health centres participating in the introductory trial (Pandi et al., 1992). Even with close monitoring, the more realistic service setting indicates an important difference in patterns of use.

Use of the clinic case record allows the service provider a system for monitoring the user's reaction to the technology. With NORPLANT® implants, for example, this data collection system was effective in improving provider sensitivity to the bleeding pattern disruptions experienced by many users, and improved their understanding of the counselling issues involved. Service providers, who were accustomed to recording clinical observations, found this an easy way to track user's complaints about side effects (Spicehandler, 1989).

The introductory trial would generally precede service and user research by a sufficient amount of time - at least 6-12 months, depending upon the method - so that users and providers could gain some experience with the technology. The service provider and the user then become a critical resource as subjects for further study. Issues that may impact on effective service delivery generally emerge at this point. The inputs of both the service providers and users, as well as observations of the clinic setting and the user/provider dynamic will therefore be able to inform the design of instruments for service delivery and user research.

The introductory trial has limited value as an isolated activity and should be undertaken in conjunction with service delivery and user perspective research. In cases where the introduction objective is to examine underutilized methods, or the medical community is already familiar with a product, the researchers would proceed with service delivery and user perspective research without the need for an introductory trial.

Service delivery research

Service delivery research focuses on the organizational, management, and policy context within which services are provided. It also includes an examination of the specific aspects of the clinic's physical environment that would impact on the method or methods under consideration, such as equipment and storage facilities, as well as on the capabilities of the logistics system to monitor and ensure the flow of supplies. This research identifies the level of preparedness of the delivery system and assesses interventions that could improve introduction or expanded utilization of methods.

There are a number of methodological approaches to undertaking Stage II research. These are discussed in-depth in the literature and include the family planning situation analysis approach (Fisher et al., 1991), and the management approaches described by Simmons and Simmons (1990). Cleland et al. (1990) offers a compendium of

possible methodologies reviewing the pros and cons of different types of social science research design. The research team needs to evaluate carefully the objectives of the service delivery component and choose those techniques that would be most effective given the scope of the study and available resources. Within the context of this framework, however, the research design selected remains focused on examining quality of care in the context of the larger system's organizational capabilities.

One example of a research design applicable under this framework is the study conducted on Cyclofem™ in Indonesia (Lubis et al., 1994; Simmons et al., 1994)[3]. This study examined the operational requirements for introducing Cyclofem™ in the public and private sectors. The research looked at three elements of the Bruce (1990) quality of care framework: choice - the extent to which a range of options is made available; technical quality of care - the medical standards and techniques employed; and interpersonal quality of care - the interaction between client and provider. The study was conducted using in-depth interviews with policy-makers, service providers and users, and observations of service delivery in health centres, some of which were participating in introductory evaluations and others that were not.

A qualitative research approach was selected because it offered insights into the way in which decisions about contraception were made, information was offered, policies and management procedures were actually carried out, and technical procedures were performed. Secondary data supplied important information about contraceptive use in the areas under study.

The study findings have important implications for decision-making about the niche for another injectable contraceptive in the Indonesian public sector programme. The research pointed out, for example, that Cyclofem™ would only broaden choice if a clear distinction were made between this method and the other available injectables, in terms of counselling, screening, and logistics management. As discussed earlier, when staff are not trained to distinguish between the characteristics of methods, or provided with appropriate record-keeping systems to monitor users and resupply, the additional method may confuse rather than enhance service delivery. In the public sector programme the results suggested that significant managerial adaptation would likely be required (Lubis et al. 1994; Simmons et al. 1994). The findings did indicate, however, the potential for delivering this method within the private or social marketing sectors in a way that would provide adequate levels of quality of care.

User perspective research

Users' decisions to seek services and the methods they choose are influenced by, but not limited to, the characteristics of the contraceptive itself. Differences in the ability to tolerate side effects, the desire for additional children and the conditions which govern users' daily lives and personal experiences influence decisions on method selection and continuation. The socio-cultural context, perceptions about the motivations of the programme, and the experience of

[3]This study was conducted in conjunction with the National Family Planning Coordinating Board of Indonesia (BKKBN) for the purpose of gaining a better understanding of the niche for Cyclofem™. Although this particular study did look at method niche, it was done after the introductory trial, rather than before as recommended by the new strategy.

friends and neighbours with a specific method also play a role. Areas for research include user attitudes about the advantages and disadvantages of the method, attitudes about previously used methods and preferences, health and other concerns perceived to be related to method use, experience with service providers and health care facilities, counselling and informational needs, and access to method administration and reversibility. User perspective research explores these issues and their relationship to contraceptive choice and continuation. Survey research, focus groups, and in-depth interviews have all been used to study these issues. Cleland et al. (1990) provide several suggestions concerning appropriate methodologies.

In the context of this framework, user perspective research serves primarily as a management tool. Feedback from those served by the clinic or those in the surrounding community who do not seek services can help to assess service strategies as well as identify the niche for a specific method. The information can also be used to determine at what level of services a particular method is most appropriately offered (public versus private sector, services with access to specific facilities, etc), and the counselling and informational needs of users and providers.

User research in Stage II faces certain limitations in projecting future demand and market niche. Its primary aim would be to examine user experiences and concerns among the population under study in the introductory trial, or attending the centres participating in an intervention focussed on an underutilized method. Thus care must be taken when applying findings to the overall programme.

Outcomes from Stage II

Together, the introductory trial, service delivery and user perspective research should provide a composite picture of the potential role of new technology in a given service setting. Using Figure 2 as the guiding paradigm, there are three sets of questions concerning the user/technology/service interface that the data should be able to address.

The user/technology interface

Do users find that the advantages of the method outweigh its disadvantages? Do they have specific health related concerns or fears about the method? Is there additional information they would require to have a more satisfactory experience with this method? Do they have difficulties with side effects? If so, what are their mechanisms for coping and what service interventions may be required? Do they have difficulties using the method on a regular basis, or have concerns related to mode of administration or removal? Do users need to face great inconvenience to obtain resupply of methods? Are there social pressures from the partner, family members, or others in the community not to use specific methods for personal, religious or cultural reasons? Are user fears about methods taken seriously and addressed?

The user/service interface

Do users find the health centre easily accessible in terms of distance and cost? Are they treated respectfully by staff? Are waiting times lengthy? Are clinic hours convenient to the community? Do users feel they receive adequate responses to their questions and concerns? Do they feel welcome at the clinic? Have they experienced any problems related to technical procedures (unusual discomfort or pain, infection,

expulsion) and was the staff's response appropriate to the situation?

The technology/service interface
Is the method suitable given the service conditions available? What service interventions were made during research? Will they be sustainable without further external support? Can they be developed in a larger network of clinics or health posts? What is the minimal level of facility required to offer this method appropriately? Do mechanisms exist for providing, supervising and evaluating training? Do the service related costs to include the method outweigh the demand for the method?

Stage III: Utilization of Research for Policy and Planning

The primary objective of this three stage exercise is the *application* of research to a more systematic decision-making process that yields improvements in services, and ultimately upgrades the level of quality of care. In this strategy, research utilization is part of a longer process of interaction and collaboration that must be nurtured from Stage I. The broad based participation of key stakeholders - advocates for the user community, service providers, researchers and policy-makers is therefore absolutely essential for success. Traditionally, although the burden of primary responsibility during Stage II is on the researcher, it shifts to the policy-maker in Stage III, without whom research cannot be translated into action.

The discussion and utilization of findings requires an atmosphere of confidence and trust, making it crucial that all stakeholders are focused on mechanisms for constructive use of findings from the outset of the collaboration. Research is often published and disseminated within the research community before it has been shared with the programme. When researchers analyze the intricacies of programme management issues, there is a heightened sensitivity among managers and policy-makers that research will be used to critique the programme. If research is published or broadly disseminated prior to adequate opportunity for constructive dialogue, positive interaction among stakeholders is undermined. An important element of Stage III is therefore the organization of workshops and the promotion of dialogue prior to publication, to ensure that the implications of findings are fully understood and that consensus is reached in order to have positive impact on the implementation process.

Stage III allows an opportunity to pause, evaluate and plan, using service and user research as the foundation for next steps. In examining the bigger picture, policy-makers must now determine whether the method is compatible with what the service system can offer, how to scale up services, and which service delivery points are most appropriate. Additional interventions suggested by the research may need to be tested or refined. Should the decision be made to incorporate the method on a larger scale, plans for gradual phased-in expansion are needed if the integrity of the quality of care focus is to be maintained as the expansion proceeds.

Rather than the automatic leap to large scale distribution that has been seen in the past, here the option exists to proceed with limited service delivery in order to provide an opportunity for further adaptations in the delivery

system. The design of pilot projects at a district level would allow programme managers to test the viability of implementation on a larger scale before it moves to a state or national level.

Conclusions

Introduction can be a valuable opportunity for implementing major change in programmatic decision-making. A programme that is interested in considering expansion of the method mix is also signalling an awareness of the need for service-related improvement. When technology driven approaches are pursued, as has often been the case in the past, new methods may mistakenly be used to address long-standing service delivery problems that may have impeded earlier efforts to expand family planning coverage and improve quality of care. In such instances, additional technology will only exacerbate the problem.

If viewed from the broader perspective suggested by this three stage framework, technology becomes only one element contributing to an effectively functioning service delivery environment. Technology is useful only inasmuch as it facilitates the programme's ability to meet the needs of the clients in the community. In order to better address their needs, we must first understand the constraints that impede user access to family planning. It is also necessary to understand why potential users are not seeking methods or services when they are available in the community. Once the root of the problem is addressed, decision-makers will be better equipped to assess the appropriateness of specific technologies.

Those in the family planning field must also face certain realities. First, the perfect contraceptive is not on the horizon. Although biomedical researchers continue to pursue the development of new contraceptive options with improved efficacy and side effect profiles, past experience confirms that each of these products will confront users and family planning programmes with other trade-offs. It should be recognized that contraceptive decision-making for the individual user is strongly influenced by a variety of factors beyond the specific attributes of a particular contraceptive.

The three-stage framework presented here recognizes three basic principles. The first is that there are differences among individual users in any given society. Programmes should acknowledge and reflect this in the way services are provided. The second is that service infrastructures differ significantly within countries as well as across regions. There is therefore no single method or programme model for service delivery that is best suited to all situations. Evaluation and assessment must be considered an ongoing process as programmes expand, as needs change in the community over time, and as new technologies become available.

The third is that quality of care and enhancing user satisfaction with available services should always be the central focus of the introduction process. The addition of a specific technology is less significant than the opportunity to assess and strengthen various components of the existing service system.
The framework, when applied within this context, should help policy-makers focus on selecting methods more appropriate

to and sustainable within the given service system.

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Annex I. Stage I Assessment Questions

Potential for User Demand

What information is available to assess the potential niche for a particular new method in the country's family planning programme, from the perspective of potential demand? In order to address this question, programme management would need to look at the following kinds of questions:

What methods are currently available? Through what service delivery points are these methods delivered? What is the level of activity in both the public and private sector in terms of family planning service delivery?

Are there particular medical concerns reflected by the general health status of the population or reproductive health status that need to be taken into consideration in determining the appropriateness of the method (e.g., in the case of the IUD one might be particularly concerned about the prevalence of anaemia or reproductive tract infections; in terms of procedures requiring strict attention to asepsis, what is the prevalence of STDs)?

What are the current contraceptive use patterns and what information can they offer about the niche for the new method?

What do socio-economic factors tell us about contraceptive use and preferences in the country? Do specific age groups have specific contraceptive needs or preferences, or show an unmet need (e.g., lack of birth-spacing technologies limiting the coverage of younger users, lack of longer acting methods for those who have achieved desired family size and may not have access to sterilization, etc.)?

What are the sociocultural factors that have implications for the selection and use of methods with specific characteristics? Is there a specific method niche due to sociocultural factors (e.g., lack of availability of surgical sterilization for religious or sociocultural reasons and the need for alternatives)?

Is there existing information on users' perspectives on similar modalities that will help inform us of the potential niche or desirability of the new method?

What is the potential cost of the method to the user (including purchase of contraceptive, service cost, need for resupply, transportation and waiting time)?

Service Delivery Issues

To assess management capability, an understanding is required of issues that would affect policy decisions as well as the health service delivery system's existing or potential capability for providing the services required by the method.

A) Policy Level Issues:

Is their an explicit government policy on the use of contraception? on abortion?

What are the sociocultural factors affecting the decision-making processes associated with contraceptive choice and continuation? (examples?)

What is the government's relationship with different donor agencies? Is there influence from a particular donor government or agency to move toward use of specific methods? What is the window for governments to effect changes in donor policies to respond to national needs?

What are the private sector influences on the government's purchasing decisions (e.g., marketing strategies of specific companies)?

Is technology transfer an issue? On what basis should this be considered? What are the capabilities required and the costs of undertaking this endeavour? Are the potential markets worth the cost (e.g., will there be a lower price to programmes based on volume or is the market potential so small as to not effect a savings to the programme)? How does the decision to introduce manufacturing influence the government's marketing decisions within its programme?

B) Management Level Issues

What are the intrinsic characteristics of the method as they relate to establishing service requirements (e.g., need for special facilities or equipment, record-keeping systems to remind users when duration of efficacy has passed, etc.)

What systems must be in place to ensure that the health system is at the appropriate level of preparedness for adequate service delivery?

- What is the interface between the intrinsic characteristics of the technology and the delivery system (what changes of organizational or individual behaviour may be required?)

- What adaptations are needed in the service system to introduce the new method with adequate attention to quality of care?

- What are the range of service delivery systems available through the public sector and the private sector in a given country?

- What is the service system's ability to make the required adaptations to ensure quality of care in the introduction of the proposed method (what is the burden on the system, and the non-monetary costs and capabilities of managing that burden? Does the programme offset the required monetary/non-monetary investment?)

- Will the sustainability of the method in the system depend on some form of cost recovery from the user or subsidization of the programme? Will resources or income levels allow for this sustainability?

- What is the intensity of the user/provider interface required to mobilize demand (i.e., what efforts are required to disseminate information to make the method known?)

- Does the method differ significantly enough from other similar modalities in terms of higher efficacy, fewer complaints about side effects, and duration or ease of use to warrant changes in training if the techniques for administration and reversibility are different from those for the currently available modality?

For each of these elements the following should be considered: supervision, staffing, training, facilities, counselling/IEC needs, referral networks, record-keeping/follow-up systems, staff morale, outside resources required, and product and logistics management requirements (including registration, quality assurance and distribution).