The Strategic Approach to Contraceptive Introduction

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The introduction of new contraceptive technologies has great potential for expanding contraceptive choice, but in practice, benefits have not always materialized as new methods have been added to public-sector programs. In response to lessons from the past, the UNDP/UNFPA/WHO/ World Bank Special Programme of Research, Development, and Research Training in Human Reproduction (HRP) has taken major steps to develop a new approach and to support governments interested in its implementation. After reviewing previous experience with contraceptive introduction, the article outlines the strategic approach and discusses lessons from eight countries. This new approach shifts attention from promotion of a particular technology to an emphasis on the method mix, the capacity to provide services with quality of care, reproductive choice, and users' perspectives and needs. It also suggests that technology choice should be undertaken through a participatory process that begins with an assessment of the need for contraceptive introduction and is followed by research and policy and program development. Initial results from Bolivia, Brazil, Burkina Faso, Chile, Myanmar, South Africa, Vietnam, and Zambia confirm the value of the new approach. (STUDIES IN FAMILY PLANNING 1997; 28, 2: 79–94)

Over the past several decades, new methods of contraception have made essential contributions to couples' well-being by allowing them to avoid unwanted pregnancy and abortions and by permitting improvements in the timing of childbirth. The oral contraceptive, which became widely available in the 1960s, was the first of the modern reversible methods, followed by the intrauterine device (IUD). Shortly thereafter, injectable preparations entered the market, and subdermal implants were introduced beginning in 1983. Without doubt, health and social problems resulting from unwanted fertility could be alleviated if the contraceptive technologies that now exist were more broadly available, accessible, and affordable to a wider range of people than those who currently benefit from them. Introduction of new technologies has long been seen as one important way of expanding contraceptive use and addressing unmet need. More recently, introduction of new methods has also been regarded as a means of improving quality of care by making available a wider choice of contraceptives.

Although the introduction of new contraceptive technologies into service systems has great potential, three decades of experience have also shown that in practice, the benefits of technology have not always materialized. Close examination of contraceptive introduction in the public sector of Southern countries suggests that the availability of new contraceptives alone will not expand use or broaden choice unless the existing constraints faced by programs in delivering adequate services are addressed (Simmons, 1971; Soni, 1984; Ward et al., 1990; Simmons et al., 1994; Lubis et al., 1994; Snow and Chen, 1991). Even when users are

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satisfied with methods, a program's inability to attend to the technical requirements of a method, for example, the necessity to remove Norplant® implants after five years of use, is problematic (Hull, 1996). The issues to be considered in policy choices related to technology introduction are complex. Above all, they require greater systematic attention to the social and institutional context of method choice and broader input from relevant stakeholders than they have received so far.

In response to these lessons from the past, the UNDP/UNFPA/WHO/World Bank[1] Special Programme of Research, Development, and Research Training in Human Reproduction (HRP) has taken major steps to reframe its strategy for contraceptive introduction and to support governments interested in implementing new approaches. This process of redefinition was initiated at a strategic planning meeting in December 1991, organized by the Task Force on Research on the Introduction and Transfer of Technologies for Fertility Regulation within HRP. Experts from the World Health Organization and other institutions revised the existing concept of introduction to avoid focusing on single technologies, to advocate instead an examination of what can be learned about services and users that will better inform the decisionmaking process for selection of methods (Spicehandler and Simmons, 1994). This new model, referred to as "the strategic approach to contraceptive introduction," also suggests that new technologies must be introduced within a quality-of-care and reproductive-health framework and must incorporate the perspectives of a broad range of stakeholders, including those of users, providers, managers, policymakers, and women's health advocates.[2]

Since the end of 1993, WHO has been providing support to public-sector programs in Bolivia, Brazil, Burkina Faso, Chile, Myanmar, South Africa, Vietnam, and Zambia, in order to implement this strategic approach. Experience has confirmed that this new way of proceeding can be a means of enhancing the capacity to provide quality services. This article provides an overview of the strategic approach and presents lessons from the implementation experience in eight countries. Although many illustrations in this paper refer predominantly to the introduction of contraceptive methods, the strategy addresses fertility-regulation technologies broadly defined to include menstrual regulation and abortion.

Previous Approaches

Approaches to contraceptive introduction have evolved considerably over the past three decades, progressing from simplistic and mechanical assumptions to much broader understandings. Widespread introduction of the IUD in the 1960s, especially in India, proceeded on the notion that the provision of new contraceptive technology on a large scale was a routine matter. The device itself was widely considered to offer the solution to India's population problem. The importance of the social impact of method use and of the new service-delivery requirements involved in providing the IUD with an appropriate level of quality were ignored (Soni, 1984), as was the need for early evaluation (Simmons, 1971). As a consequence, the Indian program was unable to ensure appropriate levels of technical competence and counseling; it did not provide adequate logistics and supplies; and it did not support women as they experienced the physical and social consequences of IUD use. After an initially favorable response to the method, the IUD soon became discredited, depriving Indian women of the benefits that could have been provided if introduction had proceeded more cautiously and with greater attention to both the social and institutional contexts of method use.

Bridging Clinical Testing and Introduction with Applied Research

The Indian IUD experience shaped subsequent approaches to contraceptive introduction in public-sector settings. Research on experience with and acceptability of new methods within routine service-delivery settings served as a bridge between clinical testing and broad introduction of the methods. This approach consisted initially of two components: introductory or field trials and acceptability studies. In the late 1980s and early 1990s, several projects with a focus on service-delivery research were added.

Introductory trials are organized after the safety and effectiveness of methods have been established, at least provisionally, through a series of clinical trials conducted to examine methods under rigorously controlled conditions, according to clinic-based research protocols. Introductory trials continue to examine safety and effectiveness, but their focus shifts to introducing program providers to the requirements of the new method and to examining patterns of, and reasons for, discontinuation. Acceptability studies document the user's perspective on the new method and typically are conducted through individual or group interviews with users or potential users. Service-delivery research is undertaken to study the organizational and operational adaptations necessary to ensure quality of care if and when delivery of new methods is scaled up for routine provision in national programs.

Such a bridging approach has characterized the Norplant introduction undertaken by the Population Council (Beattie and Brown, 1994). Clinical and introductory trials were organized in more than a dozen countries, including Chile, the Dominican Republic, and Indonesia. Acceptability studies were undertaken in Colombia (Vollmer, 1985), the Dominican Republic, Egypt, Indonesia, and Thailand (PIACT, 1987), and service-delivery research was initiated in the late 1980s and early 1990s in Colombia, Indonesia, and Peru (Ward et al., 1988 and 1990; Simmons and Ward, 1991). Family Health International also conducted Norplant introductory trials in several countries, including Bangladesh, Nepal, Pakistan, the Philippines, Senegal, and Singapore, as well as acceptability studies in Bangladesh, Nepal, Haiti, and Nigeria, among others (Kane et al., 1990; Grubb et al., 1995).

WHO followed a similar approach in its introduction of a monthly injectable, Cyclofem™. Introductory trials were initially undertaken in five countries (Indonesia, Jamaica, Mexico, Thailand, and Tunisia), and subsequently in Brazil, Chile, Colombia, and Peru (Hall, 1994). Service-delivery research was conducted in Indonesia.

The main objective of Norplant and Cyclofem introductory trials was to provide data for national regulatory approvals, develop national training capabilities, and offer first-hand experience to leading health-care providers. Systematic feedback from service providers and users was channeled into the preparation of technical and counseling guidelines and training activities (Spicehandler, 1989). Findings from service-delivery studies underlined the importance of identifying management and program parameters required to integrate new methods into service-delivery systems.

Evidence from Research in Indonesia

These applied introductory research efforts produced the knowledge that induced WHO to question this approach and to undertake a strategic shift in introduction initiatives. Two service-delivery studies in Indonesia were most influential in this transition. One of these, the Population Council-supported Norplant study (Ward et al., 1990), was conducted at the time of the transition from field studies to large-scale expansion within the national program. It demonstrated that the national program was inadequately prepared at that time to provide Norplant with appropriate quality of care. For example, method choice was not guaranteed, removal on demand was not routinely available, side-effect counseling was minimal or absent, and the pace of training in removal was inadequate. While some of these quality-of-care and operational inadequacies were subsequently remedied (Beattie and Brown, 1994), the existence of these problems at the time of scaled-up introduction demonstrated that earlier detection of these potential weaknesses would have been important. The second study examined the implications of adding Cyclofem to the Indonesian national family planning program while focusing both on quality of care and quality in management of the delivery system (Simmons et al., 1994; Lubis et al., 1994). The major conclusions from that study are reviewed here because discussion of that research provided the impetus for the formulation of the new strategy for introduction.

The study showed that although Cyclofem's introduction into six trial clinics had broadened women's choice to some extent, conditions of routine service delivery included a range of weaknesses likely to counteract the potential contribution of this new method to the national program (Simmons et al., 1994). Evidence from observation of nontrial service settings showed that the availability of two injectable formulations—DMPA (depot medroxyprogesterone acetate) and NET-EN (norethisterone enanthate)—in the Indonesian program did not broaden women's choices. Providers did not emphasize the difference between the two injectables to prospective clients, and routinely substituted NET-EN for DMPA when stock depletion or logistic bottlenecks occurred. Typically, women were not informed of this substitution. Providers' understanding of the differences in the hormonal preparations or the management of side effects was poor, and reinjection time frames (three months for DMPA and, initially, two months for NET-EN) were not followed rigorously. The record-keeping system made provision for injectables, but did not allow for differentiation between the two types, and the logistics system did not ensure the availability of needles appropriate for each formulation. These findings raised doubts about the wisdom of adding yet another injectable to this service-delivery setting.

Policy commitment to making major changes in counseling, information giving, record keeping, logistics, and training would have been required for Cyclofem introduction to expand contraceptive options. Commitment to such major operational change, however, was unlikely in light of the government's interest in cost reduction. Thus, although introduction of Cyclofem in the context of an introductory trial, with its associated special training, monitoring, and supply inputs, was beneficial for women enrolled in the study, the potential addition of this method to routine service settings would have been problematic.

The service-delivery study on Cyclofem introduction in Indonesia raised a central question that had not been routinely considered in advance of an introduc-

tory trial: Is it appropriate to introduce the method? The decision to proceed with the Cyclofem introduction in Indonesia had been based largely on biomedical criteria; Cyclofem was viewed as an improvement over other injectables because it generally causes fewer disruptions in women's vaginal bleeding patterns. Findings from the service-delivery study, however, revealed that the intrinsic characteristics of new methods, by themselves, do not enhance women's choices.

The December 1991 planning meeting at WHO concluded, therefore, that although the prevailing approach to contraceptive introduction constituted a clear advance over earlier patterns, the overall paradigm remained flawed. It had been technology driven and had relied on decontextualized assumptions about method introduction. The addition of technology, ipso facto, had been assumed to increase reproductive choice, and the relationship between technology and choice had been considered largely in a social and institutional vacuum. Attention to the social context of method choice had been limited, the fit of the new method into the range of existing methods within a country remained unexplored, and questions about the capability of service-delivery systems to provide quality of care in the process of introduction and beyond was only beginning to be examined. Moreover, concerns for the perspectives of users, as well as service capability, had been viewed as essential only with regard to facilitating the process of introduction, not as a set of questions to be raised prior to the decision to introduce a method.

The Strategic Approach

The 1991 WHO meeting led to the development of a new approach that views contraceptive introduction not as a narrow operational issue, but places it in the context of overall program strategy. This strategic approach shifts attention from promotion of a particular technology to an emphasis on quality of care, reproductive choice, and users' perspectives and needs. It recognizes the implications of technology introduction for changes in program management systems. When policy choice and research are guided by a systems framework that allows for the integration of technologies, programmatic capabilities, and the social context of method use, outcomes are likely to serve users' needs. Figure 1 represents the user/technology/service system that serves as a foundation for the strategic approach.

Technology

The technology point in the triangle within the figure refers to the characteristics of contraceptive methods, including their safety, efficacy, administration, side effects, reversibility, and duration. Here, the basic questions identified by Bruce (1990: 63) as the defining elements of method choice should be raised:

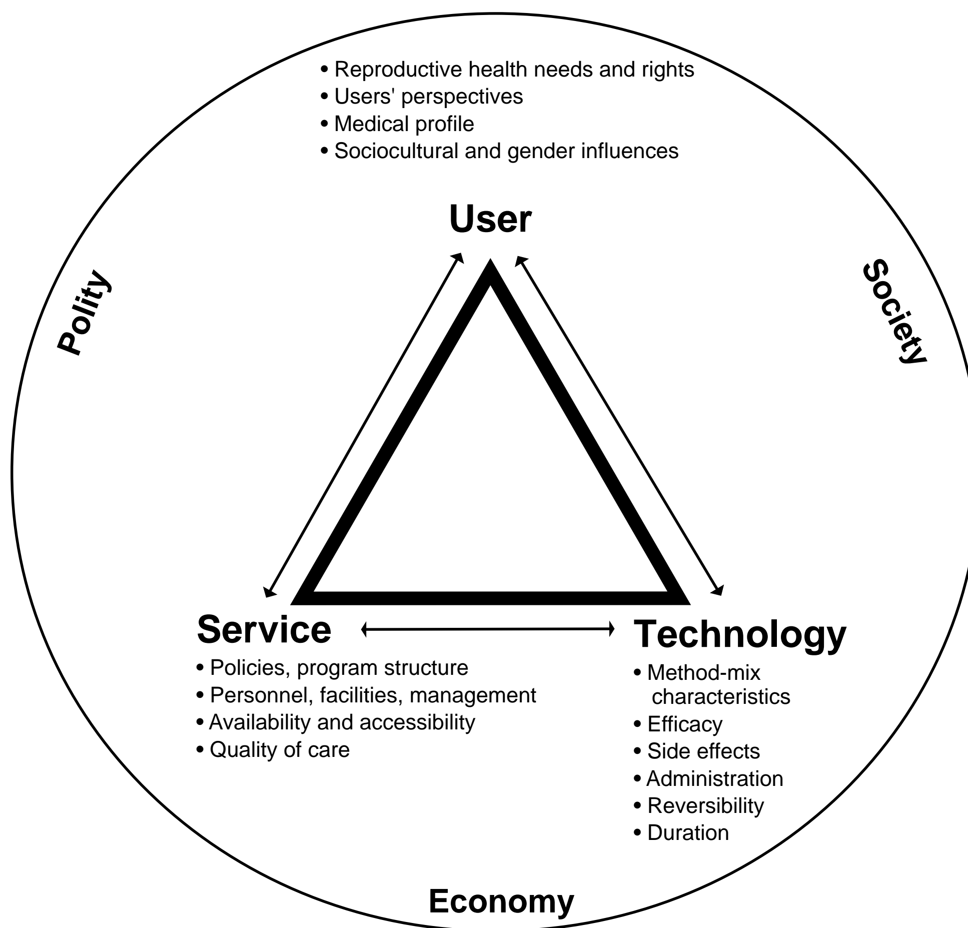
> Which methods are offered to serve significant subgroups as defined by age, gender, contraceptive intention, lactation status, health profile, and—where cost of the method is a factor—income groups? To what degree will these methods meet current or emerging need (for example, adolescents)? Are there satisfactory choices for those men and women who wish to space, those who wish to limit, those who cannot tolerate hormonal contraceptives, and so forth?

Characteristics of methods provided within a service-delivery system, as well as attributes of those with potential for introduction, should be considered. This emphasis shifts attention from an exclusive focus on methods considered for introduction to the characteristics of the actual or potential method mix. When introduction activities are focused on increasing variability in the characteristics of available methods, reproductive choice is enhanced.

Users' Perspectives and Needs

Technology must be appropriate to the reproductive health needs of potential users and to the sociocultural context into which they are introduced. Reproductive health needs and people's perspectives on technology and on the service-delivery system should be considered when decisions are made about which contraceptives to offer. Attention to women and men in various stages of the life cycle is essential. In the framework described in the figure, users' perspectives and needs are placed at the apex of the triangle to reflect the preeminence they deserve. The user–technology interface suggests such questions as these: Do users find that the advantages of a particular method outweigh its disadvantages? Do they have specific health-related concerns or fears about the method? Do they experience side effects, and if they do, what is their significance within the cultural and social context of the women's lives? Are pressures brought to bear by partners, family members, or others in the community to use or reject specific methods for personal, political, religious, or cultural reasons? In populations where the incidence of reproductive tract infections (RTIs) is high, consideration of IUD services should be linked to the capacity for RTI diagnosis and management; where the threat of HIV/AIDS is high,

Figure 1 Systems framework guiding the strategic approach to contraceptive introduction



the need for dual protection must be a priority. Where maternal mortality from illegal abortion is high, consideration of methods and services must focus on how such deaths can be avoided.

The user–service interface, in turn, suggests the following questions: Do users find the health center easily accessible in terms of distance and travel cost? Are waiting times acceptable? Are users' rights to adequate levels of information and their voluntarism in contraceptive use and method choice respected? Are people treated respectfully by staff? Are women with incomplete abortions provided with adequate care? Are contraceptive methods affordable? Where clinic-based services are widely used and service providers are trusted by the local people, introduction of new methods is likely to have important payoffs. Where the opposite is true, addition of new technology may have no effect or may possibly increase social distance, distrust, and suspicion. When women's power to negotiate contraceptive use is limited, methods requiring male cooperation or consent are of limited value; so are contraceptive services offered in distant clinics in cultures where women's limited status restricts their mobility.

Program/Service Capacity

Policy choice related to technology introduction must also be guided by the capabilities of service-delivery systems. Central questions are: Does the service-delivery system have the necessary managerial capacity in terms of human resource development, planning, logistics, and monitoring? Does it have the technical capacity to provide new methods with appropriate levels of quality of care? Do existing policies support voluntarism in contraceptive use and method choice? Does this capacity exist in both the public and the private sector? Is it feasible to provide the method within a large network of clinics or health posts or should it be restricted to special settings? Are the costs of new methods affordable within the limitations of existing resources? Are some methods too expensive to warrant introduction?

Where service-delivery systems do not have the capac-

ity to provide methods with appropriate levels of quality of care, addition of new methods may not be warranted. In such circumstances, focusing on building the capacity to increase availability, management support, and quality of service in provision of the methods that are already within a program may be more important.

In the figure, the user/technology/service triangle is embedded in a circle that draws attention to the broad social, economic, environmental, and political context within which relationships occur. Users' perspectives and needs are anchored within a social structure and a set of gender relations. Religious and cultural norms, as well as the power relations between men and women, shape views about contraceptive methods and affect the legitimacy of formally organized efforts to address reproductive health needs. Economic conditions and political ideologies, in turn, determine the resource pool available to address health needs and to build institutional capacities for organizing provision of contraceptive methods with attention to quality of care.

A Participatory Process

The strategic approach to contraceptive introduction involves a change in the process of policy choice, emphasizing country ownership, broad-based participation, and transparency of decisionmaking. Although international agencies make essential contributions to facilitate and support the strategic approach, the process must be led and implemented by key decisionmakers from all relevant sectors of the country. Moreover, broad-based participation implies expansion from a relatively narrow group of decisionmakers toward inclusion of other stakeholders from governmental and nongovernmental institutions representing multidisciplinary perspectives. Transparency in decisionmaking necessitates a commitment to an open process and widespread dissemination of information. Such a participatory process increases the likelihood that contraceptive introduction abides by ethical principles and enhances reproductive choice.

A participatory process and a systems framework guide the following three stages of work within the strategic approach: assessment, research, and use of research for policy and planning. Each of these phases also corresponds to a funding category within which WHO has supported these activities with increasing involvement from other agencies. The three stages of work are described below.

Stage I: Strategic Assessment of Need

Stage I is an assessment of national family planning services focused on the method mix, the extent of coverage, and the capability of the service-delivery system to provide quality services, to assure voluntarism, and to respond to the needs and perspectives of actual or potential users. A systematic assessment with input from a broad range of stakeholders conducted prior to making decisions about introduction constitutes a major departure from previous approaches.

The central purpose of these assessments is to answer the following three questions: (1) Does a need exist for the improved provision of existing methods? (2) Is there a need to remove methods from a service-delivery setting in cases where the safety or efficacy of these methods has not been systematically established or in cases where they have been replaced by improved formulations or devices? (3) Does a need exist for the introduction of new contraceptive methods, and if so, for what level of service delivery are they appropriate? These questions shift attention from considering exclusively methods that are new to a program to a concern for the improved provision of currently available methods or to the potential removal of methods from a service system. Thus, within this context, the very concept of introduction assumes a broadened meaning.

The assessment is not envisaged as an extensive analysis or as a baseline research study. Assessment reports make recommendations for policy and research with regard to the strategic questions of contraceptive introduction and related policy, programmatic, or operational issues. The strategic assessment is a first step in a larger process, as well as a valuable tool in its own right. The data-collection component of these assessments comprises: existing secondary data; a number of key informant interviews with policymakers, program managers, service providers, community people (including young people), users, and women's health advocates; as well as selective observations of service-delivery practices. Prior to field observations, the interdisciplinary team summarizes secondary data and available literature in a background document to ensure that the assessment addresses areas where information is lacking.

Overall, the extent of primary data collection in these assessments is limited. However, the methodology emphasizes evaluation of existing field conditions through qualitative interviews and observations of service conditions in major regions of a country. Although the main emphasis has been on an examination of public-sector services, assessments have also included some attention to the private sector, in particular in those settings where government services are limited and the private sector is the sole provider in large parts of the country.

Assessments are government led, involving rel-

evant national decisionmakers in all aspects of the process including in the development of instruments, site selection, conduct of field visits, analysis of findings and recommendations, preparation of the assessment report, and the dissemination of results. The team also includes women's health advocates, local researchers, and representatives from national NGOs. Technical support has been provided by WHO and by the agencies that have collaborated in the development and implementation of the strategic approach. Following the strategic assessment, a national workshop is organized at which key findings are presented. The workshop provides a critical forum for ensuring the ongoing involvement and input of local, national, and international institutions.

Whereas the core strategic questions related to contraceptive introduction provide the guiding framework, the flexibility of the Stage I methodology allows other reproductive health issues to be included, reflecting the country's interests and needs.

Stage II: Research

Assessments of the need for contraceptive introduction may lead to a variety of policy changes, to research initiatives related to contraceptive introduction, and to improvements in quality of care. Among policymakers and other relevant stakeholders, they also produce greater awareness of the relationship between contraceptive technology, quality of care, and reproductive health.

Stage II entails the design and implementation of applied research focused on country priorities as established by the strategic assessment. This stage may entail research on the improved provision of methods already offered within a service-delivery setting, or on the introduction of a new method or methods, with attention to the technical, operational, and managerial changes required to ensure that these methods are provided with an adequate level of quality. Service-delivery settings are studied in order to evaluate what adaptations are needed when innovations are introduced on a broader scale. Such research has included as main components demonstration or pilot projects and user-perspective and service-delivery research within public-sector settings. Both quantitative and qualitative methods are used; because of the need for in-depth understanding of program functioning, however, qualitative methods are particularly important. To guarantee research relevance and policy use, the broadly participatory process initiated during the strategic assessment is continued. Research is undertaken either by researchers from government institutions or it is conducted by local research institutions in collaboration with the public-sector program. WHO and its collaborating institutions have provided technical assistance for this research.

Stage III : Use of Research for Policy and Planning

The primary objective of Stage III is the use of research results for policy and program development. Past experience has shown that the application of lessons learned is not assured by good assessments and research findings alone but must be carefully fostered. Although attention to the use of assessment and research findings is an ongoing process, the third stage of the strategic approach focuses on initiatives intended to ensure that Stage I and Stage II are heeded as service innovations are introduced and method introduction expands.

Moving from Stage II to Stage III involves a review of the three strategic questions related to contraceptive introduction. In examining the bigger picture, policymakers must then determine how to scale up the quality of services elsewhere and decide which service-delivery points are most appropriate. Additional changes and adaptations required for scaling up from a pilot phase to regional or national implementation may require testing and refinement. If a new method is to be incorporated on a larger scale, plans for gradual expansion must be made in order to retain the emphasis on quality of care as the process unfolds. The central focus of these efforts must remain the overall improvement of quality of care and the provision of contraceptive options, not the physical availability of a particular method. If contraceptive expansion is recommended, a strategic plan is required for developing and upgrading training curricula and courses; information, education, and communication materials; infrastructure; logistics; and supply systems.

Specific activities undertaken at this stage vary and must arise out of country and program needs. They may entail additional research for scaling up from demonstration or pilot projects to a larger number of program sites, technical assistance, dissemination of results, and continued evaluation. In order to ensure that innovations from research are sustainable, Stage III activities must continue to address questions related to costs, the longer-term availability of funding, and other activities initiated during Stage II.

Continuation of the participatory and community-oriented approaches that guided the earlier phases of the strategic approach are essential. Program managers, in particular, must be part of the process of sharing results, because ultimately they will implement the recommendations that arise from research. An important element

of Stage III is, therefore, the organization of workshops and the promotion of dialogue to ensure that the implications of findings are fully understood and that consensus is reached. In addition, results from these initiatives should be disseminated through professional or policy seminars and publication of papers and newsletters.

Experience with Implementation

The strategic approach to contraceptive introduction is currently being implemented in eight countries: Bolivia (Camacho et al., 1996); Brazil (Formiga et al., 1994); Burkina Faso (CRESAR, 1997); Chile (Ministerio de Salud, 1997); Myanmar (Government of Myanmar, 1997); South Africa (Reproductive Health Task Force et al., 1994); Vietnam (Hieu et al., 1995); and Zambia (WHO, 1995). Choice of countries for this exercise has depended upon country interest in pursuing this approach and a request directed to WHO to support the process. The potential contribution of the exercise in light of the particular historical moment at which a country or program finds itself, or the extent of previous work, has also been important. For example, in South Africa, the exercise was supported in large measure because the country was in a major transition where such input would be of particular value. In Myanmar, the exercise was especially relevant because contraceptive services are extremely limited, but the government is planning major program expansion. Zambia, by contrast, faced implementation of significant bilateral funding support for its family planning program, a situation where a strategic assessment could provide critical guidance to the program-development process. Vietnam was concerned about its skewed method mix and wished to expand contraceptive options. The choice of countries has also been guided by desire for a wide geographic spread and diversity in social and economic development, in program settings, in contraceptive prevalence, and in methods currently available.

As Table 1 indicates, the process of implementation extends over several years, which is, in part, a reflection of the exigencies involved in working on systems improvements using participatory approaches. Length of implementation has also depended on WHO procedures related to ethical and scientific reviews and the funding process. As experience with the strategic approach accumulates, implementation time may decrease. The table indicates the countries in which Stage I assessments have been held and the dates for the dissemination workshop that precedes the initiation of research activities. In general, Stage II research projects are designed to last for as long as two years. The length of time between steps varies depending on the circumstances of the countries involved. Because most of the implementation experience to date covers the assessment stage and the development of subsequent research, the lessons discussed below refer primarily to these first phases of the strategic approach.

Table 1 Implementation of the strategic approach to contraceptive introduction, by country, according to stage in the process, 1993–97

Country	Stage I (Assessment)	Dissemination workshop	Stage II (Research underway)	Stage III (Initiated)
Brazil	November 1993	February 1994	✓	✓
South Africa	July 1994	September 1994	✓	—
Vietnam	November 1994	February 1995	✓	—
Zambia	March 1995	May 1995	✓	—
Bolivia	November 1995	September 1996	✓	—
Chile	July 1996	August 1996	—	—
Myanmar	September 1996	January 1997	—	—
Burkina Faso	October 1996	December 1996	—	—

— = Not yet underway or initiated.

Validating the Method-mix Focus

Experience has validated the importance of analyzing the need for introducing a contraceptive within the context of methods currently available in a particular setting. In Brazil, the assessment led to the conclusion that introduction of new methods should await improvements in the provision of currently approved methods of family planning (Formiga et al., 1994). Significant demand for family-size limitation in Brazil is reflected in the widespread use of oral contraceptives and tubal ligation. However, the current provision of these methods does not reflect a commitment to quality of care or to reproductive choice. The incorrect use of oral contraceptives is widespread (Pinotti et al., 1990; Costa et al., 1990) and, in large measure, is linked to inadequate provision of information to clients who obtain the method through pharmacies. The ambiguous legal status of tubal ligation, physicians' financial exploitation of women's demand for this method, and the frequent insistence upon sterilization as a prerequisite for employment have made women vulnerable. By contrast, IUDs, condoms and other barrier methods, lactational amenorrhea, and periodic abstinence—all of which are approved for public-sector services within the existing policy context—are little used. Therefore, instead of introducing additional methods, attention to improving access, quality of care, and provision of all approved methods is required in Brazil.

The other country assessments also revealed that reproductive choice is limited because of major method-

mix imbalances and serious shortcomings in all dimensions of quality of care. In Vietnam, providers tend to emphasize use of the IUD and discourage use of the pill, which is considered too difficult for rural women to remember to take regularly and potentially dangerous. In South Africa, most users, particularly black South Africans, are essentially limited to injectables. Access to IUDs, sterilization, and barrier methods is greatly constrained. In Bolivia, by contrast, use of periodic abstinence is widespread, yet women and providers lack accurate information about how to identify the fertile period. Unplanned pregnancies and a high rate of clandestine abortion are the results. In Zambia, where use of modern methods is low, the pill accounts for almost half of contraceptive use among married women of reproductive age, while about one-fifth use condoms and tubal ligation. According to the assessment, these methods were little used because of limitations in the service-delivery system, client and provider misinformation, and weaknesses in the management-support system.

In some settings, method cost is a major factor constraining contraceptive options, a condition that is rarely solved by introducing new methods. Cost issues manifest themselves both at the program and the individual level. For example, in Bolivia, where clients must pay for public-sector contraceptive services and supplies, the IUD is selected often as the cheapest method, rather than as the preferred method (Camacho et al., 1996). Moreover, many service settings do not even stock condoms or oral contraceptives because of limited finances. Cost constraints reinforce providers' belief that the cheapest method is the best for all women. Frequently, as a consequence, women's only option of a modern method is the IUD. In such settings, the broadening of choice among theoretically available methods or the introduction of new ones through Stage II research can only succeed if cost issues are appropriately addressed. In the private sector, cost is less problematic.

In Bolivia, South Africa, Vietnam, and Zambia, assessments have recommended that introduction of methods that were previously unavailable or not officially available can serve as a useful vehicle for increasing quality of care in the provision of all methods. Stage II research in South Africa and Zambia is particularly instructive in that it focuses on the addition of methods that have previously been neglected in introduction efforts—emergency contraception and barrier methods. The South African project focuses on barrier methods, including both male and female condoms, and on emergency contraception as backup. In Zambia, emergency contraception and barrier methods are introduced in conjunction with the reintroduction of Depo-provera. Characteristically, assessments have recommended that introduction research and policy change focus on improving quality in the provision of all methods. Thus, broadened attention to the method mix and the local program context enhances the potential for increasing reproductive choice.

Although the experience of implementation of Stage II research is still limited, emphasis on the method mix has characterized all projects and is producing important results. In Brazil, the Stage II project organized in one municipality has drawn attention to the contraceptive needs of populations that were previously ignored by the service system, namely, adolescents and men. With limited municipal resources, a referral center for family planning was created in which vasectomy, attention to adolescent needs, and distribution of condoms are all provided. Moreover, increased availability of and access to gynecological services and improvement in the collection of pap smears became possible for the total municipal service system (Diaz et al., 1997).

Removing Methods from Distribution

In all countries where an assessment has been completed, removal of methods from general distribution has been identified as important, especially with regard to hormonal methods, particularly oral contraceptives. Oral contraceptives containing 50 milligrams of estrogen were found to be used routinely in Brazil, Bolivia, South Africa, Vietnam, and Zambia. WHO has recently recommended that the use of oral contraceptives containing more than 35 milligrams of ethinyl estradiol be strongly discouraged. Triphasic preparations were encountered in Brazil, South Africa, and Zambia, and removal of these from the public sector was suggested, because service providers were unable to explain what they were or to ensure that they were taken correctly.

In Zambia, confusion prevailed about the numerous brands of oral contraceptives available in the public sector. Neither providers nor clients understood the differences among the formulations and brands. In Brazil, pills and injectables were produced by local companies in which quality control was inadequate. In both Brazil and Bolivia, the assessment team expressed concern about high-dose injectables available in the commercial market. In Vietnam, the use of quinacrine for sterilization, the safety of which has not been established through internationally accepted scientific procedures, created a major concern (Pies et al., 1994; Berer, 1995). The assessment team endorsed the Ministry of Health's decision to halt this method's introduction.

Many developing countries do not have strong drug regulatory mechanisms and, therefore, have limited influence over methods available from the private sector.

When methods are deemed no longer appropriate for distribution, ministries of health are in a position to withdraw these methods from supply. However, when methods are commercially available or available by means of highly decentralized systems where commodity purchases are made locally, method removal is difficult to accomplish. In such settings, introduction of a new method into the public sector can encourage withdrawal of inappropriate formulations from the commercial sector. For example, in Brazil and Bolivia, where high-dose once-a-month injectables are widely available through the commercial sector, public introduction of low-dose injectables has the potential to encourage a general shift to these formulations. Similarly, in Myanmar, commercial provision of a monthly injectable, which has a complex treatment regimen and low efficacy, argues for the public-sector introduction of newer products.

Linking Introduction to Quality of Care

Implementation of the strategic approach has demonstrated in several countries the value of linking the introduction of contraceptive methods to quality-of-care improvements. A concern for quality of care and the need to improve the provision of currently approved methods led to the conclusion in Brazil that the introduction of additional methods had low priority. In Vietnam, the emphasis on quality of care produced a government decision to reconsider the widespread introduction of Norplant. Extensive field observations and analysis carried out during the strategic assessment led to the conclusion that the Vietnamese program (with its target-driven, promotional approach and its weaknesses in technical quality of care and counseling) did not have the capacity to provide this method in a manner that would increase contraceptive choice. Decisions concerning future introduction have been delayed pending a retrospective analysis of earlier limited introductory trials of Norplant.

A similarly motivated, though less dramatic, shift occurred regarding the introduction of Depo-provera in Vietnam. Prior to the strategic assessment, the government and several major donors were interested in a quick, wide-scale introduction of Depo-provera throughout the national program. However, previous limited experience with provision of Depo-provera showed high drop-out rates and lack of attention to counseling. In light of these and other observed weaknesses in quality of care, the assessment recommended that an incremental and research-based approach to injectable introduction was needed. The introduction of Depo-provera is currently being supported within the context of voluntarism, broad method choice, and general quality-of-care improvements in the delivery of all methods through a Stage II research project in two provinces.

The important point of comparison with previous introductory studies is the deliberate attempt to use method introduction as an entry point for general quality-of-care improvements. In Vietnam, training has emphasized counseling and the provision of balanced and technically accurate information on all available contraceptives. Moreover, all staff providing family planning services—including community-based workers and volunteers—are being trained, not just a small subset of people addressing the special needs for a Depo-provera protocol. Stage II projects under way in Bolivia, South Africa, and Zambia will also introduce additional methods of family planning. While the specifics of these projects vary considerably, they all function within a broad quality-of-care paradigm that emphasizes voluntarism and choice, technical quality of care, counseling, and information-giving in all methods.

Managerial, Structural, and Philosophical Barriers

All of the assessments conducted so far have revealed major structural, managerial, and philosophical barriers to quality of care in services for reproductive health in general and family planning in particular. As noted, these weaknesses have been so significant in several settings that the assessments concluded that introduction of additional methods was unwarranted. Where assessments have recommended introduction of new methods, this has been done through a carefully phased and research-based process intended to encourage the development of the appropriate managerial capacity and to engender a humanistic philosophy of care.

Results from Stage II projects reinforce the importance of giving attention to management support systems and the philosophy of care. In Brazil, the Stage II project succeeded in reorganizing the service systems substantially to increase both access and quality of care. However, critical leadership and supervisory impetus for this change relied heavily on the institutional support provided by CEMICAMP. The challenge of institutionalizing such management capacity within the public sector remains unaddressed. In Vietnam, initial project results show that change in training alone has a limited and short-lived impact unless extensive supervision is provided. Without related changes in management and in the general philosophy of care-giving, providers quickly revert to old patterns of behavior. These results re-emphasize a point made earlier with regard to the introduction of injectable contraceptives in Bangladesh, that "[s]ystematic changes are needed that address critical structural and opera-

tional barriers to improving quality of care" if new contraceptive technologies are to make a contribution (Phillips et al., 1989: 243). These issues remain major challenges in the organization of Stage II research and in the subsequent use of research findings for program and policy development.

Social and Institutional Contexts

The significance of anchoring the strategic approach in social and institutional contexts of contraceptive use is well illustrated by several of the findings from strategic assessments and subsequent research. Race, ethnicity, class, religion, and sex are central forces that shape not only social attitudes and norms about contraception but also policies and programs and the power relations within which they are implemented.

In South Africa, the influence of a racially motivated and often coercive family planning program during the apartheid regime translated into an emphasis on the provision of injectables to black women, neglecting entirely their need for meaningful options and informed choice. The racially based political and administrative organization of the country produced highly differential access to services, leaving black women in rural areas with few options. In Bolivia, differences in ethnicity and class background between providers and clients explain low usage of services in the public sector, while the strong influence of the Catholic Church and political ideologies have limited government involvement with family planning. Traditional beliefs have impeded the use of modern services and specific methods. All assessments undertaken so far have provided ample evidence of the effect of gender imbalances on contraceptive choice. Viewing contraceptive introduction within a broader institutional context also raises the question of whether method introduction enhances reproductive choice or subjects people to coercive institutions of the state. Such ethical issues are particularly relevant in cases where provider-dependent, long-acting methods are considered.

Stage II research projects have been designed with a concern for the larger institutional context. In Bolivia, Stage II research will institute a process of dialogues between community representatives and service providers and managers to reduce the social distance between the two groups and to enhance opportunities for adapting services to local needs. The proposed training program will devote attention to gender dynamics. However, a single research project is limited in the extent to which it can respond to general social needs and address institutional constraints. The full benefits of framing introduction issues within a larger context will be accrued when multiple actors and institutions are able to use assessment findings.

The Participatory, Field-oriented Process

The power of a participatory process in assessments, policy development, and research has been demonstrated unmistakably in the implementation experience. The strategic approach emphasizes country ownership of the three-stage process of introduction. With one exception, assessments that have been conducted were led by senior ministry-of-health officials. In one case, the process was directed by a member of a research institution. Sustained governmental and nongovernmental participation in all stages of the fieldwork was accomplished in all assessments. WHO and its collaborating institutions provided extensive technical support and facilitated the process, but were not in charge of organizing and leading the process. The development of assessment instruments, the conduct of visits to the field, the analysis and interpretation of collected data, as well as the organization of workshops and subsequent research, were a team effort. A variety of governmental and nongovernmental institutions participated in workshops both prior to and after the assessment. Stage II research is undertaken by a government or involves a government agency in collaboration with national research institutions.

Involving senior government officials in the conduct of clinic observations and interviews with community members or providers at service-delivery points at all levels is of significant value, especially when such visits go beyond the ceremonial encounters typical of official field visits. Government authorities rarely have the opportunity of seeing the realities of program implementation at the local level. They are even less likely to converse with ordinary people in their homes, or to participate in discussion groups with community leaders in a frank exchange about the conditions of service delivery. In addition, they seldom have the opportunity to conduct a strategic analysis of policy choices regarding contraceptive introduction, using a systems framework focused on quality of care.

Expanding participation in the strategic process to other stakeholders, especially those typically not included at this level of decisionmaking, has proved to be both feasible and valuable. Collaboration of representatives from nongovernmental organizations and women's health advocates was secured for all Stage I assessments. In some settings, such participation was easily accomplished. Because close collaboration between the Women's Health Secretariat, NGOs, and wom-

en's health advocates existed prior to the initiation of the three-stage process in Bolivia, soliciting participation and establishing constructive working relationships was easy. In Zambia, team members were chosen from a group of individuals representing more than a dozen organizations, including Planned Parenthood Association of Zambia and the Young Women's Christian Association. Although some of the representatives were from women's organizations, women were also represented through legal, health, and development organizations.

Addressing women's concerns is more difficult when few or even no nongovernmental organizations exist that represent women's interests. In Vietnam, the Vietnam Women's Union (VWU) was a partner in the assessment. Although it is a governmental organization, the Union does not necessarily represent the same point of view as the Ministry of Health or the National Committee on Population and Family Planning. The participation of the VWU in the strategic process served to legitimize the perspectives of the organization and include women's voices, to encourage a client-oriented approach to services, and to strengthen the ability of the VWU to influence governmental health policy. In Myanmar, participation of the Myanmar Maternal and Child Welfare Association, an NGO working closely with the government, has provided women from that organization the opportunity to become aware of how their village-level membership could play a more active role in promoting birth-spacing services in rural areas. The assessment gave them a chance to learn not only from discussions with their own members during field visits, but also from interviews with nonmembers—that is, with villagers and local providers. Participants gained new insights into what their organization was and was not accomplishing at the village level.

In Brazil, where controversy existed between family planning providers and women's health groups in the past, collaboration in the assessment and extensive participation of women's health groups in the subsequent workshop provided an opportunity for some rapprochement of divergent perspectives, as well as for continued expression of diverse points of view. A unique result of the Stage II research project in Brazil was the creation of a community-based women's organization that has supported the action research project organized within a municipality. In preparation for the third phase of work, the project organizers are placing considerable value on the contribution of such groups in assuring replication of lessons from research.

The three principles of country ownership, participation of all stakeholders, and an open, transparent process are essential to the three-stage process. Bringing together policymakers, program managers, and researchers with community and district-based providers, women's health groups, and young people is both informative and provocative. These alliances are not necessarily natural ones, nor is working across such constituencies in a collegial manner effortless.

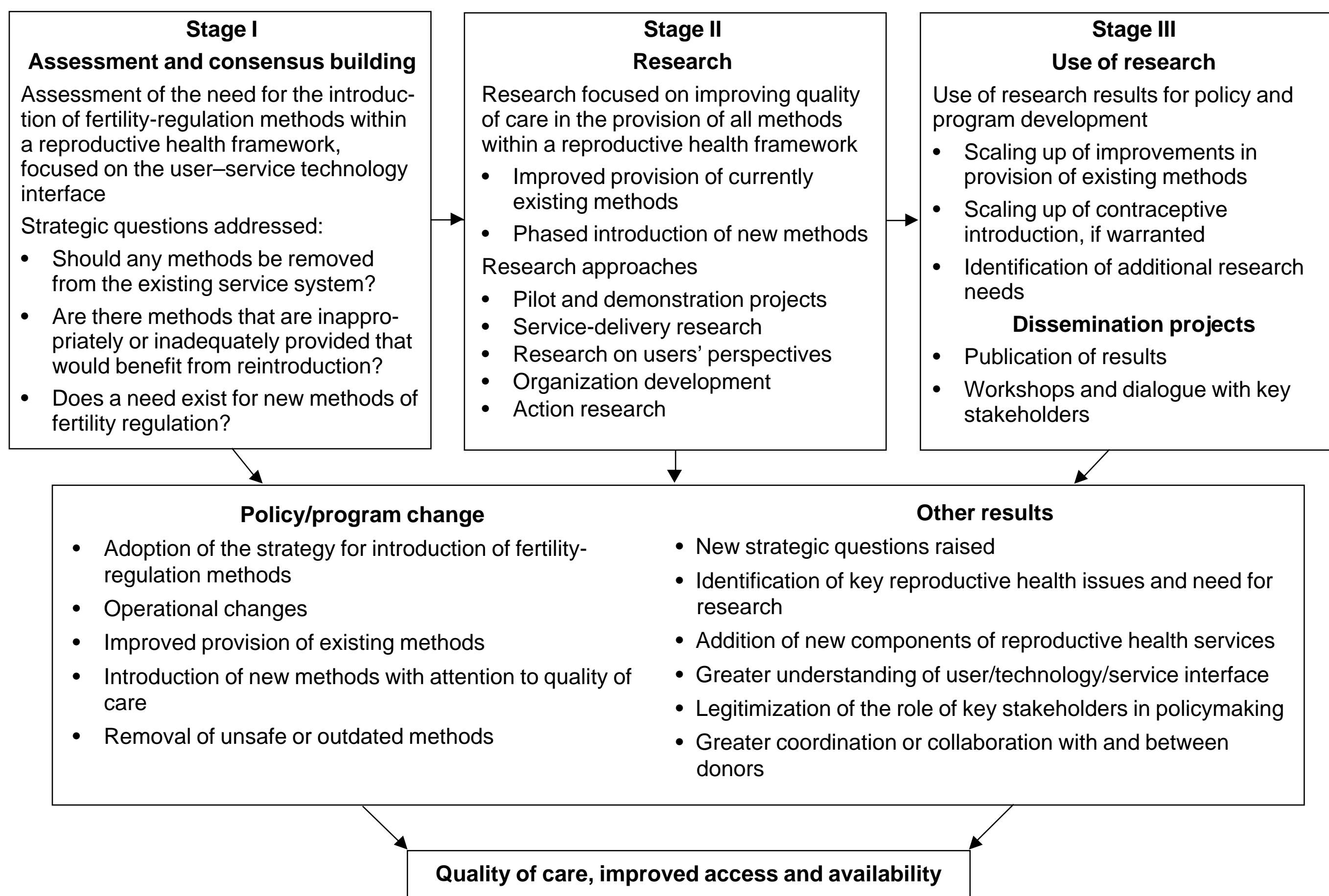
The Importance of Flexibility

The strategic approach suggests a logical process that may follow a number of paths. Flexibility is essential in assuring its participatory nature. Broad-based participation of a range of stakeholders leads to adaptations that reflect both national priorities and local concerns. Several countries broadened their approach to an assessment of reproductive health services, while maintaining an emphasis on contraception. In South Africa, doing so implied attention to sexually transmitted diseases (STDs), reproductive-system cancer screening, infertility, and abortion. In Bolivia, obstetric care was included, and in Brazil, attention to the diagnosis and early treatment of cervical cancer was added to the assessment. In all countries, the contraceptive introduction strategy has allowed significant input for identifying and addressing broader reproductive health needs. In Zambia, recommendations for policy and program changes from the strategic assessment were adopted as part of the national reproductive health agenda.

Implementation has shown that the strategic approach produces a more complex set of outcomes than originally had been anticipated and that these can occur earlier than expected. Policy, programmatic, or operational outcomes can result from Stage I assessments immediately, rather than later from Stage II research. An example is the Vietnamese government's decision to change its plans for widespread introduction of Norplant in favor of a more cautious process. The government and international agencies accepted the Stage I assessment as the national strategy for contraceptive introduction. As a result, several donor agencies wishing to introduce injectables have decided to wait until results from the introductory research in two provinces are available.

Similarly, useful research findings were expected to emerge at the completion of research. Experience has shown that dissemination and replication of such findings can occur earlier. Findings from the Stage II research project in the municipality of Santa Barbara d'Oeste in Brazil have been shared with other municipalities and with state and federal officials midway through the project. In Vietnam, the Stage II project produced a large workshop nine months after project initiation that shared preliminary results with agencies supporting reproductive health activities. The

Figure 2 Anticipated outcomes of the strategic approach to contraceptive introduction



closely interactive process of assessment, research, and policy and program development is illustrated in Figure 2.

Issues and Concerns

Although those who have participated in, or seen the results of, the strategic approach have been persuaded of its underlying value, the following four issues require attention as this approach becomes more widely implemented: (1) selection of research for Stage II ; (2) consequences of flexibility; (3) implications of undertaking the relatively lengthy process required to implement the strategic approach; and (4) assurance of sustainability.

First, the transition from assessment to research involves critical choices related to the selection of Stage II projects. Stage I assessments typically conclude with a range of recommendations about what type of introductory research is desirable. Only one project has been funded in each country from the range of research suggestions contained in the assessment report. Therefore, questions of what project to undertake and what method(s) to focus on are critical. Unless a number of researchers and funding agencies are willing to pursue the broad research agenda suggested in Stage I assessments, introductory research must be chosen to ensure that projects most critical for policy and program development are undertaken.

A second issue arises from the flexibility of the strategic approach that allows broadening of the assessment to include other areas of reproductive health. Although the rationale for such an expanded scope of work can be extremely persuasive, such broadening must be pursued with caution, to make sure that attention to strategic introduction questions is not compromised. Moreover, doing justice to several of the elements of reproductive health within the context of a single assessment is not easy. Use of sequential assessments may be an appropriate approach for some settings. For example, the Vietnamese government decided to pursue a second strategic assessment, this time addressing abortion and menstrual regulation, rather than focusing on contraceptive services. Although these issues were identi-

fied in the contraceptive method-mix assessment, they have such central significance for reproductive health in Vietnam that three years later an additional assessment is scheduled to take place. The overall framework and process remain the same, but the topic and strategic questions change.

Third, the amount of time required to implement technology introduction using a participatory approach focused on quality of care is considerable. Senior government officials, representatives of women's groups, and other participants in the process are limited in the amount of time they can dedicate to such a process. A related limitation concerns continuity and stability in government. Implementation of the strategic approach requires an ongoing rational process of policy choice and program development. Where ministries and political process are unstable, the strategic approach may not succeed fully, but the approach still has value, and the process may not need to extend over several years. In fact, the flexibility of the approach allows it to be adapted to the constraints inherent in such situations. Finally, because many countries are still dependent upon donor agencies for supply of contraceptive commodities, multilateral partners such as UNFPA and relevant bilateral donors must be involved from the outset of the strategic process. However, because assessments are country-owned exercises, it is essential that donor agencies support the process but do not influence it unduly. Such collaboration has been achieved in many of the countries where assessments have been conducted. In some of them, UNFPA and certain bilateral agencies have provided financial support for the assessment and continuing support for the Stage II research activities.

The underlying logic and philosophy of the strategic approach argue that method introduction should only proceed where a system's ability to provide services of high quality exists or can be generated. Such strengthening of quality, however, takes time. Does this emphasis on the quality of care deprive women and men of the benefits of new technology for too long? As Bruce suggests "[T]he ill-prepared introduction of a technology does not constitute the expansion of choice" (Bruce, 1990: 98). Taking the time necessary to move toward greater quality of care when introducing a method, therefore, is a worthwhile investment. Moreover, given the emphasis of the strategic approach on method mix, the results that are achieved, although they require time and effort, have an impact on all available methods, not merely on a newly introduced technology. The potential exists for ensuring that the benefits of currently available technology, of which women may have been deprived for a long time, are finally coming within reach.

A final concern is the sustainability of the strategic approach. Whereas the emphasis on country ownership, participation, and capacity building certainly has the potential for contributing to an enduring process, the issue of sustainability remains problematic. As Stage II research and Stage III activities unfold, the salience of this issue is likely to increase. Many of the changes proposed through the application of the strategic approach require strengthening the management infrastructure of public-sector programs as well as reorienting the overall philosophy and ethics of care. Such institutional change is not easily attained or maintained when results from pilot projects are transferred to larger settings. Outside support from institutions with credibility and technical skills is essential to ensure that the process is transparent and inclusive. Such support should continue as the strategic approach is more widely implemented.

Conclusion

The strategic approach to contraceptive introduction represents an important shift in perspective. It emphasizes quality of care and a reproductive-health focus as central elements in the process of improving provision of existing methods and adding new technology into the service system. In contrast to previous practice, it encourages a participatory approach that values responsiveness to a country's needs and collaboration among governments, women's health groups, community groups, nongovernmental providers, researchers, international donors, and technical assistance agencies. Implementation to date indicates that, in general, service-delivery settings are not well equipped to introduce new methods widely with adequate quality of care without significant change and adaptation in management and the philosophy of care. Improved provision of existing methods has been shown to be just as important as—at times more important than—the introduction of new ones. The strategic approach produces not only longer-term benefits with regard to improved quality of care and method choice but also has immediate policy, programmatic, and operational results that can transcend the narrow confines of existing contraceptive services to extend broader benefits in reproductive health. Although it should not be viewed as a panacea providing instant relief from the many institutional problems that afflict public-sector programs, the strategic approach is a participatory policy-development process of relevance for all countries.

Notes

1 United Nations Development Program/United Nations Population Fund/World Health Organization/World Bank.

2 Formulation and implementation of the strategic approach has involved extensive collaboration between WHO and the following institutions: the Center for Maternal and Child Health Research (CEMICAMP), a nongovernmental organization linked to the University of Campinas, Brazil; the University of Michigan; the Population Council; and the International Council on Management of Population Programmes (ICOMP). These institutions have provided major support to WHO through their participation in consultations and planning meetings of the Scientific Review Committee on Technology, Introduction and Transfer, HRP, and through their role in the design and implementation of the various stages involved in the new approach.

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