chapter 8

Research Needs

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Abstract

Meeting the needs of couples to freely choose the number and spacing of their children and of nations to develop beneficial population policies will require extensive research. Areas of need range from fundamental knowledge of reproductive processes to development of service delivery systems to better understanding of the processes that give rise to population policies. Accurate, descriptive data are needed for current and continuing evaluation of population growth and change. Present information gaps include the causes of today's wide differences in mortality, the dimensions and consequences of international migration, and the specific impacts of rapid population growth. Despite the consensus that current fertility planning technologies fall short of ideals of safety, effectiveness, acceptability, and ease of use, there is little support for basic research to develop new or improved methods for planning fertility or to correct and prevent infertility. Specific R&D efforts are needed on male contraceptive methods and new approaches to female contraception; improved barrier and periodic abstinence methods, and better methods of nonsurgical sterilization. Evaluation research on the safety and side effects of various methods is a further need, as is research aimed at improving the contraceptive R&D process itself.

Factors that influence acceptance of fertility planning technologies and the relationships between culture- and age-specific factors and these technologies require investigation, and one of the greatest needs is for a sound theoretical framework on the factors that determine fertility. Such factors include men's and women's differing roles, beliefs, and attitudes, and the influence of political and administrative systems. How various institutional arrangements influence family planning programs and how different political processes lead to population policies require clarification. Improved formulation of population policy requires the results of broad-based research on the effects of population growth, which in turn requires intensified coordination and' improvement of data collection efforts. Systematic analysis of family planning "success stories" could be productive in developing predictive capability and designing better programs. Evaluation of the impact of past and present policies and programs (both those with specific family planning objectives and those with indirect impact on population growth such as education and nutrition programs) has been identified as a critical need. Finally, there is a need to better understand what research is most needed by policymakers and how it can most effectively be brought to bear on policy. Because of the inadequacies of current technologies and the acknowledged increase in need for them in the years ahead basic and developmental research is clearly needed. But because of the long lead times in the development of new contraceptive methods, more effective use of current technologies is central to meeting less developed countries (LDCs) population goals. Research that will lead to better utilization of these technologies is thus of key importance in the immediate future.

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Introduction

A "research need" is an area of basic or applied research where additional effort would be likely to result in information or products of value to polivymakers, providers, or consumers. The focus of this chapter is on research that will improve the ability of couples to choose the number and spacing of their children and nations to develop beneficial population policies. Research needs in the population field are many. They range from fundamental knowledge of reproductive processes to characterization and development of effective service delivery systems to better understanding of the political processes that give rise to population policies. The breadth and number of research needs in this field arise from the complexity and number of factors influencing population growth and the fact that current understanding of them is limited.

Basic data and theory

Verifiable reporting of the levels, trends, and differentials of the three components of population growth-fertility, mortality, and migration—requires careful collection of data. Accurate, descriptive data are needed for countries, regions, and various socioeconomic groups so that the magnitude of population growth and the factors influencing it can be assessed.

Existing studies, for example, show wide differences in mortality among different social classes in LDCs. The causes and magnitude of these differences need clarification so that health services can be designed for maximum effect.

Both the amount and impacts of internal migration require study, as does the relationship between internal migration and the larger development contexts of particular countries. Each country's overall development goals lead to an associated political structure and basic political philosophy. These determine both the country's desire to control internal migration and the means it is prepared to use. While this general statement can be made, quantitative characterization of the forces that determine internal migration cannot presently be accomplished,

Better information is needed about the dimensions and consequences of international migration and the roles played by migrant workers in various countries. Because international migration is an increasingly emotional and potentially explosive problem, it is important to improve the factual base so that myth can be separated from reality.

The World Fertility Survey now under way is providing more accurate basic data on differing levels of fertility, but the need for better understanding of the determinants of fertility is urgent, as pointed out in chapter 7.

Specific information is also needed on the consequences of population growth for all countries of the world. The recently completed Global 2000 study clearly demonstrates that inadequate, inaccurate, and conflicting data and assumptions make prediction of energy, water, food, and other resource availability uncertain. The lack of adequate data on the United States makes program evaluation difficult and the assessment of primary impacts problematic. As the paucity of data in LDCs is far greater, it is even more difficult for these countries to develop useful resource projections. It is also difficult to evaluate the implications for more developed countries (MDCs) of projections based on such limited data. Knowledge of the relationships among population size, resources, and technology is needed for informed planning to accommodate population growth and to provide the basis for framing and implementing policies and programs aimed at modifying this growth.

New and better models of the factors that influence population growth are needed. Because

traditional explanations cannot fully account for the major declines in fertility that have recently occurred in some countries, better explanatory variables and theories are needed. Most existing explanatory models fail to consider the variables that have proved increasingly important in the past 25 years. Such variables include political systems, public policies, and methods of program implementation.

Fertility planning technologies

Basic biomedical research is fundamental to the development of new or improved methods for regulating fertility and correcting or preventing infertility. Better understanding of reproductive biology will permit identification of new points of intervention that may lead to safer, more effective and/or easier-to-use methods than those now available. However, as a National Science Foundation (NSF) report (10) points out, "mixed feelings about the value of pure science have recurred as a theme throughout U.S. history." A major reason is that the relationship between basic research and useful technology is often unclear. The report provides 26 examples of NSF-funded research over a 30-year period in which the applications were not anticipated when the research began.

Another factor in the lack of support for basic research is the long time lag between fundamental work and its application. This is especially true in pharmacologic technologies where the need to meet Food and Drug Administration requirements adds to the time between research and application. As in the case of the contraceptive pill, 20 years may pass before the fruits of research are realized. Additional deterrents are the high costs of field trials and product liability suits (see ch. 5). These factors make basic research in reproductive processes aimed at developing a new method of contraception increasingly unattractive.

Yet there is general agreement that current fertility planning technology falls short of meeting ideals of safety, effectiveness, acceptability, and ease of use, In LDCs, family planning is practiced by fewer than one-fifth of couples of reproductive age (excluding China). Discontinuation rates are high; after 2 years, nearly two-thirds of oral contraceptive users and half of those using IUDs have stopped using these methods. Sociocultural influences and distribution problems contribute to these high discontinuation rates, but drawbacks associated with the methods themselves are unquestionably significant. Although the likelihood of an ideal contraceptive is remote because the characteristics of that ideal differ among cultures and during different stages in the reproductive lifespan, new or improved methods can certainly be produced by undertaking the appropriate research. A variety of improved technologies, including those for treatment of infertility, would provide couples with more varied, effective, and safer choices to meet their changing needs for contraception.

While development of new technology in this field is often time-consuming and expensive, this is not always true. Some highly effective instruments and procedures have been developed for relatively low expenditures of time and dollars. Examples include minilap sterilization, syringe equipment for menstrual regulation and induced abortion, and cautery equipment for vasectomy. Such new developments generally depend less on new knowledge than on improvements in technology, which may arise from other fields (e.g., the fiber optics used in minilap sterilization). An opportunity for similar rapid, relatively low-cost development in the near term may lie in contraceptive delivery systems such as implants, injections, and drug-releasing IUDs and vaginal rings, and in foolproof methods for detecting the time of ovulation.

The opportunities for basic research are broad. They range from characterization of the structure of molecules fundamental to the reproductive process (such as gonadotropin) to the physiological level (such as the relationship

between sperm development and testicular support cells). The 1976 "Greep Report" (3) lists more than 230 gaps in knowledge of reproductive processes; most of these still exist.

R&D needs in specific areas of family planning technology include:

- *Development of better male contraceptives.* Prospective methods include those to suppress sperm production and to intercept sperm maturation, and simplified sterilization procedures.
- *Further development of barrier methods.* Highly effective methods that would eliminate the need for coitus-related application or for privacy during application would be welcomed not only in LDCs but by the growing number of MDC women concerned about the side effects of most nonbarrier methods. Better materials, product designs, and modes of administration could result from further research in this area.
- *Improved methods of periodic coital abstinence.* The development of means to reliably identify the fertile and infertile phases of the menstrual cycle could, by sharply increasing use-effectiveness, both increase the use of such methods and improve their low continuation rates.
- New *approaches to female contraception.* Areas of promise include LRF analogs, immunizing antigens, vaginal steroid rings, and post-coital methods such as menses inducers.
- *Better methods* of *nonsurgical sterilization.* The World Health Organization ***(WHO) (13)*** has noted that the demand for sterilization by surgery cannot be met in some LDCs because of lack of trained personnel, operating rooms, and anesthetics.
- *Better methods of preventing and correcting infertility.*

Many causes of unwanted infertility could be eliminated by improved understanding of reproductive processes.

Evaluation research, as opposed to research on new contraceptive methods, is also needed. Of primary concern are the safety and side effects of current contraceptive technologies. Specific interest lies in:

- risks for cardiovascular diseases and other diseases associated with use of oral contraceptives in different populations and under different dosages of different hormones;
- the effect of disease states such as anemia, malaria, and schistosomiasis on absorption, effectiveness, and safety of different fertility planning methods;
- the hypothesized carcinogenic effects of spermicides and therefore the need for safer spermicides to be used with various methods;
- better understanding of how genetic differences, nutrition, and body characteristics alter method safety, effectiveness, and side effects;
- the safety of contraceptive implants and injections;
- whether induced abortion under medically supervised conditions is associated with adverse outcomes in subsequent pregnancies;
- methods to counteract the blood loss associated with nonprogesterone-releasing IUDs which can result in iron deficiency;
- the long-term effects of contraceptive methods, such as the risk of cancer; and
- medical bases for high discontinuation rates.

Finally, there is a need for research aimed at improving the R&D process itself. Better understanding of species differences between animals and humans, for example, would improve testing for side effects, safety, and effectiveness of new methods of fertility planning.

Factors influencing acceptance of fertility planning technologies

LDCs are homogeneous only in their designation as "less developed countries." Intercountry and intracountry differences in economic and social structure, religious beliefs, public pol-

icies, and personal values and attitudes range through a broad spectrum and affect the relative acceptability of different fertility planning technologies. Appropriate technologies also vary with age, reproductive status, and frequency of sexual activity. The consequences of an unplanned birth are very different for a woman with no children than they are for a mother of five, and for single and married women. Thus, the relative weight placed on the criterion of effectiveness, for instance, in selecting among various methods will vary for women in these different circumstances. Other criteria vary in relative weight in similar fashion.

Therefore, a fundamental research need is the relationship between culture-specific (11) and age-specific factors and various fertility planning technologies. Theoretically, it should be possible to develop physiological and psychological self-tests for use by an individual—or as guides for family planning workers–to help a man or woman select the contraceptive method most appropriate to his or her needs and values at a given point in time. Information on age-specific factors as they affect acceptability would also be of great value to policymakers in deciding which drugs or devices to include in family planning programs.

One of the greatest needs is for development of a sound theoretical framework describing the factors that determine fertility. Information to develop such a framework requires research on patterns of social organization and their influence on the reproductive and economic decisions of individuals. The economic value of children and institutional factors governing fertility incentives need elucidation.

Among cultural factors, a very important area of investigation is women's beliefs and attitudes and how these influence their practice of family planning. These relationships require investigation on both physiological and psychosocial levels. At the physiological level, understanding attitudes toward changes in menstrual patterns is particularly important because these changes are most frequently cited as reasons for discontinuance of such contraceptives as orals and IUDs. At the same time, women who state that they will not tolerate changes in their menstrual cycles continue to use contraceptive methods that cause such changes. Much remains to be learned about what menstruation means to women of different cultures, whether and how their beliefs can be modified, and how decisions are made in selecting among contraceptive methods.

On the psychosocial level, the relationships between contraceptive practice and the following areas need investigation:

- the role of women in a given class and/or culture;
- women's autonomy for decisionmaking; and
- women's perception of themselves, their bodies, and childbearing.

Male beliefs about different fertility planning methods and about the responsibility of men for their use also require clarification. WHO studies suggest that there is demand for male contraceptives in different cultures, but the very low usage rates and the difficulty encountered by investigators in recruiting male volunteers for clinical studies raise questions about male acceptance of both existing and new contraceptive technologies.

Decisionmaking with regard to the adoption of family planning is influenced not only by the feelings and beliefs of the individual man and woman in a couple but by considerations of that couple as a family. Achieved family size and desired family size, the role and status of children within a culture, male-female communication, and participation of various family members in decisions on the number and spacing of births are all little-understood factors which influence acceptance and use of family planning and the methods specific to achieving desired family size. The same can be said of the relationships between individual men and women or between couples and their peers.

To make choices among various fertility planning technologies, individuals must be aware of the methods that exist and the benefits and consequences of each. How best to communicate such information both within a given mode (e.g., different forms of package inserts) and across modes (e.g., the media v. physicians v. family

planning workers) requires further research. The role of pharmacists, physicians, and others who provide information on family planning methods also needs attention.

Many of the conditions that determine acceptance of contraceptive technologies do not lie in the users themselves but in the political and administrative systems that distribute the technologies. Elites make decisions on what methods to use, how the distribution shall be organized, who shall be the distributors and educators, what price to charge, what the message will be, and how the methods will be packaged. Yet, the managing elite and the delivery systems themselves have rarely been the subject of systematic research. This type of program research is a major gap on both theoretical and empirical grounds and may pay high dividends in the short run.

Finally, some research on the determinants of fertility has been aimed at increasing the use of family planning services, thus enabling parents to have the family size they want. But this is only one of two fundamental social objectives in fertility policy. The other is to balance the numbers of children individual couples want for themselves with the number the whole society thinks best. Research on how this second objective is accomplished and how it influences fertility is needed.

Population policy

The relative contributions of availability of fertility planning methods and of general socioeconomic development to reducing population growth have been a subject of considerable controversy, with strong advocates on both sides. Each undoubtedly contributes and the relative contribution in a particular case will vary with culture-specific factors. Further research to bolster either position might better be directed toward broader based research on the complex interaction of the many factors that influence population growth, Methodologies are available for study of these interactions, and data collection efforts need to be designed so that these can be used. Data on social, economic, and political variables are often collected in different ways at different times by different groups, Coordination of data collection efforts would also facilitate disaggregated analysis at the subnational level, which is necessary to better design family planning programs. The comparative research within and across countries that is needed to improve predictive ability—which approach to family planning is likely to work best under what conditions—would be facilitated as well. Critical analysis of individual variables is also needed. Assistance to LDCs in experimental design and use of the new methodologies would be beneficial.

A systematic analysis of "success stories" —areas where dramatic reductions in population growth have been achieved—could be productive. Through careful analysis, factors that have led to success might be identified and ranked in probable importance for further evaluation. The objective of such work would be to improve predictive capability with regard to the factors likely to lead to effective programs in different contexts.

The need for viewing family planning activities in a broader context was recognized by Congress in 1978 in passage of an amendment (sec. 104d) to the Foreign Assistance Act of 1961. Section l04d requires that all assistance programs, not just those specifically directed at population, be evaluated for their impact on population growth.

Policymakers attending the workshops held by the International Review Group to identify social science research needs for the 1980's also identified evaluation of past and present policies and programs for their impact on population as one of their most critical needs (8). Evaluation of both those policies and programs with specific family planning objectives and those expected to have indirect impact, such as in the areas of education and nutrition, was called for. The

lack of existing knowledge, however, about how specific factors interact to influence population growth makes this an as yet impossible task and points up the need for research to make such efforts achievable.

Research is needed both on the effect of general policies and programs and on specific interventions. For example, how effective is a program which promotes breastfeeding as a method of limiting fertility likely to be? What is its cost? What are its nutritional and other effects? How does such a program compare to one promoting later ages at marriage?

The situational aspect of specific interventions should not be neglected. A finding of WHO acceptability research is that not enough is known about the application of various fertility planning methods in specific situations. Though some might not consider how IUDs are inserted in women of an Indian village as a subject for research, information on similar situation-specific applications is considered a significant need in many LDCs.

How various institutional arrangements influence family planning programs in particular countries should be further studied. Whether, how, and under what conditions family planning should be combined with health care or other socioeconomic programs are the kinds of questions on which further information is needed. Such information would permit development of guidelines that administrators could use in designing family planning programs.

Finally, there is a need to better **understand the political** processes that lead to population policies and the relationship of research to policy formation. Although it is often difficult to show that a specific piece of research has had an influence on policy, a number of cases where the relationship is clear have been documented. In a review of such work (5), evidence is summarized that clearly shows that research findings have influenced policy in four areas:

- *development of antinatalist population policies*—definitive evidence comes from Colombia, Thailand, and Taiwan;
- *service* delivery—research has supported the use of paramedical or nonmedical personnel to provide fertility planning services and information traditionally supplied by physicians. Research findings have also had a major influence on the implementation of hospital postpartum programs and on selection of particular contraceptive methods such as the pill and the IUD;
- *development of population growth targets*–research findings have been used to formulate programs and estimate budgets necessary to meet specific population growth goals; and
- *migration and redistribution* of *population—a* good example of the influence of research on policy in these areas comes from Colombia (5).

In a fifth area, that of population education, it is too early to evaluate the many recently implemented specific programs providing education on population-related topics in LDC schools, but a number of these programs include comparisons of the effectiveness of various teaching methods and the relationship between educational level and material presented. This information is of obvious value to policy makers.

Research, by showing the high mortality rates associated with abortions performed under inadequate medical conditions in Chile and other Latin American countries, was of considerable significance in the establishment of family planning programs in these countries; "programs were often justified, and sometimes evaluated, in terms of their effectiveness in preventing induced abortion" (5). Such research has also influenced policy on the legal status of induced abortion.

Much remains to be learned, however, about the research most needed by policy makers, how such research should be done, and especially how it can be brought to bear on policy. As Miro and Potter (7) point out, it is widely assumed that "if research succeeds in identifying the relationship between demographic variables and social, economic, and cultural indicators, then a tool will have been obtained for use in policy decisions. But that is as far as it goes.

Policy relevance is not attached to a thorough analysis of how, in fact, government policies eventuate and the decisionmaking processes that are involved." They argue that such information would provide a firmer basis for predicting how different research results might be used and which individuals and government agencies should be kept aware of new developmants in the field of population.

The relative importance of different kinds of research

The preceding sections cover three kinds of research that might be described as basic, developmental, and utilization research. Basic research includes studies of reproductive processes and fundamental studies in apparently unrelated areas (such as in materials science which may eventually lead to improved contraceptive devices). Also included are development of basic demographic data and theory, and development of explanatory models and new measurement techniques.

Developmental research links knowledge and practice and is particularly applicable to such important aspects of new or improved contraceptive technologies as dosage levels, mode and frequency of administration, and safety. Regulatory requirements that must be met add to the expense and risks involved in developmental research.

Utilization research, as applied to fertility planning technologies, is the study of cultural, economic, and political factors that impede or promote use of technically safe, effective technologies. The objective of utilization research is to ensure that the technology is distributed and administered in ways that are consistent with the cultural, economic, and political values of a given society. Despite its importance, utilization research is often inadequately err hasized in the process of developing and distributing fertility planning technologies.

Research on delivery systems, institutional arrangements, and evaluation of program effectiveness is included in utilization research. Also included is development of techniques that can be used to increase use of family planning methods, usually termed operations or management research. Although utilization research could be considered market research, it is broader than what usually falls under that rubric; hence the term "utilization research."

Each of these three categories of research serves different purposes. Because of the inadequacies of current fertility planning technologies and the acknowledged increase in need for them in the years ahead, basic and developmental research to develop improved methods is clearly needed. But because of the long lead times in development of new methods, current technologies will have to be used more effectively if population goals are to be met in the next 20 years. Utilization research will thus be of key importance in the immediate future.

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