Research and fertility regulation

A. de Francisco

Research into family planning becomes all the more important when evidence indicates that demographic profiles have changed over time in populations using contraceptive methods. For example, in some countries that have successfully introduced large-scale fertility-regulating methods, the population is still expected to double in less than 30 years. Such is the case of Bangladesh, where most of the population growth is due to what is termed “the population momentum”, in which the wider population base will soon become of reproductive age. There is no doubt that such populations will require larger investments and the introduction of more effective fertility-regulating programmes than in the past. Continued progress in research into family-planning methods and in programme implementation will therefore continue to be of paramount importance. At the same time, studies on the quality of services, and the safety and efficacy of fertility-regulating methods are crucial given that these activities will, to a great extent, determine ultimate programme success. In this context, research on both the safety and efficacy of fertility-regulating methods — particularly on the safety of long-term hormonal methods — is highly relevant.

The Special Programme of Research, Development and Research Training in Human Reproduction, co-sponsored by the United Nations Development Programme, the United Nations Population Fund, the World Bank and WHO, formed in 1984 a Task Force on the Safety and Efficacy of Fertility Regulating Methods. Published in this issue of the Bulletin (pp. 713–721), the article by David Skegg “Safety and efficacy of fertility-regulating methods: a decade of research” comprehensively reviews the studies on the safety and potential adverse effects of contraceptive methods endorsed by the Task Force. For policy-makers, the article provides useful information on various aspects of administration, side-effect management, and safety of available contraceptives. Managers of population programmes in developing countries will find this background material particularly useful as an aid in making decisions on the design and implementation of future programmes.

One issue that should be considered further is the practice of carrying out studies in developing countries in a post-marketing fashion. In the article, Skegg points out that most of the previous research on the safety and efficacy of fertility-regulating methods was conducted in Western Europe or the USA. However, it is clearly important for developing countries to carry out their own safety studies, given their considerable use of and requirement for contraceptives. Nevertheless, the following aspects need to be rationalized:

- **The need to conduct such trials after, and not before, the large-scale introduction of contraceptive methods.** It could be argued that this is normal epidemiological practice since phase-IV trials deal with the evaluation of products introduced though programmes at the community level. However, the reasons for carrying out such trials should be made explicit.
- **Conducting studies in developing countries using substances that are not regulated for human use in developed countries.** For example, it appears that the injectable hormonal contraceptive depot-medroxyprogesterone acetate (DMPA) was approved for use in the USA following large-scale trials in developing countries.

These issues apart, the efficacy and practicality of injectable contraceptives are likely to lead to their increased acceptance by couples, and they may therefore play an increasingly important role in fertility regulation in the developing world. Efficacy, however, should not override concerns with safety. While there seems to be clear evidence for the efficacy of Norplant, I am not aware of conclusive evidence as to its safety in phase-IV trials. These are important areas for research which require documentation in a scientific manner prior to the promotion of products.

An important contribution of research programmes relates to capacity-building in developing countries. There is no doubt that, in addition to benefits to communities, developing-country institutions also strengthen their institutional capacity by taking part in research activities. I appeal for continued inclusion of developing-country institutions and scientists within programme design and development activities.

It is worth considering the future role of research and the possibilities for expanding the focus of existing policies towards comprehensive human reproduction issues. While continuing to work on safety and delivery mechanisms of contraceptives for men and women, research programmes on family planning can also afford to include a wider perspective on reproductive health. For example, research could be conducted to look at linkages between development and reproduction, as well as to evaluate options for covering the costs of programme implementation. The concept that fertility regulation is closely linked with sexual activity should be brought into greater focus.

It is critical, in particular, to foster linkages with prevention and control of sexually transmitted diseases (STDs)/human immunodeficiency virus (HIV) and safe motherhood programmes. Interactions between the quality and utilization of reproductive health services and the education of both clients and providers may also prove to be important areas for social and quantitative research.

Reviewing research progress is an important achievement in terms of summarizing the current status of knowledge. Now that we have amassed a wealth of relevant information on fertility-regulating mechanisms, we should use it in a more disciplined way to define research priorities for the future.

---

1 Senior Public Health Specialist, Global Forum for Health Research, c/o World Health Organization, 1211 Geneva 27, Switzerland.

Ref. No. 0032