Review article

New strategies for providing hormonal contraception in developing countries

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Abstract

Even with progress in increasing access to effective contraception over the past decades, and the growing range of contraceptive methods available on the market, women in developing countries continue to report an unmet need for family planning. This constraint continues to challenge reproductive health policies and programs, while the momentum of population growth and the young age structure in developing countries leads to larger numbers of potential contraceptive users and increasing global demand in contraceptive markets. Of late, there is a renewed focus on increasing access to long-acting hormonal methods to effectively meet this need, establishing and effectively implementing new service delivery strategies. A number of processes have profoundly affected the procurement and use of hormonal contraceptive methods in developing countries: a supportive policy environment, evidence-based practices and an increasing diversity of delivery strategies play a significant part in increasing number of contraceptive users and the demand for hormonal contraception.

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1. Introduction

The link between individual fertility regulation and the achievement of broader development goals is perhaps the central message for policy makers and program managers in the health and finance sectors in the 21st century [1]. But it does not happen by chance; to see the benefits, we have to provide the services in developing countries where the need is greatest. With the global population now estimated at 6.8 billion and a young age structure in most developing countries, population momentum will contribute to population growth for the next several decades, with 95% of this growth in developing countries, until we reach around 9.4 billion people in 2050 [2].

Despite the progress made in recent decades in fertility reduction in developing countries (e.g., total fertility has declined from about six to three children born per woman, on average, outside China), up to 120 million women (10–12% of married women in most regions and more than 24% in sub-Saharan Africa) in developing countries continue to report an unmet need for contraception. The Millennium Development Goal (MDG) target of universal access to reproductive health reaffirms the need for contraceptive options as well as access to other key reproductive health services, including safe abortion, to reduce maternal mortality (MDG 5) and achieve gender equity (MDG 3).

Since its introduction in the 1960s, hormonal contraception has been increasingly accessible and widely used for both spacing and limiting births in developing countries. During the past 50 years, the range of types of hormonal contraception and their distribution in developing countries, as well as quality assurance processes [3], have evolved with marked national patterns of client and provider preferences. For example, Bangladesh and Zimbabwe have large oral contraceptive (OC) markets (more than 30% of
users), while Malawi and Ethiopia are experiencing high demand for injectables (about 60% of users) [4]. Hormonal products come in a range of presentations, are useful for both spacing and limiting, can be used by clients as well as being provider dependent and are generally quite effective (more than 90%) [5,6].

Due to its early introduction in many developing countries, increased access and high unmet need in many countries have led to rapid uptake as both providers and users become familiar with OCs as one of the first methods used by women in developing countries. As a result, the OCs have the widest geographic distribution of any contraceptive method, with 9% of married women aged 15 to 49 years using them. Pill prevalence is relatively high, ranging from 20% to 55%, in four countries in Africa, four in Asia, 11 in Latin America and the Caribbean [4], with highest developing country prevalence in Morocco and Zimbabwe (both over 40%).

Given the cumulative nature of protection provided by sterilization and the long-term efficacy of the IUD, these two methods are the most widely used in developing countries. However, in terms of the share of hormonal contraceptive use in overall contraceptive use, there are more countries where at least 30% of contraceptive users rely on OCs than there are countries where a similar share is accounted for by either female sterilization or the intrauterine device (IUD). Other modern hormonal contraceptive methods are also popular in selected regions. In East and Southern Africa, for instance, injectables and implants are the most popular methods, accounting for over 40% of overall contraceptive use [4].

The cost of commodities is a critical element for both donors and countries planning procurement. According to the UNFPA [7], contraceptive commodities required for reproductive health in developing countries cost about US $840 million per year in 2005 and will increase to about US $984.5 million by 2015 (including non-hormonal methods). The cost of contraceptive commodities will grow faster than the number of users because of the changing method mix: given the young age structure of new users, pill use and injectable use in parts of Africa should increase the fastest. The result will be that pills, costing about $3.60 per year of protection, will play a more substantial role in procurement budgets than female sterilization or the IUD, which have lower annual costs of protection but are more appropriate for users who desire longer spacing or have completed their desired family size.

Between 2000 and 2015, the use of all methods, but particularly OCs, will increase by 37% (from a base of 998.2 million cycles) and so will the use of injectables by 31% (from a base of 123.1 million per unit) [7]. Increases in contraceptive users will be seen in all regions, although the absolute numbers and the method mix will differ significantly, e.g., 51 million new users in India between 2000 and 2015. To meet this demand, some regions such as Africa may have to build new networks and scale up existing services, while others such as South Asia may see their greatest concern in commodity support. Procurements of hormonal contraceptive methods from major international donors increased dramatically for combined OC (60 to 200 million cycles per year) and injectables (from about 10 to 60 million units) from 2000 to 2008, but remained low and stable for emergency contraceptives (EC) and implants (both under 10 million units). Moreover, the combined value of these shipments of hormonal contraceptives during 2008 alone was about $120.4 million [8].

To address the need for contraceptive protection over a longer period of time with lower discontinuation, there is a renewed focus on longer acting methods of which many are hormonal based. Innovations are seen in the increasing availability of methods with either greater ease of use or provision (e.g., the use of paramedical personnel for the provision of implants Jadelle®, Implanon® and Sino-Implants®) and in the use of depot medroxyprogesterone acetate (DMPA) in Unject®, facilitating the safer provision of injectables at the community level.

2. Major processes

Beyond demographic trends and the increasing demand for products, there are a number of processes which have profoundly affected the procurement and use of hormonal contraceptives in developing countries in the past 50 years, namely, a supportive policy environment, the adoption of evidence-based practices and increasing diversity of service delivery strategies.

2.1. Policy environment

The improved policy environment in support of reproductive health and rights has contributed greatly to the availability and access to all contraceptive methods (including hormonal methods). In 2007, 92% of countries supported contraceptive provision, either directly through public services (74%) or indirectly through non-government service outlets (18%) [9]. This favorable policy environment, often linking contraception with maternal and child health programs, not only facilitates procurement through international donations and national purchases, but also enhances access through a supportive public information environment. The policy environment was reinforced by the International Conference on Population and Development (ICPD), Plan of Action and is now reinforced by the MDG of improved maternal health through universal access to reproductive health services, including contraception. The challenge implicit in this supportive environment is the trend toward the decentralization of both health policy and product procurement to municipalities, health districts and states, making commodity decisions more complex. This changing environment is also evident in the evolving relationships between the public and private sectors, with both state and donors interested in exploring new ways of operation, from outsourcing, updating regulations, licensing and
accreditation to social insurance (see Abt Associates PSP-
One project for practical examples of these interventions)
[10]. The private sector is also looking for opportunities for
local manufacturing and distribution of products, and
supporting networks of providers where they can both
make a profit and serve the public interest.

Of the 1.76 billion persons who will be added to the
world’s 6.8 billion population by 2024, about 86% will be in
urban areas of developing countries [11]. As the population
becomes increasingly urban, potential contraceptive users
have access to a greater array of products, providers and a
community with a different ideation about the benefits of
contraceptive use. Although urban slums, accounting for
about 43% of urban residents in developing countries (even
higher in South Asia and sub-Saharan Africa), are perhaps
the exception to this process, the increasing concentration of
a growing population in urban areas will undoubtedly be
reflected in greater demand for hormonal contraceptives.

One of the most significant contributions to the change in
availability and access to hormonal contraception is the
development of new and diverse service delivery strategies
that respond to the need for meeting clients’ needs within
diverse market conditions. One responds to the need for
consensus among providers about what is appropriate care
for an individual client, while other focus on alternative
approaches to increasing access and reducing the costs of
services to all clients. Each of these strategies has profoundly
influenced the way in which hormonal contraceptives are
understood by the community and how they are provided.
Innovative strategies contributing to the diversification of
service delivery systems are expanded upon below.

2.2. Evidence-based practices

The first of these strategies is developing a better
understanding of the evidence base on client eligibility and
health risk of use. Moving beyond the clinical experience of
individuals, efforts like WHO’s the Medical Eligibility
Criteria for Contraceptive Use [12] and systematic reviews
[13] provide globally relevant evidence-based recommenda-
tions on whether an individual can safely use a
particular contraceptive method, including the full range
of hormonal methods. This guideline was intended for use
by policy-makers, program managers and the scientific
community in the preparation of national family planning
and reproductive health programs for the delivery of con-
traceptives. The importance of this development is its
critical review of available evidence as an alternative to
traditional forms of clinical reference and inevitable con-
lict among “expert opinions” without reference to globally
relevant safety data. While this review is global in scope,
it is intended to serve as guidance for national service
delivery guidelines.

Medical eligibility criteria also facilitate a better under-
standing of safety issues at the intersection of two fields of
care. For example, while hormonal methods provide no
protection against infections such as HIV for women in the
general population, hormonal methods do not increase the
risk of becoming infected with HIV. Moreover, commonly
used antiretroviral regimens do not significantly affect
hormone levels in DMPA users and therefore are not likely
to decrease its contraceptive effect [5]. Despite this lack of
infection protection, relatively few women actually report
the use of hormonal contraception with other forms of
infection prevention such as male or female condoms in
stable relationships [14]. The consensus on safety and
appropriate screening offer greater confidence in the practice
of using trained staff at many levels in the provision of a
range of family planning services.

As a response to the estimated shortage of 4.3 million
health workers in developing countries and the need to
improve access to critical health services, many governments
have sought to train more health workers, particularly for
Africa [15], while at the same time allowing other health
workers and community members to take on tasks that are
critical for health, known as task sharing and task shifting.
as the rational redistribution of tasks among health workforce
teams in order to maximize the efficient use of health
workforce resources. The main cadres of workers among
whom tasks can be shifted are medical doctors, non-
physician clinicians, nurses and community health workers,
all with appropriate training.

Forty years ago, Rosenfield et al. [16] documented that
paraprofessionals could provide OCs with an equivalent
level of quality as physicians, when indeed physicians are
not available, as was the case in Thailand and certainly still
ture to much of sub-Saharan Africa and South Asia. More
recently, WHO conducted a consultation and systematic
review of data on the practice of providing injectable
contraception at the community level and concluded that the
provision of progestin-only injectable contraceptives (spe-
cifically DMPA) by appropriately trained community health
workers is safe, effective and acceptable to users [17].

2.3. New array of service delivery vehicles

The general trend to greater public acceptance of family
planning concepts and an acknowledgment of the right to
decide has led to an increased range of delivery systems
involved in the provision of hormonal contraception.
Beyond hospitals, public clinics and private physicians,
there are now a full range of delivery systems, including
pharmacies, medical sellers, social marketing and, more
recently, social franchises (SFs). There seems to be renewed
interest in a modified community-based distribution model
for the 10 low prevalence countries in sub-Saharan Africa,
with total fertility rates of more than 5, where access is
challenging, private sector is weak and community support is
required for acceptability of family planning [18].

Social marketing programs followed shortly thereafter.
These used pharmaceutical manufacturer’s models of
distribution to pharmacies and other medical outlets with a branded product, but with a subsidy for prices in exchange for promotion through diverse social communication and marketing strategies. In this sense, social marketing programs are designed to complement commercial approaches, in that their educational campaigns and distribution strategies focus on areas where commercial suppliers show little interest. For example, Population Services International and DKTI International provide hormonal contraception (and more recently bed nets and oral rehydration therapy) to poor population segments in more than 25 African countries. The goal of all these strategies is increase access to services, particularly among the poor, and their programs are designed to reduce inequities of wealth and ability to pay.

As a further development of commercial models for serving the market for hormonal contraception, SFs have been functioning in many developing countries including PROSALUD in Bolivia, Gold Star Network in Kenya and Greenshare in Pakistan. Like its commercial counterpart, SF systems have identifiable key elements of operation [19]. SFs have become particularly popular in large markets with the need for brand identity and range of providers. The desired result of these network strategies is to sustain the presence of qualified providers in rural and peri-urban areas, build local capacity to improve the quality of care and offer services at a more affordable cost to poorer clients than in the commercial and fully private markets.

The emergence of these new service models has led to new partnership arrangements with producers, procurers and providers of hormonal contraception. For example, as part of a public–private partnership with the United States Agency for International Development (USAID) during the next 5 years, Bayer Schering Pharma will deliver up to 50 million cycles per year of Microgynon® and Microlut® for public markets, and up to 60 million cycles per year for social marketing programs in more than 50 supported programs globally [20]. More recently, demand side financing strategies such as vouchers for family planning have been adopted by Kreditanstalt für Wiederaufbau (KfW), the Gates Foundation and others as a way of giving more decision-making power to poor clients. These alternative financing schemes offer client-controlled vouchers for selected reproductive products and services at a subsidized price at qualified outlets. The innovation lies in the focus on clients’ choice and financial decision making as a way of stimulating improved services in qualified service outlets, rather than financing these services through the health systems directly. These systems have been functioning in Bangladesh, Cambodia, Kenya, Uganda and elsewhere, providing prenatal care, skilled attendance at birth and a range of contraceptive services. The use of accreditation systems and cost analyses within these schemes ensures that providers meet required standards (of infrastructure and quality of care) and are willing to provide services at the established price.

In terms of long-acting hormonal methods, there are two specific service provision developments. The International Contraceptive Access (ICA) Foundation of Turku, Finland, a partnership between the Population Council and Bayer Schering Pharma, provides service-delivery organizations with the levonorgestrel-releasing intrauterine system (LNG IUS) on a not-for-profit basis to serve the reproductive needs of women and families in developing countries. To date, they have made over 31,000 donations to 13 countries [21]. At the same time, Family Health International is facilitating the introduction of Sino-implant (II) in several developing countries. Sino-Implant (II) is a low-cost subdermal contraceptive implant biosimilar to Jadelle®, containing two rods (each with 75 mg levonorgestrel) labeled for 4 years of use and manufactured in China by Shanghai Dahua Pharmaceutical Co., Ltd. [22]. To date, Sino-implant (II) is approved by drug regulatory authorities in Kenya and Sierra Leone and will be distributed by Pharm Access Africa Limited (PAAL). PAAL is seeking approval of the implant in nine African countries, while Marie Stopes International (MSI), DKTI International, Progyne and Profamilia are moving forward with registrations in other countries. Sino-implant (II) costs about 70% less than implants currently on the market and, as a result, can be offered to women on a much broader scale. This use of market segmentation strategies to provide a range of products to different clients with the ability to pay a range of prices is pursued with the hope of expanding the total market in the long run.

Price and proximity of source are two main determinants of access, with safety and efficacy the most sensitive determinants of client use. As a consequence, there is increasing interest in the use of generics and second-tier pricing strategies to ensure that, for hormonal contraception, the lowest prices are available to users. Once new products are off patent, generic producers seek to develop market share with the provision of lower priced products, often in national and emerging regional markets. With the demand for hormonal contraceptives increasing in many markets by up to 5% per year, there is enough profit even for low-priced products to keep generic producers engaging in this market, albeit with only modest confidence. With nearly half the world’s population (and nearly two-thirds of the population in sub-Saharan Africa) living on less than $2 per day, finding the right market niche for hormonal products is certainly a challenge [2].

Nevertheless, the Reproductive Health Supplies Coalition members, including the Deliver Project of John Snow, Inc. (JSI), work with donors, procurement agencies, manufacturers and other organizations concerned with commodity security continue to support the development of sustainable contraceptive markets, the use of good manufacturing practice, improving procurement capacity and strengthening logistic management systems [8]. In addition, it hosts a site to share information about the sources, shipments and costs of contraceptive products. Specifically, the RHInterchange (www.rhsupplies.org/resources-tools/rhinterchange.html)
provides access to up-to-date, harmonized data on more than $1 billion worth of shipments of contraceptive supplies for more than 140 countries around the world.

3. Conclusions

Hormonal contraception is often the first method of exposure for young women in many developing countries, even when it does not provide protection against unwanted sexually transmitted infections as would barrier methods such as the male and female condoms. The choices from EC to the LNG IUS make hormonal methods appropriate for an array of lifestyles and needs. The clinical and non-clinical nature of the products imply that different types of training, standards of quality and diverse levels of providers must be included in the analysis of the role of hormonal contraception.

Given the expected growth in both users and the costs of contraception, the issue of contraceptive security must be on the policy agenda of most developing countries. New service strategies including the use of trained paramedical health providers, community-based service providers, social marketing, social franchising and insurance schemes will help make products more accessible, even in countries with current low contraceptive use. This will be particularly true in urban areas where the developing world will see the largest growth in population and in the demand for quality contraceptive services.

The promise of the use of hormonal methods for men is still a long way off, but we suspect that with the growing interest in the role of men in reproductive health programs, we will see progress in the coming years. In the long run, however, the field will likely see more investment in user-controlled long-acting delivery systems, non-hormonal options and dual-protection methods that protect against unwanted infections as well as unwanted pregnancy. In the interim, with the number of contraceptive users in developing countries increasing significantly in the future, the demands for hormonal contraception and its providers will only increase.

References