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Improving the safety and effectiveness of contraception in China: a case-study in promotion and improvement of family planning

Reviewer

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Executive summary

HRP has a long history of successful collaboration in China. WHO is widely respected in that country, and HRP benefits from its prestige. Since 1979, HRP has helped establish and strengthen a network of research institutes and provided support to build the capacity of Chinese sexual and reproductive health researchers. Today, HRP facilitates a wide array of research and capacity-building activities that are contributing in strategic ways to improve the quality of care and outcomes in family planning and sexual and reproductive health in China.

This case-study addresses one example of this long, multi-faceted collaboration: HRP's assistance in improving the safety and effectiveness of China's locally produced contraceptives. The terms of reference for this case-study called for examination of HRP's role in the withdrawal of less effective IUDs (stainless-steel and copper rings) and the once-a-month oral contraceptive, in particular.

All contraceptives used in China are produced domestically. IUDs are the most widely used, by about 110 million women, constituting about 50% of contraceptive methods. A pivotal study was conducted in 1991–1992 to quantify the numbers of unplanned pregnancies, abortions and cases of reproductive morbidity due to use of the steel-ring IUD. It projected the health cost savings and other benefits that would accrue from shifting IUD use from steel rings to copper-T IUDs (TCu 220C and TCu 380A) and recommended this shift. In 1993, the Chinese Government banned production of the steel-ring device. Factories, however, turned to producing a copper-treated variant, which was also considerably less effective than the recommended copper-Ts.

Once-a-month oral contraceptives have been the most popular and most widely used oral contraceptives in China. Concern about their efficacy and long-term safety were raised during a strategic assessment conducted in Chongqing, which led to systematic reviews, the results of which guided recent decisions about procurement.

Methods

The case-study was based on extensive document review, a study visit to HRP counterparts in China (interviewed in Chinese and English, 5–13 December 2007), in-depth telephone interviews and hundreds of e-mail exchanges with key informants, a follow-up questionnaire, and feedback from multiple reviewers.

Findings

Effective collaborations

Achievements were made possible by collaborative relationships. HRP's principal partner was China's National Population and Family Planning Commission, which oversees the national family planning programme. HRP's principal research partner in this work was the Shanghai Institute of Planned Parenthood Research, which HRP has assisted since 1979.

Process

The HRP formula that brought about the changes described is a combination of evidence-based research methods and processes that involve policy-makers from the start. HRP's Strategic Approach was a significant innovation, involving high-level policy-makers in rural field assessments (carried out in the year 2000), which gave them perspectives and feedback from providers and clients. HRP then worked with Chinese counterparts to complete seven systematic reviews that involved policy-makers in a series of experts' meetings (years 2002–2004) and generated evidence on the safety and effectiveness of commonly used contraceptives, providing the evidence base for policy-making.

Outputs

The most significant outputs were:

- the research findings;
- recommendations that four widely used contraceptives should be removed from the national family planning programme on the basis of considerations of safety and effectiveness: these were the copper ring, the once-a-month pill, a 'visiting' pill and a daily pill;
- a new conceptual guiding framework for overall quality of care in sexual and reproductive health in China; and
- better understanding by colleagues in family planning and sexual and reproductive health about systematic, evidence-based research and evidence-based contraceptive improvement.

Other outputs included generation of new research questions, individual and institutional capacity-building, training and dissemination workshops, and more than a dozen publications in authoritative English and Chinese journals.

Cost-effectiveness

This work was highly cost-effective in comparison with research for policy change in other large programmes for family planning and sexual and reproductive health. The financial input of HRP for this work has been modest: total expenditure for the strategic assessment and the systematic reviews was approximately US$ 300 000 over five years (2000–2004). There is no evidence that HRP resources could have been used much more effectively.

Outcomes and public goods

The outcome of this collaboration was the policy decision, in 2004, by the National Population and Family Planning Commission to withdraw the four problematic contraceptives from the national family planning programme. They were removed from the list of centrally procured contraceptives, and, as of 2005, they were no longer purchased or provided by the National Commission. The research findings and recommendations also led to decisions in India (and perhaps Thailand) not to import the Chinese once-a-month pill. Publication in the prestigious journal *Contraception* of findings on the high estrogen content and potential safety concerns about this pill reduces the likelihood of formal importation by other countries.

Impact

The phasing-out of less-effective IUDs and higher-dose hormonal contraceptives might be averting millions of unplanned pregnancies, abortions and adverse reactions. We consider that the decrease in reported abortion rates since 1991 may be attributable to three main factors: phasing-out of steel and copper rings in favour of more effective copper-bearing IUDs; changed Government policies; and improved quality of care in family planning services. We estimate that about one third of the decrease in abortion rates might be due to phasing-out of ring IUDs (about 1.4 million abortions averted in 2007).

Conclusions

- Removal of the four contraceptives from the procurement list for the national family planning programme was a major policy achievement by China, attributable in significant part to collaboration with HRP and leading to a significant reduction in the numbers of unintended pregnancies and abortions and associated pain and suffering.

- While UNFPA and other partners provided important support for China's family planning and sexual and reproductive health quality-of-care movement, it is unlikely that the translation of research to policy and the decision taken in 2004 would have occurred when it did without the input by HRP. The National Population and Family Planning Commission and Chinese researchers have stated that, without HRP, the decision would have taken much longer and the process would have been less rigorous.

The phasing-out of the contraceptives is still under way, as they continue to be manufactured, are available for purchase and are provided through some public channels in China. Family planning manuals contain cautions about using the once-a-month pill, although it is still available, and it is reportedly available in the private sector in neighbouring countries.

Recommendations

- Future engagements of HRP should be strategic to ensure that its investment has the greatest impact on health. The National Population and Family Planning Commission and researchers have stated that their greatest need from HRP is technical support to ensure that their research and programmes are up to date. HRP should support the unfinished research that emerged from the Chongqing strategic assessment and the systematic reviews (e.g. rationalizing the mix of available contraceptive methods and reconsidering the efficiency and the need for a quarterly IUD check-up). HRP should help conceptualize the research agenda and provide modest technical assistance. It should consider supporting use of the Strategic Approach by Chinese colleagues in assessing the actions required to improve the quality of care in abortion services.
- WHO in general should use its prestige in China to ensure that contraceptives of established safety and efficacy are used in China or exported, including supporting the full phasing-out of the four contraceptives from health facilities throughout the country and the discontinuation of production. Given UNFPA's commitment to the Programme of Action of the International Conference on Population and Development and its position to provide "contraceptives of assured quality", HRP and WHO should use the WHO/UNFPA Strategic Partnership Programme and other links with UNFPA to support China's progress towards these goals.

Introduction

Issues of population and sexual and reproductive health in China have a long, important history, not only because of the size of China's population, now over 1.3 billion, but also because China sees itself as a leader in Asia and in the world. Over the years, it has considered that its programme to limit births makes a major contribution to controlling population growth globally.

At the time of the establishment of the People's Republic of China in 1949, China had a population of just over 540 million and a total fertility rate of 6.14. Many in the Government (even Mao Zedong) argued that a large population was good. The Health Ministry, directed by pro-natalist military doctors opposed to contraception, issued a ban on importation of foreign contraceptives. China's first census, in 1953, showed that 87% of its population was rural and that it was growing faster than the agricultural output. By the mid-1950s, many in China's leadership had shifted from pro-natalist stances to 'approving' and then 'advocating' birth control as essential for lifting China's large population out of poverty. This would include providing low-cost contraceptives and loosening earlier restrictions against abortion and sterilization (Greenhalgh, Winckler, 2005).

Local production of contraceptives began in 1955 (UNFPA, 1995). The most important means was an IUD consisting of an inert stainless-steel ring, which became the main form of birth control after sterilization. So predominant was the 'steel ring' that even today Chinese generally refer to any IUD as a 'ring' (*huan*), regardless of its shape; thus, for example, the '*TCu-220 huan*'. Linked to socialist economic planning, China's birth planning efforts proceeded in relative isolation from international family planning efforts for the next two decades.

Collaboration with HRP

HRP has a history of almost 30 years of successful, well-appreciated collaboration in China. WHO is widely respected in China, and HRP benefits from WHO's prestige. In early 1979, after some three decades during which Maoist China was largely closed to the Western world, WHO was the first United Nations agency to establish an office in China, and HRP was the first WHO programme to send a mission. HRP was the first international organization to collaborate in China with the Government, to address the country's needs in population and family planning. UNFPA was also an early partner, launching its first country programme in 1980 (Andersen, 2004), and was also a major cosponsor of HRP. Over the years, the two organizations have worked in distinct but complementary ways. In China, HRP's contributions centred on creating and supporting a network of sexual and reproductive health research institutions, building their capacity and linking them with the international community working on population, family planning and sexual and reproductive health (researchers as well as programme and policy-makers). Its emphasis was to support clinical, biomedical and social science research in accordance with the highest possible scientific and ethical standards (Annex 1). This allowed Chinese scientists and institutions to participate in multinational research, to become familiar with Western contraceptive products and concepts and to build capacity for programme research on issues of quality, efficacy and safety. A principal HRP partner has been China's National Population and Family Planning Commission, the Government body in China responsible for population matters, formerly the State Family Planning Commission. (In this report, the name National Population and Family Planning Commission is used, even for events before the name change in 2003.) HRP is widely praised in China for its support.

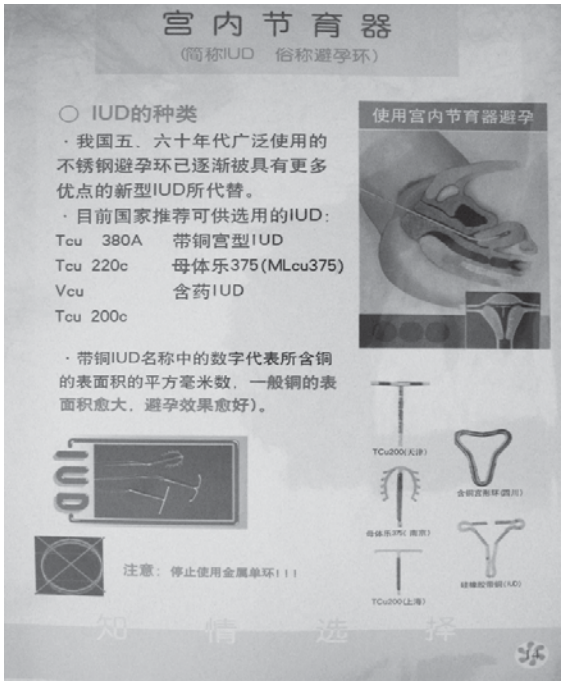
Contraceptives used and the predominance of the IUD

China has approximately 260 million married women of reproductive age and a contraceptive prevalence rate of about 83%. In order to understand the importance of HRP's contribution, it is necessary to understand the predominance of the IUD in China (Table 1). China has always relied heavily on IUDs, which now constitute approximately 50% of the methods used and account for perhaps 90% of reversible contraception (80% in 1994) (Li Yong Ping et al., 1994). The National Population and Family Planning Commission calculates that about 110 million Chinese women use an IUD (about 75% of the worldwide total of 160 million women using IUDs). Current trends show a substantial increase in IUD use, primarily as a preferred alternative to sterilization. Under the modernizing regime that assumed leadership in 1978 and the one- (to two-) child policy in 1979–1980, the prevailing norm was that a couple with two children should undergo sterilization, while the woman in a couple with one child would have an IUD. This policy has now officially been replaced by informed choice (State Council *Regulations on Family Planning Technical Service Management*, 2001, cited in National Population and Family Planning Commission, 2005). A wide variety of IUDs are used, including locally manufactured versions of international products as well as IUDs developed and manufactured only in China (see photo).

In the national family planning programme during 2005, 9.82 million IUDs were inserted, 2.36 million IUDs were removed, 2.16 million women and 290 000 men were sterilized, and 130 000 women received implants (data provided by National Population and Family Planning Commission, Department of Science and Technology, by email, 20 December 2007). These figures do not include procedures performed in facilities under the Ministry of Health, which would increase the total further, to perhaps 20 million IUD insertions annually (Annex 2 and below).

Table 1. Contraceptive methods used in China in 1992 and 2005

Method	Percentage	
	2005	1992
IUD	50.57	40.12
Female sterilization	33.84	41.66
Male sterilization	6.98	11.81
Condom	6.31	1.80
Hormonal pills and injections	1.54	3.75
Implant	0.35	–
Other	0.41	0.81



Rationale of HRP's work in China

As the safety and effectiveness of contraceptive products has been a priority for HRP globally, the Programme was ready to work with China in assessing contraceptive methods. The inert stainless-steel ring IUD, then the main form of contraception used in China after sterilization, was of particular interest, as it was reportedly associated with millions of unplanned pregnancies and related abortions (UNFPA, 1992; Li Yong Ping et al., 1994). While the steel ring had the benefit of low cost to the Government, it was relatively soft, thus easily changing shape in the uterus, and was frequently expelled, partially or wholly. Partial expulsion of the steel rings resulted in unintended pregnancies while the ring was still present. For this reason, early on in China's population/family planning programme a policy of routine (usually quarterly) ultrasound check-ups was initiated to determine whether women's IUDs were still present and properly positioned. Especially during the 1980s and into the 1990s, women with unplanned pregnancies were likely to have an abortion if the couple did not meet the local criteria for additional births (Kaufman, 1993).

It has been estimated that one quarter to one third of Chinese women have experienced contraceptive failure and that almost three quarters of abortions were related to contraceptive failure, primarily of the steel ring (Kaufman 1993; Cheng Yimin et al., 1997; Luo Lin et al. 1999a,b; Jiang Zhenghua, 2000; Xie Zhenming, Gu Baochang, Hardee, 2000; Wang Duolao, 2002; Greenhalgh, Winckler 2005). Research in 1991 (to which HRP contributed substantially) showed that the failure rate of the steel ring was six times higher than that of the copper-T (TCu 220) in the first year of use (Li Yong Ping et al., 1994). Abortions were generally performed without anaesthesia, causing substantial pain to many women (Gui Shi-xun, 1999; Jiang Zhenghua, 2000). Further, many women underwent repeated abortions and accumulated risks of complications, especially in rural areas. In a survey in Shanghai in the early 1990s, young women could expect to have an average of 2.3 abortions and some as many as five (Gui Shi-xun, 1999). Greenhalgh and Winckler (2005) present Chinese abortion data showing that there had been 3.9 million abortions in 1971, rising to a peak of 14 million in 1991, and decreasing to 6.3 million in 2001.

Some Chinese scientists and sexual and reproductive health policy-makers, as well as HRP, recognized that the steel ring was associated with multiple negative physical and psychological consequences for millions of women, including ectopic pregnancies and consequences of abortions after steel-ring failure (e.g. Li Jingzhi, Zhang Zhicheng, 1990). When HRP began working in China, improving the safety and effectiveness of contraceptives used, and providing a better IUD to replace the steel ring, became a high priority. HRP's and UNFPA's comparative advantage in the 1980s lay in the fact that they were esteemed international authorities and the only international organizations collaborating with China in the field of human reproduction. UNFPA relied on HRP, however, for technical guidance. The Program for Appropriate Technology in Health (USA) was also present early on, but under UNFPA as UNFPA's executing agency for UNFPA-supported local contraceptive production projects in China. Other important partners contributed later (see below).

How does this topic fulfil criteria for public good?

Assessing the safety and effectiveness of contraceptives and removing those deemed less safe and effective from central provision to the national family planning programme constitutes an important national public good for the women of China and

savings for the family planning programme. The populations of China (1.3 billion) and its neighbours constitute more than 40% of the world's population. Over the years, China has considered that its programme to limit births makes a major contribution to controlling population growth globally. China is influential in Asia and increasingly important in the world. The public goods generated nationally in China and regionally have real global importance. Chinese contraceptives flow to South-east Asia, and there have been discussions about exporting Chinese contraceptives to other countries and regions. Removal of less safe and effective contraceptives from China's family planning programme contributes to reducing and preventing their use in other countries.

Process

Replacing the steel ring by a better IUD

The TCu 220 IUD, which was used with favourable results for safety and effectiveness internationally, was proposed as a better alternative to the steel-ring IUD. HRP's support for improving research capacity played an important role in subsequent developments. Over the years, HRP has sponsored numerous courses on biostatistics in China and supported the training of many Chinese statisticians. The courses included one on statistical methods for medical research, organized in 1985 by HRP and held at the Shanghai Institute of Planned Parenthood Research, where HRP began building capacity in 1979 and which has become a major partner. The training included methods for multicentre randomized controlled clinical trials. Subsequently, HRP sent a researcher from the Institute to England for one year of training in modern computing methods for clinical trials. She then began contributing to contraceptive research and became an HRP collaborator. In 1986, the Shanghai Institute began a multihospital clinical trial to compare the steel ring with the TCu 220C, in a 'national key project' funded by the Chinese Government as part of its sixth five-year plan. HRP provided technical advice on the study design and coordination, although it was not formally involved. In 1989, the Institute published a report on the outcomes at three years (Chen Junkang et al., 1989). The results suggested that the steel ring should be replaced by a more reliable method, the copper-T, which led to the large international study described below.

To enable the shift to copper-Ts, UNFPA financed establishment of two plants for the manufacture of TCu 220C, one in northern China (in Tianjin in 1984) and one in the south (in Wuxi in 1990), with the State Pharmaceutical Administration of China as the implementing agency, the Program for Appropriate Technology in Health as the executing agency and the National Population and Planning Commission as the main buyer. Together, the two facilities supplied 5.8 million TCu 220 IUDs to the national family planning programme in 1992 and 4.5 million in 1993. Subsequently, UNFPA funded establishment of two TCu-380A production facilities, in Siping in 1993 and in Shanghai in 1995. The demand for and use of copper-T did not meet production capacity owing to their novelty, price and lack of promotion (UNFPA, 1995). By 1990–1991, China had a prevalence rate of contraceptive use of about 63%, IUDs accounting for 41% of all contraception and the steel ring for about 90% of all IUD use (UNFPA, 1992; Kaufman, 1993). The cost of the steel ring was only 0.28 Chinese yuan (equivalent to about US$ 0.03–0.04), while the China-manufactured TCu 220C cost 1.2 Chinese yuan (US$ 0.22) (Kaufman, 1993).

In 1991, the important 'IUD conversion study' was carried out, titled *Study of Stainless Steel Ring and Copper-T IUD Efficacy, Use, Cost/Benefit and Conversion in China,* which urged conversion to the TCu 220C (UNFPA, 1992; Li Yong Ping et al., 1994). The study was led by the Shanghai Institute of Planned Parenthood Research, with guidance from HRP staff and the participation of researchers at the prestigious Peking University and Peking Medical University. Funding was provided by UNFPA, with the National Population and Family Planning Commission as the implementing agency. HRP provided guidance and analysis of the clinical data and participated in a series of workshops for the study (Rowe PJ, *Review of clinical, demographic and epidemiological data on stainless steel ring and CuT efficacy*. Unpublished paper. HRP, 1992).

Analyses of clinical, survey, financial and economic data showed that a shift from the steel ring to copper IUDs would greatly reduce the numbers of abortions and unwanted pregnancies and significantly improve women's health. It was calculated that if, beginning in 1993, *all* IUDs inserted were copper-T IUDs, this would, over the next 10 years, avert 41 million pregnancies, some 26 million induced abortions, 9 million live births and 790 000 spontaneous abortions and stillbirths, and would greatly reduce pregnancy-related complications (UNFPA, 1992; Li Yong Ping et al., 1994). If conversion were to proceed at a 'moderate' rate (within 4 years), it was projected that 31.5 million pregnancies and 20 million induced abortions might be averted over the same 10-year period (Li Yong Ping et al., 1994). In either case, the conversion would be of "overwhelming cost effectiveness". The report stated that, "In China, IUD failure is very expensive to the government because… the state pays for a much larger portion of the consequences…whether the pregnancy ends in a state-funded induced abortion, or in a child who then receives state-funded day-care, schooling and health care" (UNFPA, 1992). The study concluded: "Economic efficiency is not, however, the primary reason why unnecessary IUD failure should be minimized. Accidental pregnancy takes a heavy toll on women's physical and psychological health. Although some cases of unintended pregnancy are inevitable, they should not be caused by the distribution of substandard contraceptives. For economic, demographic and humanitarian reasons, the supply and distribution of the TCu should be improved in China, and information about their distinct advantages over the stainless steel ring should be publicized to women and family planning workers" (Li Yong Ping et al. 1994).

The study had a direct and major effect on policy. Prompted by the findings, the National Population and Family Planning Commission decided in September 1992 to stop buying steel rings for the national family planning programme. Accordingly, the Government issued an order that production of the single steel rings must cease as of January 1993 – a very significant act. And production did cease. In late 1993, the World Bank formulated a project for a loan of US$ 25 million to the National Population and Family Planning Commission to upgrade IUD production; this was the Bank's first direct involvement in family planning in China (Gu Baochang, unpublished background document: *China's population program and prospects in the 1990s*).

The Government's order, however, only required that factories cease manufacture of the steel rings: it did not require that family planning providers no longer insert the steel ring. Before the ban went into effect, manufacturers stockpiled steel rings so that they could supply them to customers for quite some time after the ban (personal communication, Margaret Britton, 11 February 2008). As many provinces had large amounts in their warehouses, and some reportedly still have stock, insertions of the 'soft' steel ring have continued. Thus, steel ring insertions did not cease, because supply and demand existed, and demand reportedly continues. The steel ring was inexpensive and providers were familiar with inserting it; women were also familiar with it, knowing that their mothers, aunts and other women had them.

A second development also impeded the envisioned shift to the copper-T. After the 1993 order was issued, some providers are said to have asked that the steel ring still be made available. This led to production and use of a new stainless steel ring produced with better quality of steel, which made it more rigid and thus less susceptible to expulsion. This was known as the 'steel ring 165' because it

required 165 g of force to crimp it. Although data are not available, it has been reported that the steel ring 165, which is less easily expelled, resulted in somewhat fewer unintended pregnancies and thus fewer abortions than the earlier 'soft ring', although pregnancy rates with both types of ring remained unacceptably high (interview with Fang Kejuan and Zhou Weijin, 12 December 2007; Zhuang Liu-qi et al., 1988).

Introduction of the copper ring

The copper ring is simply the 'steel ring 165' to which copper was added when it became known that copper improves the effectiveness of IUDs. This resulted in the 'copper ring 165' or simply 'the copper ring'; it was also called 'active 165'. This was the same flat ring, about the size of a grape in diameter, although the steel and copper rings come in different sizes. The addition of copper did not significantly improve the clinical performance as frequent expulsions, as well as pregnancies with the ring still in the uterus, were reported. Copper was apparently electrolyzed onto the surface of the steel ring and thus it was subject to erosion (personal communication, Olav Meirik). Soon thereafter, a drug, indomethacin, was added to the copper ring to reduce bleeding after insertion. If there was any effect, it would have lasted about three months. This IUD was called the 'medicated copper ring 165' or the 'high strut strength IUD' (National Population and Family Planning Commission. *2003-2006 Niandi Jihua Shengyu Biyun Yaoju Taotai Mulu* [List of withdrawn family planning contraceptive products, 2003–2006], unpublished document, 2006).

A complete shift to copper-Ts did not occur; rather, there was an unanticipated shift from steel rings to copper rings (which had not existed in significant numbers before the 1992 directive to stop steel ring production). As steel rings were no longer manufactured as of January 1993, the copper ring displaced the steel ring in manufacture and eventually for new insertions, although a few stockpiled steel rings may still exist and be inserted in remote areas. While the numbers or proportions of steel rings, copper rings and copper-Ts being inserted are not known, the shift to copper-Ts was definitely slower than projected. Although the two TCu 220 factories established by UNFPA were reported to have supplied 5.8 and 4.5 million TCu 220 IUDs to the national family planning programme in 1992 and 1993, respectively, this cannot be equated with use. The Siping facility set up in 1993 produced 0.8 million TCu-380As but was to decrease production to half that (0.4 million) in 1994 because of limited demand, which was attributed to the novelty of the IUDs, their price and lack of promotion (UNFPA, 1995). (See Annex 2.) Additional information of steel ring and copper ring usage is given below in the section entitled *Outcome*.

HRP support for quality of care

In the 1990s, economic reform and development of the market economy affected nearly all aspects of Chinese society, including family planning and contraception. This society-wide transformation set the stage for the programmes of action of the United Nations International Conference on Population and Development in Cairo (ICPD) in 1994 and the Fourth World Conference on Women in Beijing in 1995 to influence China's National Population and Family Planning Commission. These two global meetings introduced major new ideas and trends to them. Through the ICPD process, policy-makers in the Commission and their research colleagues advanced their understanding of sexual and reproductive health and reproductive rights. Through the Beijing women's meeting, they embraced the concepts of women's rights and gender equality (Xie Zhenming et al., 2007).

China's earlier efforts to address its large population and rapid population growth were characterized by 'administrative' quotas and targets. The paradigm of the International Conference on Population and Development meant a shift from the administrative approach to an emphasis on quality of care and service for clients. Since 1994, the National Population and Family Planning Commission has been committed to improving the quality of care and has welcomed collaboration towards this goal from international organizations with expertise in quality improvement (e.g. Kaufman et al., 2008).

HRP has been an important partner in the quality-of-care movement especially by evaluating contraceptives and assessing service delivery, in particular in collaboration with the National Population and Family Planning Commission's Department of Science and Technology. HRP's special contribution has been the introduction of new research methods, and technical guidance for their application, for critically examining the contraceptive technologies produced and commonly used in China and for evaluating the quality of care. This has complemented the important contributions of other international organizations, especially UNFPA, the Ford Foundation, the Rockefeller Foundation and the New York-based Population Council. These partners have established pilot programmes for integration of quality-of-care concepts into the national family planning programme, transforming how sexual and reproductive health services are provided throughout China. While all partners have had important roles, none of the other international (or national) partners is as well positioned to provide the research training and support that is HRP's special strength and contribution. (See also *Contributions of other stakeholders*, below.)

HRP's Strategic Approach and the Chongqing assessment

HRP's Strategic Approach to Strengthening Reproductive Health Policies and Programmes was designed in the 1990s by HRP's Task Force on Introduction of Contraceptive Technologies. Its objective is to ensure that quality of care and rights are taken into account during the introduction of new contraceptives, rather than considering this an exclusively technological issue (Simmons et al., 1997; WHO, 2000a,b; Fajans et al., 2006).

The approach was introduced in China in 1998 for evaluating the introduction by the National Population and Family Planning Commission of quality of care into six pilot counties (Ma Li et al., 1998). Subsequently, the Commission's Department of Science and Technology requested HRP's support to conduct a strategic assessment of the introduction of contraceptives, with an emphasis on IUDs. The Strategic Approach came to China mainly because the Executive Director of the Science and Technology Department participated in HRP's Scientific and Technical Advisory Group and came to the view that this method could improve the quality of care in China. In 1997, HRP was requested to support a project on quality of care and conducted an important workshop on the Strategic Approach for 25 Chinese family planning officials.

Participation in HRP's application of the Strategic Approach in October 2000 was an attitude-changing new experience for the invited senior policy-makers and researchers who have led China's population and family planning programme. The HRP-guided assessment took them to distant rural and urban field sites in Chongqing municipality, Sichuan Province, where for two weeks they had the novel and compelling experience of visiting service delivery sites and interviewing women and families in their homes, as well as family plan-

ning providers and community leaders, about their experiences with the family planning programme and contraceptives. This allowed them to see family planning services differently and familiarized them in very concrete ways with the concepts of quality of care (WHO, 2002c). Chongqing municipality was chosen because, with a population of 30 million, it afforded a valuable mix of both urban and rural sites. Those who participated found the approach innovative, effective and different from other experiences. It helped high-level policy-makers to hear the views of people who were directly affected by their decisions and policies. They valued its interdisciplinary and participatory interaction and welcomed the sessions at the end of each day when the participants would sit together and review what they had learnt from the day's interviews and observations. The assessment identified numerous issues and produced a candid, detailed analysis of challenges (WHO, 2002c). It was found that a broad range of contraceptives was available at most higher levels of service delivery (county and municipal), but that, in some townships, services were limited to IUDs and quarterly IUD checks. The main conclusion was that there were many opportunities to improve quality of care, by scaling up the provision of currently available contraceptive methods and services, removing some contraceptives and introducing new contraceptive methods and other sexual and reproductive health services (Annex 3).

The assessment team recommended that a scientific panel of national and international experts be convened to review the scientific evidence on the safety, effectiveness, side-effects and cost–effectiveness of the IUDs and hormonal contraceptive products currently available. The panel should recommend that a small number of the safest, most effective IUDs be made available throughout China. It should also determine which hormonal methods should continue to be provided, the objective being to issue fewer, safe, effective oral contraceptives.

The recommendation to consider stopping the provision of some contraceptives and not add new methods or brands was contrary to what had been expected and demonstrates the value of using a systematic approach to assessing services before changing them (Fajans et al., draft working paper, *Contraception in China: using evidence to influence policies and programmes*. HRP, 2007). The lesson continues to influence the National Population and Family Planning Commission's management of its family planning programme.

Two workshops were convened in early 2001, one in Chongqing in March, followed by a national workshop in Shanghai in May, which identified the next steps for improving informed choice and ensuring quality of care in family planning and other sexual and reproductive health services. It was decided to conduct systematic reviews of the safety and efficacy of the most commonly used contraceptives in order to generate evidence-based information for decision-making.

Systematic reviews of contraceptive safety and efficacy

Following the Chongqing assessment, the next step was to conduct a formal, systematic analysis of the safety and effectiveness of the contraceptives. HRP recommended and introduced use of the systematic review method of the Cochrane Collaboration (Annex 4; reviewed by Sweet, Moynihan, 2007). The method is a powerful one. If the reviews had been carried out strictly according to that method, however, the findings might not have captured policy-makers' attention. The key to success was engagement of stakeholders in the review process, just as a broad range of stakeholders had been engaged in the Chongqing assessment. The goal was to provide a basis for rational, evidence-based selection and management of the contraceptives that the National Population and Family Planning Commission provides through its family plan-

ning programme. According to some participants, this was the first application of the principles of evidence-based medicine to the field of contraception in China.

HRP and the Commission's Department of Science and Technology laid out a workplan in 2001, anticipating broad participation (although, in the end, the Ministry of Health did not participate). In accordance with the recommendations of the Chongqing strategic assessment, the Commission convened a group of national and international experts to conduct formal systematic reviews by the Cochrane method. The Shanghai Institute of Planned Parenthood Research coordinated the reviews in collaboration with HRP advisers. The reviews began in early 2002 and continued through 2003 by means of a consensus-seeking process that included both the experts and high-level decision-makers. This secured stakeholders' involvement from the outset and engaged them throughout the two-year process. Had HRP only funded research with presentation of the findings at the end, there would not have been the buy-in from the high-level officials who accepted the reviews' recommendations.

Seven reviews were conducted. Three dealt with IUDs: the copper ring 165 IUD, other copper IUDs developed in China and copper IUDs developed in the West and used in China; and four reviews dealt with hormonal contraceptives: daily combined oral contraceptive pills, once-a-month oral contraceptive pills, progestogen-only visiting pills and emergency contraceptive pills. The main outcome variables for each contraceptive were its effectiveness, safety and continuation rate, as a proxy for acceptability. The review covered published and unpublished papers in Chinese and English describing randomized controlled clinical trials, controlled clinical trials, other observational studies with or without a control group, and studies of pharmacokinetics when relevant. The Shanghai Institute team searched for research papers electronically in Chinese and international databases and manually for papers not available electronically.

At a two-day national consensus workshop in April 2004, the experts agreed on the significance of the reviews and recommendations to be forwarded formally to the National Population and Family Planning Commission. The reviews showed that many of the contraceptives had not been evaluated since they were first marketed. The experts judged the reviews to be of great importance and practical significance for improving clinical family planning research in China, enhancing management and use of fertility regulating methods and advancing the quality of care, as well as disseminating the method of systematic reviews.

The conclusions and recommendations of the workshop concerning all the contraceptives studied were forwarded to the National Population and Family Planning Commission. The consensus recommendation was to discontinue use of four less effective and potentially unsafe contraceptives provided by the national family planning programme and many facilities under the Ministry of Health (see Box 1). The Commission accepted the recommendation, and, the following year, 2005, did not purchase any of the four (see below, *Outcome*). As of 2006, the cost of contraceptives purchased by the Commission was reported to be 420 million yuan (US$ 52.5 million) (http://english.peopledaily.com.cn/200606/22/eng20060622_276433.html).

Box 1. Four contraceptives no longer distributed by the national family planning programme:

- the copper ring IUD
- once-a-month pills
- visiting pill No. 53
- daily pill No. 0

Outputs

Many of the outputs of this investment by HRP have already been identified under *Process*, above. These include the following, in approximate order of importance:

- *Policy recommendations*. The conduct and findings of the Chongqing strategic assessment led to the systematic reviews, which resulted in recommendations for policy change that were accepted. We can say with confidence that these collaborations are having positive impacts on women's health and lives and that the benefits will increase over time (see section entitled *Outcomes* below).
- *New conceptual guiding framework*. HRP's Strategic Approach gave China a better understanding of quality of care and contributed to the wider movement for quality of care in China that has been transforming family planning. The 'triangle graphic' (Annex 3) introduced by the Strategic Approach has been embraced by Chinese colleagues as an effective formula for improving the quality of care, by addressing clients, quality services and good management within existing social, political and cultural contexts. In fact, this graphic has become a basis for the overall approach in China to quality of care (Xie Zhenming et al., 2007).

> "The best aspect of the strategic assessment was that it changed our thinking."
> *Member of the Chongqing team*

- *Greater understanding of and appreciation for systematic, evidence-based research and evidence-based contraceptive improvement*. Beyond acquiring the Cochrane method itself, researchers at the Shanghai Institute for Planned Parenthood Research and national experts acquired heightened appreciation for more rigorous, systematic approaches to research. As with the Strategic Approach, participants acquired not just new methods but also new mental orientations and value sets. They also gained a better understanding of the importance of contraceptive safety and effectiveness and the importance for women of having high-quality contraceptives.
- *Individual and institutional capacity-building*. Substantial capacity-building took place through the processes of using the two new methodologies. A related achievement that also involved institutional capacity-building was establishment of the Centre for Contraceptive Adverse Reaction Surveillance, in Nanjing, supported by the Centers for Disease Control and Prevention (USA) with limited HRP input. This Centre was not in the terms of reference for this case-study, but the National Population and Family Planning Commission urged that it be included (Annex 5). Chinese colleagues have a deep appreciation for HRP as a standard setter, they value the guidance and technical support of HRP, and they value the fact that HRP keeps them informed of the latest relevant developments internationally. They are very grateful, for example, for HRP's *Sexually transmitted and other reproductive tract infections: a guide to essential practice* (WHO, 2005) and of the fact that it is being translated into Chinese.

In addition to these broad achievements, the process had several concrete educational and scientific outputs:

- more than a dozen local and national training and other workshops, including training researchers in the Strategic Approach, training in the method for Cochrane systematic reviews and training in surveillance of adverse reactions to contraceptives;
- at least 15 publications, in English and in Chinese, on the results of the systematic reviews and the Chongqing assessment; and
- new research questions and future directions for policy evaluation.

Outcomes

Copper ring and selected hormonal contraceptives removed from the procurement list

As stated above, in September 2004, the National Population and Family Planning Commission issued the list and catalogue of the contraceptives that it would buy and provide in 2005 for the national family planning programme without cost to clients. Each year, after consultation between its Science and Technology Department and its Contraceptive Supply Department, the Commission issues a catalogue listing the contraceptives it will purchase for local governments to provide in family planning clinics. Occasionally, one of the two departments may convene a group of experts to discuss and make recommendations. The Contraceptive Supply Department then makes a decision, writes an opinion and sends it to the leadership group in the [Communist] Party Committee of the Commission, which is its highest entity. The Party Committee, which meets often, makes the final decision.

The contraceptives deleted from the list for procurement for 2005 were the copper ring 165 and the medicated copper ring 165, once-a-month pills, visiting pill No. 53 (Anordrin) and combined daily pill No. 0 (35 μg ethinylestradiol, 0.5 mg megestrol and 0.3 mg noresthisterone). The decision was based on the following judgements, which were outcomes of the HRP-facilitated systematic reviews (Fang Ke-juan et al., 2004; Meirik O, Fajans P, Fang Kejuan, draft working paper, *Contraception in China: using evidence to influence policies and programmes*. HRP, 2007).

IUDs. "In general, IUDs with ≥ 300 mm^2 copper surfaces should be given priority over those with < 300 mm^2 surfaces. There is sufficient evidence to conclude that the copper ring (medicated) 165 has significantly poorer clinical performance than the other IUDs it was compared to. The National Population and Family Planning Commission should be phasing out provision of the copper ring (medicated) 165. It is suggested that a randomized comparative trial of uterine-shaped device with 300 mm^2 copper surface and TCu 380A should be conducted." Furthermore, "The copper ring 165 IUD has a copper surface area of 200 mm^2. It was introduced in the early 1990s and is a copper version of the stainless-steel ring. The copper ring 165 is inexpensive and among the most popular IUDs in China. The data show that the copper ring 165 consistently presents the highest pregnancy rate, highest expulsion rates, and lowest continuation rates compared to the modern copper-IUDs (Liu Shan-min et al., 2005). The high pregnancy rate is largely caused by unobserved expulsions of the device. In one comparative trial the rate of expulsion of the copper ring IUD was nearly five times that of the TCu 220C and the Gamma IUD. The reviewed data indicated that provision of the copper ring 165, rather than more effective IUDs, results in a substantial number of IUD reinsertions, unwanted pregnancies, and abortions entailing substantial costs to individuals and the public family planning programme" (Meirik O, Fajans P, Fang Kejuan, draft working paper, *Contraception in China: using evidence to influence policies and programmes*. HRP, 2007).

Once-a-month pills. "There is sufficient evidence to state that the estrogen dose in the once-a-month pills is far too high for it to be safe in longer term use. The rate of short-term side-effects of the once-a-month pills is high and the discontinuation rate is high. The National Population and Family Planning Commission should halt supply of once-a-month pills as soon as possible." The monthly estrogen dose of the once-a-month pill is 4.8 times higher than that of low-dose combined pills containing 30 μg ethinylestradiol. The latter gives a monthly dose of 0.63 mg ethinylestradiol. The monthly levonorgestrel dose of the Quin-LNG pill is 2.3 times that of the low-dose combined pills

containing 125 µg levonorgestrel (Fang Ke-Juan et al., 2007). Furthermore, "Once-a-month pills were developed in the late 1960s and are the most commonly used hormonal contraceptive in rural China. Available data suggest it is less effective than daily pills and combined injectable contraceptives. A substantial proportion of users complain of nausea, vomiting, and leucorrhoea [vaginal discharge], and the incidence of elevated blood pressure appears to be as high as 7%. Continuation rates are generally low. The high estrogen dose gives rise to concerns about safety of the pill, but there is little information on the long-term safety of this contraceptive." (Meirik O, Fajans P, Fang Kejuan, draft working paper, *Contraception in China: using evidence to influence policies and programmes*. HRP, 2007). (See also Annexes 3 and 6.)

Daily pills. "The monophasic daily pill with 30 µg EE [ethinylestradiol] and 150 µg levonorgestrel is the pill for which most evidence of safety has been assembled in international literature. There is also a good deal of evidence of safety for the 35 µg EE and 625 µg norethisterone pill (pill no.1). The National Population and Family Planning Commission may wish to give priority to provision of the monophasic levonorgestrel daily pill. The National Experts Group suggested that the National Population and Family Planning Commission should phase out provision of daily pill no.0 (35 µg EE, 0.5 mg megestrol and 0.3 mg noresthisterone)".

Visiting pills: "Some experts recommended limiting the number of visiting pills provided by the National Family Planning Programme with priority given to pill types containing levonorgestrel that contain a progestogen with reassuring information on safety. [The] majority of experts noted that there is sufficient evidence to state that the dose of levonorgestrel visiting pill is unnecessarily high. The dose corresponds to taking one full dose of levonorgestrel emergency pills (1.5 mg levonorgestrel) daily for 14 days or more. If there is a real need for this type of contraception, the National Population and Family Planning Commission must find a safe and effective alternative to the current visiting pill." HRP staff recommended eliminating all visiting pills and replacing them with emergency contraception followed by one month of a daily oral contraceptive pill; however, Chinese colleagues considered that a visiting pill was needed.

In order to observe the long-term safety of contraceptives, it was suggested that the post- marketing surveillance of contraceptive methods should be strengthened. This is now in progress, having been initiated with support from the Centers for Disease Prevention and Control (USA) with input from HRP (Annex 5) .

Adoption by the National Population and Family Planning Commission of nearly all the recommendations of the experts meeting in April 2004 was clearly a major policy achievement. Copper rings and the three pills had been on the 2003 procurement list, but were there no longer. Most important was removal of the copper ring. As IUDs are the method used by roughly 50% of all Chinese women, ending central procurement for the family planning programme of copper ring IUDs means that thousands or millions of women are spared pain, distress and even possibly death. Reducing the numbers of unintended pregnancies due to copper ring failure also means saved costs of abortions, care for complications of abortion when they occur and IUD reinsertion, the latter being borne by women.

Ending central procurement of the once-a-month pill, which was the most popular pill but the one with the most side-effects and a poor safety profile was also very important. Although a relatively small proportion of Chinese women use oral contraceptives, the proportion still translates into millions.

Both the Chongqing assessment and the systematic reviews strongly recommended reducing the plethora of contraceptives provided and keeping

only those known to be safe and effective. From 2003 through 2006, 15 contraceptives were removed from the commodities list and catalogue of the National Population and Family Planning Commission. Among these are six IUDs, one of which is the copper ring 165 (listed in English on the list as 'high strut strength IUD'). Others are listed in English as Multiload 375, Cu IUD by Organon (although it is domestically produced), fixed IUD, V-shaped IUD, IUD with plastic, and IUD with copper bead. As of December 2007, production of one or more of those six IUDs has reportedly stopped, although it was not clear which. The important recommendation of the Chongqing assessment that sterile inserters be supplied with all IUDs was accepted and is being promoted by the National Population and Family Planning Commission to improve the prevention of infection (Annex 3).

Impact and public goods

China and neighbouring countries have more than 40% of the world's population, and positive developments in China have a regional impact. National and regional public goods generated in China inevitably become global as well. The public goods at these three levels are listed in Box 2.

To what extent can these public goods be attributed to HRP's work?

These public goods can definitely be attributed to HRP's technical assistance, including the partnerships and inputs of others (researchers, experts, National Population and Family Planning Commission and other stakeholders) whom HRP brought together to conduct the research and formulate recommendations. Would this have been achieved without HRP? The answer is, "Probably not until years later". It was HRP that developed the innovative Strategic Approach and application of the Cochrane systematic review method. HRP helped to identify the issues, effectively liaising with Chinese policy-makers in family planning and sexual and reproductive health and linking them with HRP in Geneva, introducing effective new methods and providing technical guidance to local researchers. All persons interviewed in China, and many others, say that no other organization could have achieved what HRP did. It was HRP's long relationship of trust with Chinese researchers and officials, plus its pre-eminence in research, that positioned HRP uniquely to achieve these important policy and programme changes.

Contributions of other stakeholders

The National Population and Family Planning Commission and the Shanghai Institute for Planned Parenthood Research were clearly the primary partners in the successes facilitated by HRP. Other contributors were the policy-makers who participated in the Chongqing strategic assessment, the national experts who contributed to the systematic reviews and the Chinese institutions in which they work (Annex 4). Other stakeholders in the broader effort to conceptualize, promote and implement quality of care were major international partners, notably UNFPA, the Ford Foundation, the Rockefeller Foundation and the Population Council. While HRP played an instrumental role in promoting the safety and effectiveness of contraceptives, the others were partners in the broader quality-of-care movement. They contributed to HRP-led translation of research into policy, informally or by participating in workshops and experts' meetings but did not provide direct funding for the strategic assessment or the systematic reviews. Over the years, UNFPA was a major source of programme funds for HRP. It is difficult to estimate the financial value of the contributions, in time and in kind, of all these stakeholders. Stakeholders in these organizations give high marks to HRP for the body of work described here and the policy and programme changes it produced.

Box 2. Public goods at national, regional and global levels

National public goods

By improving the overall quality of IUDs, the National Population and Family Planning Commission through the national family planning programme provides an estimated 20 million IUD insertions to Chinese women per year. As a result, China is having or expected to have:

Fewer unplanned pregnancies due to IUD failure and expulsion, leading to fewer abortions. This implies:

- reduced morbidity and mortality (as well as pain and suffering) resulting from abortion of unplanned pregnancies;
- reduced costs to women resulting from fees for IUD reinsertion and from abortion and its consequences, including opportunity costs for time lost and post-abortion care;
- reduced costs to the national programme resulting from unplanned pregnancies, abortion and IUD expulsions resulting in the need for reinsertion of IUDs; and
- decreased public dissatisfaction resulting from contraceptive failure and termination of pregnancies.

The National Population and Family Planning Commission has instituted important changes in the procurement of hormonal contraceptives.

The Commission has initiated a surveillance system for monitoring adverse reactions to contraceptives.

Regional public goods

Removing the once-a-month pill (and visiting pill) from public sector procurement by the National Population and Family Planning Commission may reduce or stop the availability of the method in pharmacies in neighbouring countries, especially if production is discontinued. Negative consequences (side-effects, morbidity, unintended births and abortions) are or will be reduced in those countries.

Introduction of the high-estrogen content once-a-month pill to India (and perhaps Thailand) was considered but rejected on the basis of the findings of the systematic reviews.

Global public goods

HRP, by helping to address public health concerns about IUDs and hormonal contraceptives, is also helping China's family planning programme to become a more positive example for other programmes. As other countries respond to the need for effective long-acting contraceptive methods, the shift in China towards more effective IUDs appears to have been cost–effective and was achieved with a concurrent decline in the number of abortions. HRP has also supported scientific assessment of selected hormonal contraceptives (once-a-month pills and 'visiting pills' for couples who are together infrequently), which, after systematic evaluation, were judged potentially unsafe or ineffective. Disseminating these findings helps other countries to avoid such problems. Published in *Contraception,* the research findings concerning the safety risks of the once-a-month pill might be averting its use in other countries.

Cost-effectiveness

HRP financial input

HRP financial inputs for this body of work have been modest (Table 2). Total expenditure for the strategic assessment and the systematic reviews was approximately US$ 300 000 over the five-year period, 2000–2004. (For more details, see Annex 7.) The cost to HRP of the 1991 'IUD conversion study' was about US$ 23 000. This assumes that the one month of senior consultant time and two separate visits to China would be costed as in 2005. These direct expenditures were then scaled up by 36% and converted to 1991 costs by consumer price index figures for the USA.

HRP's investment has been cost–effective as judged by the standard of other activities designed to influence policy in sexual and reproductive health programmes. There is no clear evidence that resources could have been used more effectively, given existing constraints in China (see below). Cost–benefit calculation is not possible, given the lack of data on how use of specific contraceptives has been reduced by their removal in 2005 from the National Population and Family Planning Commission procurement list; however, the expenditure for the effort would seem to be in line with similar efforts around the world.

For example, the Health Policy Initiative of the United States Agency for International Development and its predecessor the POLICY Project worked for more than 10 years to improve policy for expanded access to and use of sexual and reproductive health services. The measure of success in the Project was often changes to strategic documents, including procurement lists. Over a six-year period, the POLICY II Project worked in 33 countries and on seven regional efforts (POLICY II, 2006). During that time, it expended approximately US$ 160 million, which works out on average to US$ 666 667 per country–year of effort (US$ 160 million divided by 40 programmes divided by six years). This is a rough measure as not all country programmes were operating in every year of the Project. The approximately US$ 300 000 invested by HRP over a five-year period compares very well. The POLICY II Project also carefully tracked its results. In all, it documented 857 results (POLICY II, 2006). By this metric, the Project generated one result for each US$ 186 697 expended (US$ 160 million divided by 857). HRP's expenditure on the effort required to achieve its results in China are within the bounds of expectation for policy change activities.

Table 2. HRP expenditures for assessment and reviews

Costs	US$
Direct costs	
Chongqing strategic assessment	86 534
Systematic reviews	103 580
Total	190 114
HRP staff costs	106 954
Total	**297 095**

Benefits due to use of improved IUDs

Abortions averted

It is too soon to see decreases in abortion rates as a result of the 2005 shift in the national family planning programme to use of more effective IUDs. Nevertheless, data show that the number of abortions performed in China has declined dramatically since 1991–1992 when the 'IUD conversion study' set in motion the shift from steel rings to copper-Ts. While other factors are also important, the data strongly suggest that a major determinant of this decline has been increased use of more effective IUDs, the contraceptive method used by about half of Chinese couples. Other important factors include changing Government policies and improved quality of care in service delivery.

Globally accepted estimates are that, in China, the abortion rate and the number of abortions decreased by about 20% between 1996 and 2003 (Sedgh et al., 2007). Chinese health statistics show a drop of about 50% between the 1991–1992 peak and 2001 (*China Health Yearbook 1984, 1999 and 1999–2002, cited in* Greenhalgh, Winckler, 2005). Over the past 15 years, overall use of contraception in China has remained steady, at about 83% (Ross et al., 2005); however, there have been significant changes in the methods used, most notably a large increase in IUD use (along with a small increase in condom use). Most of the increases in IUD use result from a shift from sterilization, as family planning policy introduced informed choice of methods (see Table 1). As stated above, women with unplanned pregnancies are very likely to have abortions; about 70% of abortions in China have been attributed to contraceptive failure (Wang Duolao, Altmann, 2002). While accidental pregnancies due to IUD failure have not always resulted in abortions in China, over the years most have (Kaufman, 1993).

The preceding paragraphs imply a paradox. In general, sterilization is an effective method of contraception. Therefore, with constant overall use of contraception, a shift from sterilization to IUDs would theoretically imply more contraception failure and more abortions. Abortion rates have, however, decreased. A partial explanation for the decreased abortion rates is almost certainly increased use of more effective IUDs during the same period.

The pregnancy rates in clinical studies in the 1991 'IUD conversion study' were about 5.8% for steel rings and about 1% for copper-T IUDs (UNFPA, 1992). Under field conditions, the researchers estimated, the rates of pregnancy would be doubled. The study used these disparities in pregnancy rates as the basis for predicting large decreases in the number of pregnancies if steel rings were replaced by copper-Ts. As described above, large numbers of relatively ineffective copper rings have been inserted rather than the copper-Ts.

Now that steel-ring production has stopped and the National Population and Family Planning Commission no longer buys copper rings, shifting China's IUD use from less effective ring IUDs to copper-Ts and other more effective copper-bearing IUDs (including the uterine-shaped IUD and the yuangong IUD) reduces the number of unintended pregnancies. Here we estimate the proportion of the reduction in abortions due to the use of more effective IUDs. Given the lack of detailed service statistics, it is impossible to determine the degree to which conversion from ring IUDs to copper-Ts (and other more effective copper-bearing IUDs) has occurred. Many varieties of IUDs are used, many IUDs are provided outside the family planning programme, and no centralized information is available on the numbers of the different types of IUDs that are currently being inserted.

Nevertheless, the trends indicate a slow transition from the less effective steel and copper rings to the more effective copper-bearing IUDs. The following is a conservative estimate of the degree of conversion:

- In 1992, 90% of IUDs were steel rings (UNFPA, 1992).
- In 2005, 50% of IUDs were effective copper-bearing IUDs, and 50% were steel or copper rings.

To estimate the impact of improved IUD use, we conservatively assumed that the pregnancy rates with ring IUDs and copper-T IUDs are 5.8% and 1.0%, respectively. The 1991 study used preg-

nancy rates of 10.6% for steel rings and 2.0% for TCu 220C. If these numbers are used, the impact of improved IUD use would double. The second column of Table 3 shows an interpolation of the abortion rate from 1992 to 2005. Sedgh et al. (2007) presented data for 1996 and 2003, and the rates for the other years are linear interpolations, back-casting or forward-casting on the basis of those two rates. The third column presents the number of abortions that would occur if the estimated abortion rate for 1992 (i.e. 32.4 abortions per 1000 women) persisted until 2005. The number of abortions would have continued to increase because the number of women aged 15–44 years continues to increase in China. The fourth column is an estimate of the actual abortions that occurred, based on the abortion rates in the second column. The fifth column is the difference between the third and fourth columns. It represents the number of abortions averted as a result of the decreased abortion rate. The sixth column represents the assumption about the conversion from steel rings to copper-T IUDs, a reduction from 90% to 50%. The seventh column is the implied number of abortions averted by the improved quality of the IUDs, which was calculated as the difference in pregnancy rates for the two types of IUDs (ring IUDs and more effective copper-bearing IUDs), multiplied by the percentage of IUD users who obtain an abortion following an unintended pregnancy (about 60%; UNFPA, 1992), multiplied by the percentage of married women aged 15–44 years using IUDs, multiplied by the percentage of IUD users using the more effective copper-bearing IUDs. Finally, the last column is the percentage of averted abortions accounted for by conversion to a better IUD. On the basis of these assumptions and calculations, one third of the decrease in the number of abortions can be attributed to the phasing-out of steel and copper ring IUDs.

Health costs to women

Another significant cost of IUD failure is the health cost to Chinese women. Over the years, most IUD expulsions without pregnancy have resulted in reinsertion of another IUD or in an abortion in the case of pregnancy. In rural China, where many women suffer from anaemia, reinsertions and abortions in rural family planning stations pose various risks, including reproductive tract infections (Kaufman, 1993; Zhou Jian et al., 2007) along with mental health burdens. These represent major costs to the women undergoing these procedures and to the health system, costs that are reduced by use of more effective contraception.

Table 3. Estimates of annual percentages of abortions averted (in thousands) due to use of improved IUDs in China

Year	Abortion rate (abortions/1000 women)	No. of abortions that would have occurred if the 1992 abortion rate had persisted	No. of abortions that actually occurred	No. of averted abortions due to all causes	% IUDs that were reliable copper-bearing (TCu & others)	No. of abortions averted annually due to phasing out steel and copper ring IUDs	% abortions averted annually due to phasing out of steel and copper ring IUDs
1992	32.4	9575	9575	0	10.0%	0	
1993	31.6	9675	9419	256	13.1%	67	26.3%
1994	30.7	9758	9243	516	16.2%	138	26.8%
1995	29.9	9823	9044	779	19.2%	213	27.3%
1996	29.0*	9887	8842	1045	22.3%	291	27.9%
1997	28.1	9922	8610	1311	25.4%	372	28.4%
1998	27.3	9943	8366	1577	28.5%	456	28.9%
1999	26.4	9974	8128	1845	31.5%	542	29.4%
2000	25.6	10022	7903	2119	34.6%	633	29.9%
2001	24.7	10092	7691	2401	37.7%	730	30.4%
2002	23.9	10181	7490	2691	40.8%	832	30.9%
2003	23.0*	10276	7288	2988	43.8%	957	32.0%
2004	22.1	10358	7073	3285	46.9%	1089	33.1%
2005	21.3	10417	6838	3579	50.0%	1227	34.3%
2006	20.4	10450	6583	3867	53.1%	1325	34.3%
2007	19.6	10456	6310	4146	56.2%	1421	34.3%

* From Sedgh et al. (2007). Rates for other years interpolated from these two (1996 and 2003).

Future

Conclusions

1. Removal of four less effective and potentially unsafe contraceptives from availability for procurement for the national family planning programme was a major policy achievement, attributable in large part to research collaboration with HRP and leading to a significant reduction in unintended pregnancies, abortions, pain and suffering.
2. While UNFPA and other partners provided important support for China's movement for quality of care in family planning and sexual and reproductive health, it is unlikely that the translation of research into policy and decision in 2004 would have occurred when it did without HRP's input. The National Population and Family Planning Commission and Chinese researchers say that, without HRP, the process would have been much slower and less rigorous. The impact of HRP's investment would have been greater if the Ministry of Health had been involved; however, it is unlikely that HRP could have affected its decision. The impact might also have been greater with more active engagement of UNFPA, given its commitment to safe and effective contraception.
3. HRP's introduction of evidence-based research methods may lead to outcomes and impacts even greater than removal of the four contraceptives. Some Chinese leaders in family planning and sexual and reproductive health emphasize that HRP contributions have transformed attitudes and approaches to research, policy and decision-making in much broader ways.
4. This case-study illustrates HRP's success in helping build an essential health research infrastructure. It demonstrates ways in which investment over the years in essential health research and infrastructure has come to fruition and can yield further benefits.
5. There is still much that can be done to increase the health impact of HRP's contributions. Progress is being made in reducing insertion of ring IUDs and provision of high-hormone content pills. It will take time and effort, however, to complete the process, given the size of China, programme structures and manufacturing interests:
   - First, unlike the 1993 Government order to discontinue manufacture of the steel ring, the decision to remove the copper ring and the three pills from the National Population and Family Planning Commission procurement list in 2004 was only a notice that the central Government would no longer buy and provide these items for local governments and family planning clinics. As the Commission is not a drug regulatory authority, the contraceptive pills and IUDs not on its list can still be manufactured and supplied to the health-care sector.
   - Second, many family planning clinics still have considerable supplies of copper rings, once-a-month pills, Anordrin visiting pills and some steel rings, and are likely to be hesitant to destroy their stocks (Meirik O, Fajans P, Fang Kejuan, draft working paper, *Contraception in China: using evidence to influence policies and programmes*. HRP, 2007; confirmed in interviews, December 2007).
   - Third, the family planning clinics under the National Population and Family Planning Commission also receive funding from local governments to buy contraceptives and can make purchases independent of the Commission. It is estimated that about 40% of contraceptives are purchased locally in this way. As the once-a-month pill is the least expensive pill (and is preferred for convenience over daily pills), it is likely that local purchase will continue. As copper rings are

the cheapest IUDs, are easy to insert, are familiar to clinic staff and are a long-standing norm among women, it is likely that the copper ring is being purchased for some clinics. The prices of the various types of IUDs are shown in Table 4.

Table 4. Approximate cost of various IUDs in China

IUD	Cost (approximate)
TCu-380a	≥ 8 yuan (US$ 1.10)
TCu-220	4 yuan (US$ 0.55)
Uterine-shaped IUD	≥ 3 yuan (US$ 0.45)
Yuangong IUD	≥ 3 yuan (US$ 0.45)
Copper ring 165	≥ 1 yuan (US$ 0.15)
Old inert steel ring	0.6 yuan (US$ 0.08)

In an effort to discontinue insertion of the ring IUDs, the National Population and Family Planning Commission has provided pictorial instructions to clinic staff not to insert ring IUDs along with wall charts showing the approved, centrally provided methods: TCu 220C, TCu-380A and other effective copper-bearing IUDs (see photo in *Introduction*). Knowledgeable persons consider that this is having an effect, but slowly. Data are not available to document this transition (Annex 2). It has been stated inaccurately that the TCu-380A is being phased out or has been eliminated from China's national family planning programme; however, it remains on the latest Commission procurement list. While the TCu-380A is not as popular as other IUDs, the principal reason for its relatively low usage is believed to be its cost, as it is the most expensive of all IUDs used in China.

- Fourth, China has two separate systems providing contraceptive services. Initially, the Ministry of Health was the sole provider. In 1981, the State Family Planning Commission (now the National Population and Family Planning Commission) was established as a ministry-level Government agency to oversee the national family planning programme. The 'family planning system' under the Commission and the 'health system' under the Ministry of Health operate independently, the Commission leading the national family planning programme. Therefore, services provided through the health system under the Ministry of Health are not officially part of the national family planning programme. The Commission and the Ministry each purchase contraceptives separately from China's factories, and each provides them separately to the clinics in its own system. The two systems have separate service statistics, and no single office compiles and provides overall data on family planning and sexual and reproductive health for China. For this reason, it is difficult to obtain firm data on overall contraceptive use (e.g. prevalence and methods used). Because the clinics and hospitals under the Ministry of Health are independent of the Commission, they can purchase and provide contraceptives that the market offers. It has been reported that Ministry clinics and hospitals are increasingly using copper-Ts, and some are discouraging use of the copper rings, although these facilities may continue to provide them. It is also reported that once-a-month pills and visiting pills are used less in Ministry of Health clinics than five years ago (personal communication, Katherine Ba-Thike, email 2 February 2008). The newly-issued national family planning standards for China include the once-a-month pill as well as the visiting pill (No. 53), but each with a caution that the dosage is very high and that significant negative side-effects are to be expected. The standards were set by a group of eminent Chinese family planning and sexual and reproductive health researchers and experts, who took as

references HRP's *Medical eligibility criteria for contraceptive use* (WHO, 2004a) and its *Selected practice recommendations for contraceptive use* (WHO, 2004b) (personal communication, Katherine Ba-Thike, email 2 February 2008). These experts, who work with both the Commission and the Ministry, serve as a bridge between the two entities (Wu Shangchun, interview, 6 December 2007). HRP collaborates intensively with both the Ministry and the Commission, facilitating knowledge transfer between the two.

- The remaining challenges are to complete the phasing-out of the four contraceptives removed from the Commission's procurement list, to end their use in other countries and to discontinue their manufacture. It is probable that production of copper rings will slow and that insertion of both steel and copper rings will end. How long this will take cannot be predicted, given the many factors influencing purchase and use.

Major recommendations

1. *The copper ring and hormonal contraceptives.* WHO, and not HRP alone, should use its prestige in China and its relations with the Ministry of Health to help the Ministry adopt measures to ensure that only contraceptives of established safety and efficacy are used in its clinics and hospitals. This includes supporting the full phasing-out of the four contraceptives and discontinuation of their manufacture and movement to other countries.
2. *Greater engagement of UNFPA.* Given UNFPA's commitment to provide contraceptives of assured quality, HRP and WHO should use the WHO–UNFPA Strategic Partnership Programme and other links with UNFPA (such as the upcoming fourth WHO/UNFPA high-level consultation scheduled for June 2008) to support progress towards these goals, in China and in countries to which Chinese contraceptives may be exported, whether through formal or informal channels (Annex 6).
3. *HRP's agenda.* Future engagements of HRP should be strategic to ensure that its investment has the greatest impact on health. The National Population and Family Planning Commission and researchers state that their greatest need from HRP is technical support to ensure that their research and their programmes are up to date.

- HRP should support follow-up of the research agendas that emerged from the Chongqing strategic assessment and the systematic reviews (e.g. the unlikely benefit of a quarterly IUD check, finding a contraceptive to fill the niche of the once-a-month pill); HRP should publish the Chongqing assessment, already prepared, on its website (WHO, 2002c). HRP should help in the conceptualization of research agendas and provide modest technical assistance.
- HRP should continue working with both the National Population and Family Planning Commission and the Ministry of Health to facilitate the engagement of both in research, policy and knowledge transfer. As part of HRP being more strategic in its investments in China, it will be important for the different HRP teams engaging in China to resume and strengthen their own knowledge-sharing processes. HRP should consider supporting use of the Strategic Approach to help Chinese colleagues assess and improve the quality of care in abortion services. This could link with work to draw up guidelines for post-abortion care reportedly commissioned by the Ministry of Health.

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Annex 1. The case-study in the context of HRP's broader contribution

Since 1979, HRP has provided technical and financial assistance to establish and strengthen a network of research institutions that can address China's needs in the field of contraception and sexual and reproductive health. HRP has supported a broad array of research, training and capacity-building activities in China, with the aim of enabling Chinese institutions to conduct research on sexual and reproductive health to the highest possible scientific and ethical standards. For the first 10 years, until about 1990, HRP was alone in capacity development in China's research programme in family planning and sexual and reproductive health, including training fellowships abroad. Collaboration with the Western nongovernmental organizations that now work in China was negligible or nonexistent.

When China began to open to Western countries, in 1978, WHO was the first United Nations agency to establish an office in China, and HRP was the first WHO programme to send a mission to China, in early 1979. Soon thereafter, a group of Chinese scientists visited Geneva, and an HRP team went to Shanghai and Beijing in October 1979 and established collaboration with the Shanghai Institute of Planned Parenthood Research. "SIPPR was just a name and there were a handful of scientists occupying rooms in various old houses in what had been the foreign sections of town." A UNFPA mission also went to Beijing in October 1979, and in 1980 UNFPA launched its first country programme. HRP was the executing body for the UNFPA project that supported capacity development in Beijing. *(Information provided by Frank Webb, a former staff member of HRP who helped to establish HRP's presence in China.)*

HRP's collaboration with China began in 1979, with major support to the Shanghai Institute of Planned Parenthood Research and the National Research Institute for Family Planning, Beijing. The National Research Institute, and later institutes in Chengdu and Tianjin, were supported by UNFPA projects that were managed by HRP and renewed throughout the 1980s. HRP support continued at the same pace in Shanghai while adding institutes in Hangzhou and, later, Peking University, Peking Union Medical College Hospital and the National Toxicology Centre in Shanghai.

Support to the national network evolved as the institutes established their facilities and recruited and trained research staff. They gradually broadened their research agendas from an initial emphasis on contraceptive research and development to include a variety of social science research programmes that addressed the needs of the national population and family planning programme and sexual and reproductive health care. As the centres became established, both nationally and internationally, HRP provided support for research management at national and institutional levels to help national and institute directors maximize the effectiveness of their resources. Shanghai in particular received advice on resource development and diversification of its funding base.

Out of these efforts has grown a network of 16 research institutes throughout China that are engaged in a wide range of research and training activities, covering all aspects of sexual and reproductive health. These institutes are generally judged to have excellent research facilities, with competent scientists who are able to determine their research priorities, design appropriate research projects and conduct them to high standards of professionalism. In addition to research relevant to the sexual and reproductive health needs of China, the institutes participate increas-

ingly in WHO's global research efforts, including HRP's multinational trials, and provide technical support to other countries, especially in the Asia–Pacific region. The institutes that collaborate most closely with HRP are now self-sufficient. Of the primary institutions, seven are officially designated WHO collaborating centres.

Both the Chinese Government and HRP have made strong, persistent commitments to support and promote mutual cooperation. Likewise, HRP and UNFPA have collaborated over the years in a complementary way. Between 1979 and 2003, total funding was approximately US$ 30 million, with US$ 17 million from HRP's funds and about US$ 13 million from UNFPA (provided until 1996 to support four of the research institutions through country projects funded by UNFPA and executed by HRP). The Chinese Government has invested at least twice the combined WHO and UNFPA input, covering all the costs of capital construction, staff salaries and other running costs.

Overall, the return on the HRP and UNFPA investment has been good, because of a combination of factors unique to China: the high priority given by the Government to population matters and sexual and reproductive health, especially family planning; the Government's recognition of the value of research in support of public health policy, programmes and interventions; generous financial support from national and provincial authorities for infrastructure and running costs; and the centuries-old tradition of science in China. The centres remain the backbone of China's research in population and family planning (undated WHO Memorandum, Frank Webb).

The developments associated with the nearly three decades of HRP presence are widely regarded as an outstanding example of successful collaboration between a developing country and a United Nations specialized agency.

Research projects funded by HRP

The research described in this case-study is part of a much wider collaboration. The research under way in 2007 is listed below (from Katherine Ba-Thike, HRP Asia Desk Manager).

- *Post-ovulatory methods of fertility regulation*: National Research Institute for Family Planning, Beijing; International Peace Maternity and Child Health Hospital, Shanghai; and Department of Obstetrics and Gynaecology, Queen Mary Hospital, Hong Kong.
- *Phase III trial of testosterone undecanoate* as a male contraceptive was completed in 2007: family planning research institutes of Henan, Yunnan, Sichuan, Hebei, Jiangsu; National Research Institute for Family Planning, Beijing; Institute of Family Planning, Tongji Medical University, Hubei; Zhejiang Institute of Planned Parenthood Research, Zhejiang; and Birth Control Institution, Guizhou.
- *Phases II and III of the Strategic Approach* continued in Yunnan, increasing access and quality of care for a range of sexual and reproductive health services for the poorest people of the Province. The counterpart institution is the Reproductive Health Research Institute of Kunming Medical University.
- *Follow-up of Strategic Approach for reproductive tract and sexually transmitted infections* (programme guidance tool) in Shenzen and Yunnan in activities implemented by the Ministry of Health, the National Population and Family Planning Commission and other WHO collaborating centres, with support from the WHO–UNFPA Strategic Partnership Programme (described below).
- *Study on household economic costs of maternal mortality in rural China* was finalized. The partner and implementing agency: Mother and Child

Health Department, School of Public Health, University of Peking, Beijing.

- Results became available on *parent–child communication on sexual and reproductive matters* and the *impact of community-based interventions for sexual and reproductive health*.
- Projects initiated during the year included: *reproductive health risks among unmarried Tibetan and Yi youth* and *parents' perspective on provision of sexual and reproductive health services for unmarried youth*.
- A study funded at the end of 2007 will assess the sexual and reproductive health needs of workers in the entertainment sector in Sichuan Province.
- A scientific writing workshop for biomedical researchers was conducted in Nanjing (27 participants).
- The one-week version of the WHO training curriculum on 'Gender and rights in reproductive health', focusing specifically on maternal health, was conducted by the Chinese Ministry of Health.
- In 2006, the secretariat was invited to lead an *external evaluation of a one-year rural health project* conducted in 97 poor rural counties in China, supported by the World Bank and the United Kingdom Department for International Development. The evaluation was concluded in June 2007. The findings are available in both English and Chinese.
- Support for research on *identification of the function of MNSF-beta at implantation* was provided to a mid-level researcher from Shanghai Institute of Planned Parenthood Research, Shanghai, who had returned from an MSc training course in Australia.
- The report of the study on *prevalence of lower genital tract infection in rural women in Sichuan Province* was finalized.

Intensified focus for the WHO–UNFPA Strategic Partnership Programme

China is one of the countries participating in this joint WHO-UNFPA programme. The team is composed of representatives from the Ministry of Health (Department of Mother and Child Health), the National Population and Family Planning Commission, the Women and Children Health Centre of Peking University, Beijing, and programme officers from the WHO and UNFPA country offices.

Translation of the *Medical eligibility criteria for contraceptive use wheel* and *Family planning: a global handbook for providers* was undertaken by a team from the National Research Institute for Family Planning, Beijing, a WHO collaborating centre. The Commission disseminated the wheel and the *Decision-making tool for family planning clients and providers* in limited numbers in all counties.

Family planning training for Ministry of Health service providers is essential, as both married and unmarried clients seek services at Ministry clinics, whereas the Commission's clinics cater only for married women. This has been recognized as an issue for post-abortion care that is not adequately addressed. A handbook on family planning for county-level providers was being written for the Ministry of Health by the same team of experts who translated the family planning guidelines for the Commission.

A revised version of the handbook for providers on reproductive tract and sexually transmitted infections was prepared, printed and distributed. A new pamphlet on sexually transmitted infections in men

was prepared, in addition to four other pamphlets. Training materials for courses on reproductive tract and sexually transmitted infections were designed, and meetings to introduce the guidelines were followed by provincial and county-level training, with upgrading of laboratories to conduct diagnostic tests for these infections. Implementation is under way in the six counties involved in the first year of support from the WHO–UNFPA Strategic Partnership Programme and in five new counties.

Following translation of *The WHO Reproductive Health Library* and a national training-of-trainers workshop in Shanghai, provincial training workshops were conducted in Chengdu, Hangzhou, Shanghai and Tianjin.

HRP-supported research centres in China

Eight centres share one resource maintenance grant:

- Institute of Population Research, Peking University, Beijing
- Department of Obstetrics and Gynaecology, Peking Union Medical College Hospital, Beijing
- National Research Institute of Family Planning, Beijing
- Sichuan Family Planning Research Institute, Chengdu
- Family Planning Research Institute of Zhejiang, Hangzhou
- Shanghai Institute of Planned Parenthood Research, Shanghai
- Tianjin Municipal Research Institute for Family Planning, Tianjin
- National Evaluation Centre for the Toxicology of Fertility Regulation Drugs, Shanghai

The first seven are officially designated WHO collaborating centres. The work of the eight centres is shown in Table 1 below.

Table 1. HRP-supported research centres in China and their research focus

Centre	Research and new features
Institute of Population Research, Peking University, Beijing	*Research*: Key issues related to the economy in transition of China, health and the environment
Department of Obstetrics and Gynaecology, Peking Union Medical College Hospital, Beijing	The WHO collaborating centre status of the Reproductive Endocrinology and Infertility Division was extended to the Department of Obstetrics and Gynaecology, which coordinates the national programme on prenatal screening for fetal chromosomal abnormalities and neural tube defects *Research*: Basic and clinical research on long-term, small-dose hormone replacement therapy for postmenopausal women
National Research Institute of Family Planning, Beijing	*Research*: Of 20 projects, 10 are HRP multicentre trials on: male hormonal contraception, emergency contraception and post-ovulatory fertility regulation, IUDs and incidence and risk factors for pelvic inflammatory disease after induced abortion A new centre – the Social Medical Centre – conducts research on quality of care in family planning programmes in midwest China and cross-border studies with neighbouring countries on sexual and reproductive health issues and HIV/AIDS
Tianjin Municipal Research Institute for Family Planning, Tianjin	*Research*: Emergency contraception, vaginal microbicides, prevalence of reproductive tract and sexually transmitted infections and cervical cancer screening; a study on sexual and reproductive health of middle-school students *HRP-supported research*: long-term follow-up of IUDs
Sichuan Family Planning Research Institute, Chengdu	*Research*: Of 16 projects, seven are supported by HRP on: long-term follow-up of IUDs; long-acting male hormonal contraception; contraceptive effectiveness of female and male condoms; prevalence of lower genital tract infection in rural women in Sichuan Province; and effects of long-term androgen administration on the prostate
Family Planning Research Institute of Zhejiang, Hangzhou	*Research*: Reproductive biology, transdermal drug delivery systems for postmenopausal hormone replacement therapy, and family planning and reproductive tract infection service delivery
Shanghai Institute of Planned Parenthood Research, Shanghai	*Research*: 71 projects, 16 initiated in 2004; basic and clinical research on contraception, quality of sexual and reproductive health services, HIV prevention and sexual and reproductive health advocacy, and community-based sexual and reproductive health services for unmarried young people The Department of Epidemiology and Social Science Research set up a new branch of molecular epidemiology
National Evaluation Centre for the Toxicology of Fertility Regulation Drugs, Shanghai	*Research*: 14 ongoing projects: establishment of toxicology assessment techniques and assessment of the reproductive and genetic toxicology of fertility regulation drugs

Annex 2. The data dilemma

In China, it is difficult to calculate changes in IUD use over time or the benefits resulting from HRP's investment in improving contraceptive safety and effectiveness, as firm data on overall contraceptive use (e.g. prevalence and methods used) are not available. First, as noted in the text, contraceptive services are provided through two separate systems: the family planning system under the National Population and Family Planning Commission and the health care system under the Ministry of Health. Both are in the public sector, but they do not share service statistics. No single office or function compiles overall family planning and sexual and reproductive health data.

At the lowest level of service delivery, the family planning worker (under the Commission) may also be a health worker (under the Ministry), reporting various data upwards to both systems, but this varies. China has over 1 million family planning workers, and their reporting of family planning service statistics is not standardized; until recently at least, each county in China had its own reporting form. In general, the forms specify name, occupation, marital status, first marriage date, total pregnancies, total live births, total living children, contraception status, type of contraception used, time of start and discontinuation and, in some cases, reason for discontinuation (Xiao Shaobo. *Minutes of workshop on surveillance of adverse reactions to contraceptives in China*, Atlanta, Georgia, Centers for Disease Control and Prevention, 2001).

For the two commonest methods, IUDs and sterilization, Commission sources estimate that the family planning system and the health system (Ministry) each provides about 50% of all services nationwide (Table 1). The Commission provides the bulk of IUD services in the rural areas where most Chinese live, while Ministry of Health hospitals and clinics provide most of the IUD and sterilization services in the cities and many of the sterilizations in rural areas as well.

Second, no data on the numbers of each type of IUD purchased or inserted each year in the Commission's national family planning programme are publicly available**.** The Commission's Contraceptive Supply Department receives and fills orders sent from the provinces on the basis of the current procurement list. The Department holds order data as well as data on how many IUDs of each type it has purchased from each manufacturer in a given year, but this is procurement-sensitive information which is not shared with other departments of the Commission. Family planning clinics do report service statistics to the Commission in Beijing, including the numbers of IUDs inserted and removed in a given year. The Commission aggregates these data, but the numbers of each specific type of IUD are not routinely aggregated and not systematically reported. Some service statistics forms may include a section for staff to check the type of IUD, but it is not clear how widespread this practice is.

This case-study nevertheless identified an exception: data provided by the Commission's Con-

Table 1. Provision of IUD and sterilization services by the family planning system and by the Ministry of Health system

	Family planning system	Ministry of Health system
Nationwide	50%	50%
Rural areas (~70% of population)	70–80%	20–30%
Urban areas (~30% of population)	10%	90%

traceptive Supply Department to the Shanghai Institute of Planned Parenthood Research for the systematic reviews. These data showed that, in 2001, before the systematic reviews, copper-Ts were clearly on the way to replacing copper rings in the national family planning programme (see Table 2). The data showed that 10–11 million IUDs were being purchased annually for the programme by the Commission during the three-year period 1999–2001. During these three years, the total number of TCu 220C and TCu-380A IUDs supplied centrally to the national family planning programme was 11.50 million, significantly more than the 7.07 million copper rings supplied during the same period. The largest quantity of IUDs supplied by the Commission, however, were uterine-shaped copper IUDs made in China (13.22 million). When the HRP-supported systematic reviews of the copper ring 165 and other IUDs began in 2002, the Commission was supplying almost 2 million copper rings per year to the national programme, slightly more than 22% of all the IUDs it supplied. In actual usage, however, the proportion of copper rings being inserted was much greater than 22%, given that many local officials preferred to purchase the cheaper, more familiar copper ring.

Third, the centrally provided contraceptives are only a portion of what family planning clinics provide, but no data are available on the quantities of contraceptives purchased by local government or provincial family planning offices. The family planning clinics and their local governments must buy the remainder of the contraceptives they supply, perhaps between 40% and 60%, from commercial manufacturers. Especially in rural and poor areas, they tend to buy the cheaper products, e.g. the copper ring and once-a-month pills, even though these are no longer on the central procurement list.

A fourth difficulty in seeking to determine the numbers of contraceptives used is the rapidly expanding volume of sales of contraceptives and services through the private commercial sector (clinics and pharmacies). Increasingly, many people, especially those who are young and unmarried, go to private-sector pharmacies to buy contraceptive pills as well as condoms, which have become increasingly popular with heightened awareness of AIDS and sexually transmitted infections and as unmarried persons have become more sexually active. Migrants are also major consumers of private-sector contraceptive services. Data are not available on the volume of these sales.

Table 2. IUDs supplied to the national family planning programme by the National Population and Family Planning Commission contraceptive supplies centre during 1999–2001 (millions)

Type of IUD	1999	2000	2001	Total	Total	%
Uterine-shaped copper IUD, non-medicated	3.80	4.05	3.72	11.57	13.22	42%
Uterine-shaped copper IUD, medicated	0.50	0.36	0.79	1.65		
TCu 220C	2.61	3.08	3.83	9.52	9.52	30%
Copper ring 165, non-medicated	2.02	1.18	1.63	4.83	7.07	22%
Copper ring 165 (MCR165), medicated	1.52	0.48	0.24	2.24		
TCu 380A	0.59	0.56	0.83	1.98	1.98	6%
Total	11.04	9.71	11.04	31.79	31.79	100%

Source: Liu Shan-min et al. (2005) Systematic review of medicated copper ring 165. *Chinese Journal of Family Planning,* 13:158–161.

Annex 3. Most relevant findings of the Chongqing strategic assessment

The Strategic Approach

A Strategic Approach to strengthening sexual and reproductive health policies and programmes was conceptualized by HRP's Task Force for Contraceptive Introduction in 1991 to ensure quality of care (including needs and rights) rather than an exclusive focus on contraceptive technology (products and devices) (see box). The method has been used in about 30 countries to identify and set priorities on sexual and reproductive health service needs, test appropriate interventions and scale up successful innovations (Simmons et al., 1997; WHO 2000a,b; Fajans et al., 2006). The Strategic Approach provides not only a systematic approach to assessing services but also opportunities to introduce new ideas.

Key features of the Strategic Approach

- A philosophy of sexual and reproductive health that embraces reproductive rights, gender equity and social justice.
- Linkage between the strategic needs assessment, applied service delivery research and scaling-up of successful innovations.
- A client-centred framework for identifying and correcting the management, technical, sociocultural and resource problems that affect the provision of equitable access to appropriate services of good quality in a health system.
- Country ownership and a participatory process for involving programme managers, policy-makers and other stakeholders, including service providers, researchers, social scientists, women's health advocates and influential leaders of women's, youth and community groups.

Source: Fajans et al., 2006.

The Strategic Approach comprises three stages. The first stage is a strategic assessment of the current situation and consideration of alternative approaches. A multidisciplinary team that includes senior decision-makers conducts fieldwork. New data are gathered by a predominantly qualitative approach involving interviews and observations.

The method was first used in China in 1998 to evaluate the introduction of quality of care into the first six pilot-counties of the project implemented by the National Population and Family Planning Commission since 1995 with support from the Ford Foundation (Ma Li et al., 1998). The 20-member evaluation team included an HRP consultant and Chinese policy-makers. The process contributed to better understanding of quality of care. Two participants in this evaluation subsequently participated in and conveyed their experiential learning to the Chongqing strategic assessment.

Chongqing assessment

The report of the Chongqing strategic assessment in 2000 (WHO, 2002) gives a wide range of findings and recommendations. Chinese participants welcomed the technical guidance provided throughout the assessment by HRP, which included assistance for planning, field work, report writing and dissemination. The findings and recommendations covered many aspects of quality of care. Those most directly related to the contraceptive products are described here.

IUDs: The assessment showed that the IUD is well accepted by many women and is preferred for its long life-span, reversibility and effectiveness and because insertion is free. Many types of IUD were available in the municipality, including the copper ring, TCu220C, TCu380A, Multiload, uterine-shaped IUD with 200 mm² or 300 mm² copper, 'fixed pattern' and gamma. The types available at township level also varied extensively. IUDs were

available in up to three sizes, pre-sterilized or not, with or without a disposable inserter, and some contained indomethacin to decrease bleeding during the three months after insertion. Very few (other than the copper-Ts) had strings attached for removal.

In some townships, more than 10 types or variations of IUDs were available, but in many clinics only the cheaper IUDs were supplied (e.g. copper rings without disposable inserters or the uterine-shaped IUD, which was not sterilized and had no disposable inserter), because the cost of the IUD took precedence over other characteristics, such as effectiveness. Both the programme managers and providers who were interviewed considered that the characteristics of IUDs are important and also that women should be offered a wide choice of IUDs. Each type of IUD generally requires a specific technique for insertion and removal and generally has a specific life-span. The providers were not always well informed about when an IUD should be replaced, and the team found that IUDs were usually not removed and replaced when their period of recommended effectiveness had ended and were often not removed from women reaching menopause. The team also saw evidence that IUDs and their inserters were not always sterilized correctly, and expired IUDs were often found in service facilities.

Quarterly ultrasound check: In almost all the townships visited, women with an IUD had an ultrasound check every three months to ensure their IUD remained correctly in place. While women expressed a variety of views about this quarterly IUD follow-up, there was considerable dissatisfaction with the fact that the check was limited to ultrasound to verify the presence of the IUD and did not address side-effects or women's health. The team recommended that IUD follow-up be conducted according to established evidence-based medical criteria. It further recommended that the quarterly ultrasound checks be discontinued, as they represented unnecessary medical care and were costly in terms of personnel and other resource requirements.

Hormonal methods: Many hormonal contraceptive methods were available throughout the municipality, including a variety of brands of daily pills, once-a-month pills, visiting pills and emergency contraception pills. The variety of types and brands led to considerable confusion among both providers and clients concerning the method characteristics and appropriate use (e.g. medical eligibility for specific methods, follow-up and management of complications).

Multiplicity and quality of products: Past emphasis on the introduction of new methods led to a proliferation of contraceptives in the programme, which resulted in a deterioration rather than an improvement in quality of care. The assessment team expressed concern that, in addition to the wide variety of similar methods provided, a number of the contraceptives were not of optimal efficacy and were in some cases of uncertain safety. According to the Science and Technology Department of the National Population and Family Planning Commission, such problems were common to the programme in other geographical areas as well and were thus key issues to be addressed to promote quality of care and informed choice.

Informed choice: The assessment team found that both users and members of the community were unfamiliar with the concept of informed choice. While women were aware of some changes in practice, most did not know that the current family planning policy gave them the choice of methods other than the IUD. Providers also did not fully understand the concept of personal choice in selecting a contraceptive method.

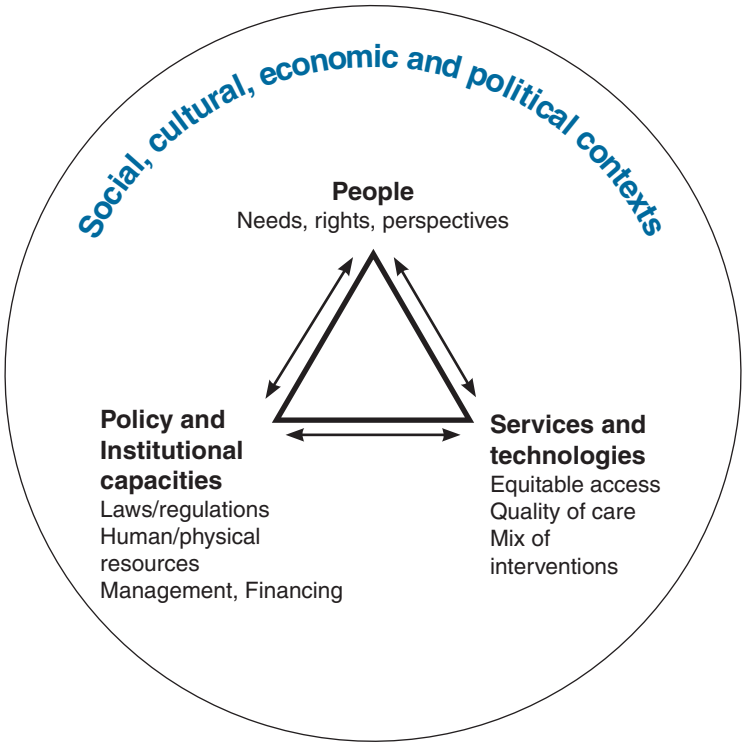
New guiding framework for quality of care

HRP's Strategic Approach gave China a better understanding of quality of care and contributed to the larger movement for quality of care that has been transforming the family planning programme. The 'triangle' graphic introduced in the Strategic Approach was greeted by Chinese colleagues as an effective tool for presenting the elements involved in improving quality of care: addressing clients, quality services and good management within the existing social, political and cultural contexts.

"The best of this project was that the strategic assessment changed our thinking," said a member of the Chongqing assessment team. "The triangle was very powerful for conveying this concept and change. From 1980 when I began working in this field, there was always the population control approach, never any mention of service. With Judith Bruce's six elements of quality of care, we began to realize the importance of service and these elements. But the Strategic Approach was most important; it included the technical dimension which Judith Bruce didn't. Six elements was just a list. The triangle of the Strategic Approach represented and communicated in quick way—gave us a new vision and path!"

An evaluation of the Strategic Approach concluded that it had broken new ground by applying a systems perspective to sexual and reproductive health policies and programmes. This is represented in

The systems framework guiding the Strategic Approach



World Health Organization. *The WHO Strategic Approach to strengthening sexual and reproductive health policies and programmes.* Geneva, 2007.

the triangle set in the circle. The framework has been used in China in speeches by Zhang Weiqing, Minister of the National Population and Family Planning Commission, and most recently provided the structure for a guide on quality of care in family planning in China (Xie Zhenming et al., 2007), which will be influential in improving sexual and reproductive health services in China (see photo – Discussion at a provincial workshop emphasizing that the guide on quality of care in family planning in China is organized around the elements in the graphic).

Continued use of the method

In addition to "changing the way of thinking" about programme implementation, the method itself continues to influence some research. The Shanghai Institute of Planned Parenthood Research team has implemented the second stage of the approach, action research, in Sichuan Province. Other researchers say it has a direct influence on how they design research, even if they are not fully implementing the method.

Upon request, HRP has subsequently supported implementation of the Strategic Approach in two additional contexts in China. One is in Yunnan Province, addressing access to services by the poor, including the serious issues posed by China's 'floating population' of migrants from poor rural areas, numbering in the millions, isolated rural women and the border areas that are the centre of China's AIDS epidemic. A programme guidance tool based on the Strategic Approach has also been used in reproductive tract and sexually transmitted diseases programming.

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Photo courtesy of Ruth Simmons

Annex 4. The systematic reviews and the process of engagement

HRP and its two key partners, the National Population and Family Planning Commission and the Shanghai Institute of Planned Parenthood Research, designed an innovative workplan, which built on the Cochrane systematic review method. Had the reviews been carried out strictly according to that method (see box), however, their findings might never have captured the attention of policy-makers. The key to success was involvement of stakeholders in the review from the outset, with continued engagement through a series of experts' meetings in an iterative, consensus-seeking, two-year process.

The Cochrane Systematic Review

The review begins with a comprehensive, systematic search for all published and unpublished literature on the issue under review. The next step is to examine the trials that are found by *a priori* criteria, according to the method and principles of clinical epidemiology proposed by the Cochrane Collaboration, to determine whether the studies meet the eligibility criteria for the review. Eligible studies are then pooled for qualitative and quantitative analyses when feasible. When well conducted, this type of review provides a basis for reliable, comprehensive conclusions about the effectiveness and safety of health interventions.

Experts' meeting, April 2002. To launch the review process, the Commission brought together national and international experts to discuss priorities and strategies for the systematic review. The participants included senior staff of the Science and Technology Department and the Contraception Supply Department of the Commission, HRP staff, family planning specialists from academic institutions, national and regional family planning research institutes and the pharmaceutical industry. They affirmed that the purpose of the review was to assess safety and effectiveness of commonly used contraceptives in order to provide a basis for rational, evidence-based selection and management of the contraceptives that the Commission provides to the national family planning programme. Half of the three-day workshop was devoted to the method of systematic reviews of health techniques, presented by an HRP consultant and an expert from the China Cochrane Centre. Two groups were formed, one to prepare a framework for the systematic review of hormonal contraceptives and the other to prepare a framework for the review of IUDs. They agreed that seven reviews would be conducted, three concerning IUDs (the copper ring 165, other copper IUDs developed and manufactured in China and copper IUDs developed in the West but manufactured in China), and four reviews on hormonal contraceptives (daily combined oral contraceptive pills, once-a-month oral contraceptive pills, progestogen-only visiting pills and emergency contraceptive pills). The main outcome variables for each contraceptive product would be effectiveness, safety and continuation rate, as a proxy for acceptability.

Second experts' meeting. In November 2002, a two-day meeting of national experts was convened in Shanghai, during which the research group of the Shanghai Institute of Planned Parenthood Research presented the framework for the systematic review and delivered draft reports on the medicated copper ring 165, once-a-month pills and visiting pills. The experts provided valuable suggestions for completing the reviews.

Third experts' meeting. In January 2004, the Shanghai Institute convened a two-day consensus meeting, the goal of which was to agree on recommendations to be forwarded to the Commission.

The Shanghai Institute research team presented the conclusions and preliminary recommendations of all seven systematic reviews. Each presentation was followed by discussion and formulation of a draft recommendation to the Commission. The Shanghai Institute research team, together with HRP experts, then finalized the reports and prepared a summary report of the consensus reached by the participating experts.

National dissemination workshop. In April 2004, a two-day workshop was held in Shanghai to present the results of the systematic reviews on the IUDs and oral hormonal contraceptives commonly used in China. There was general agreement about the importance of the reviews. The National Expert Group noted that it was the first attempt in China to perform a comprehensive systematic review of commonly used IUDs and oral contraceptives and that the reviews made it clear that many of the contraceptive methods had not been evaluated since they were first marketed. They recognized that the method used was in accordance with international standards, and judged the research project of great importance and practical significance for improving the level of clinical family planning research in China, enhancing management and use of fertility-regulating methods, advancing quality of care as well as popularizing the method of systematic review. The two-year review showed which contraceptives ranked well in safety, effectiveness and acceptability and which did not. The recommendations from the reviews were forwarded to the leadership of the National Population and Family Planning Commission, which, expressing confidence in the process, made the important decision to discontinue purchasing and providing the copper ring IUD and the three hormonal contraceptives that did not meet the criteria of safety and effectiveness.

Participants in the systematic reviews

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Annex 5. Centre for Contraceptive Adverse Reaction Surveillance

A national network for post-marketing surveillance of contraceptive methods has been established and has begun systematic monitoring for harmful side-effects and adverse reactions to IUDs and hormonal contraceptives. This Centre for Contraceptive Adverse Reaction Surveillance (CARS) is based in Nanjing at the Jiangsu Institute of Planned Parenthood Research. International support came initially from the United States Centers for Disease Control and Prevention (CDC), with various inputs from HRP. This activity was not included in the terms of reference for this case-study; however, the National Population and Family Planning Commission called attention to it and urged that it be included.

Personnel from the Jiangsu Institute attended a WHO-sponsored training workshop on contraceptive surveillance at CDC in the late 1990s. In 1998, HRP convened a workshop on contraceptive adverse reaction surveillance in Nanjing, which was attended by several influential persons, including the Director of China's State Food and Drug Administration, the Director of the National Population and Family Planning Commission's Science and Technology Department (Dr Xiao Shaobo), Dr Zhao Baige from the National Population and Family Planning Commission, Dr Olav Meirik from HRP and Professor David Skegg from New Zealand. In 1999, the Centre was formally established in Nanjing, with support from the Science and Technology Commission of Jiangsu Province.

A planning workshop at CDC in 2001 focused on developing a CARS system for China. This received limited support from HRP. Subsequent capacity-building included visits to the Uppsala Monitoring Centre in Sweden (2003), set up by WHO as an international drug monitoring programme, and to New Zealand (2003–2004), recommended by HRP as having an outstanding CARS system, monitoring some 15 000 IUD users.

Technological standards have been set for surveillance and reporting, a dedicated online database has been established for this purpose, and personnel in Nanjing and the surveillance sites have been trained in the standards and procedures for surveillance and linked with the online database. By 2005, a network of CARS sentinel surveillance sites had been established in 10 pilot counties, one each in 10 provinces. By 2007, this pilot programme had been expanded to 31 (nearly all) of China's provinces, municipalities and autonomous regions. About 100 monitoring stations are expected to be operating across China by 2010.

Data from township family planning clinics and township hospitals are sent (via the database) to the county family planning agency and then to the CARS Centre in Nanjing. From the Centre, data are sent, as judged appropriate, to the National Population and Family Planning Commission and to the National Centre for Adverse Drug Reaction Monitoring, which is under the State Food and Drug Administration. An agreement signed in 2003 sets forth the terms of collaboration between the CARS Centre, the National Centre for Adverse Drug Reaction Monitoring and the State Food and Drug Administration.

The Centre is using data submitted from the monitoring stations to conduct research on safety, efficacy and risks associated with various contraceptives, both hormonal and IUDs. (The database has information on 33 different IUDs.) Data are now available from a two-year surveillance project (October 2005–September 2007). The results show that the CARS online reporting system registered 832 adverse events (e.g. downward displacement, fragmentation and knot loosening, partial expulsion, complete expulsion, infection and ectopic pregnancy) involving 24 types of IUD.

A progress report was presented at a conference at the National Population and Family Planning Commission in June 2006, and the results were reported in the Chinese official media (http://english.peopledaily.com.cn/200606/22/eng20060622_276433.html). The Centre received a science and technology award from the Commission in 2006 and is now considered a unit in that body.

The principal relevant research carried out at the Centre for Contraceptive Adverse Reaction Surveillance, with Chinese Government funding, includes:

- 2002: a study on surveillance of adverse reactions to new contraceptives (key programme in the 10th national five-year plan)
- 2004: a study on surveillance for and evaluation of the safety of contraceptives (key programme in the 10th national five-year plan)
- 2005: effects of use of combined oral contraceptives and the ACE and AGT genes on hypertension (National Natural Science Foundation of China)
- 2006: a study on post-marketing surveillance and risk re-evaluation for contraceptives (key programme in the 11th national five-year plan)

Annex 6. Once-a-month pills and the monthly injectable contraceptive

Since the beginning of HRP's collaboration with China's Government and scientists, there has been concern about 'once-a-month pills'. In the early 1980s, HRP's Toxicology Review Panel reportedly recommended that these be removed from use. When the National Population and Family Planning Commission asked HRP to conduct a strategic assessment of contraceptive issues, the widespread availability and use of the once-a-month pills was documented (Sun Yibin, Zhu Pengdi, 1997). As a result, in 2003, HRP provided support for a systematic review of the effectiveness, side-effects, safety and acceptability of China's once-a-month pills. The review concluded that the available data, while limited, indicated that the pills were less safe and less effective than other long-term hormonal contraceptives. The Commission subsequently ended its provision of the pills to China's national family planning programme, as of 2005. Nevertheless, once-a-month pills continue to be manufactured, used and made available for sale in the private sector in neighbouring countries.

Mechanism of action

The 'once-a-month' pill contains 6 mg levonorgestrel (a short-acting progestogen) and 3 mg quinestrol (ethinylestradiol-3-cyclopentylether), a long-acting estrogen. The estrogen blocks ovulation, and the progestogen gives rise to a progestogen peak that, as it declines, induces the endometrium to shed in menstruation-like withdrawal bleeding. The bleeding typically starts three days after the pill is taken (Fang Ke-juan et al., 2007).

Once-a-month pills

In the 1960s, various hormonal contraceptive regimens were tested by researchers in China. As a result, three different once-a-month pill formulations were developed in 1969. Because of short-term side-effects, of nausea and vomiting, however, a new formulation was produced in the mid-1970s. The once-a-month pills were designed and provided to meet a special need in the family planning programme. The methods preferred by the programme were sterilization and IUDs; however, for women who experienced substantial side-effects from IUDs, the once-a-month pill was a common alternative. Over the years, family planning workers provided the pill during monthly visits to women in their homes. Although oral contraceptive pills are used by only a small percentage of Chinese women, the number is still in the millions (see Table 1), and once-a-month pills have been one of the most popular hormonal contraceptive methods in rural China.

Table 1. Estimated numbers of married women of reproductive age in China using hormonal contraceptives

	Total no. married women of reproductive age (billions)	Prevalence of modern methods (%)	No. of women using methods (millions)	Oral contraceptives (% of method mix)	No. of women using oral contraceptives (millions)	Injectable contraceptives (% of method mix)	No. of women using injectable contraceptives (millions)
China, 1997	0.263	83.3	219	1.7	3.7	0.4	0.9
World	1.043	54.0	563	7.2	40.5	2.6	14.6

Source: United Nations Population Division (2003).

Since the beginning of HRP's collaboration with China (1979), concern has been raised about the once-a-month pill. An HRP Toxicology Panel reviewed these pills around 1980 and recommended their discontinuation because of safety concerns. Between 1982 and 1990, a series of coordinated clinical and experimental studies were conducted to examine the safety of the once-a-month pills in rural China. As a result of the findings, in 1992, the norgestrel pill was removed from the commodities provided to the national family planning programme and was replaced by a levonorgestrel pill. Since 1998, only one once-a-month pill, containing levonorgestrel and quinestrol, remained on the National Population and Family Planning Commission procurement list. The HRP-supported Chongqing strategic assessment in 2000, however, found several different once-a-month pills available in clinics, including the norgestrel pill (removed from the list in 1992). Of the oral contraceptive pills identified in the assessment, including several types of once-a-month pills, several types of daily pills, several types of visiting pills and four types of emergency contraceptive pills (WHO, 2002), the once-a-month pills were the most commonly used.

As a result, the HRP-supported systematic reviews conducted by the Shanghai Institute of Planned Parenthood Research included a review of data on the safety and effectiveness of the levonorgestrel once-a-month pill (conducted in 2003). The available data were found to be inadequate to assess the safety and effectiveness of the pill definitively, but it was concluded that it was less safe and less effective than daily pills or combined injectable contraceptives. The conclusions of the review were as follows (Fang Ke-juan et al., 2004; Ding Yong-gang et al., 2005; Meirik, 2005; Fang Ke-juan et al., 2007):

> The review of once-a-month pills revealed the lack of adequate data to assess the effectiveness and safety of the method. The available data, however, suggest it is less effective than daily pills and combined injectable contraceptives. The monthly estrogen dose of the once-a-month pill, quinestrol that is metabolized to ethinylestradiol, is 4.5 times the monthly dose of ethinylestradiol of currently used daily pills. The available data concerning safety of quinestrol is incomplete, but indicates that in the short term a substantial proportion of users complain of nausea, vomiting, and leucorrhoea [a vaginal discharge], and that the incidence of elevated blood pressure can be as high as 7.5%. Studies report adverse shifts of serum lipid profiles and liver function tests. The high dose of estrogen of the once-a-month pill gives rise to concerns about its safety in the longer term but there is no information on the long-term safety of this contraceptive.

When the results were reported at the national dissemination meeting in April 2004, the expert group brought together by the Commission agreed (Fang Ke-juan et al., 2004):

> There is sufficient evidence to state that the dose of CEE [quinestrol], which is metabolized to EE, of the once-a-month pills is far too high for it to be safe in longer term use. The rate of short-term side effects of the once-a-month pills is high and the discontinuation rate is high. The National Population and Family Planning Commission should start preparations to phase out once-a-month pills. (Later, "as soon as possible" was added at the end of the last sentence.)

As a consequence, the Commission's leadership instructed its Contraceptive Supply Department to remove the levonorgestrel once-a-month pill from the annual procurement list for contraceptive supplies to be purchased for the national family planning programme (National Population and Family Planning Commission, 2005).

Today, no once-a-month pills are on the list or being centrally purchased and provided by the Commission; however, they are still in use. This continued provision is explained partly by the fact that the Commission provides only a portion of the contraceptives that the family planning clinics provide, and the clinics and their local governments must buy the remainder from commercial manufacturers. This may include purchase of once-a-month pills (and other contraceptives) that are no longer on the Commission procurement list. In addition, the health system under the Ministry of Health and private pharmacies can also buy and provide or sell once-a-month pills.

According to researchers at the Shanghai Institute of Planned Parenthood Research, many family planning providers, especially in rural areas, like and still want to provide once-a-month pills. They are the cheapest of all oral contraceptives and much easier to use than a daily pill. Research conducted by the team in 2002–2005 in the Chongqing vicinity found that many family planning workers were still quite insistent on providing once-a-month pills (personal communication, Fang Ke-juan and Zhou Weijin, 2007).

Visiting pills. The visiting pills that remain on the Commission procurement list contain high doses of levonorgestrel but are regarded by many Chinese family planning leaders and the Army as an essential part of the contraceptive mix. One reason for their popularity is that the Army still considers them important for short-leave family visits. HRP staff recommended eliminating all visiting pills and replacing them with emergency contraception followed by one month of a daily oral contraceptive pill; however, Chinese colleagues considered that a visiting pill was needed.

Use of Chinese once-a-month pills elsewhere in Asia

Chinese products, including contraceptives, flow into South-east Asia. Chinese contraceptives are imported into neighbouring countries either through formal commercial sales or through informal channels by local entrepreneurs. Once-a-month pills have reportedly long been available and continue to be so in various countries, including Cambodia, the Lao People's Democratic Republic, Myanmar, Viet Nam and even Indonesia.

In Cambodia, for example, the once-a-month pill has been used extensively and is regularly available from drug sellers. The perceptions of women towards the pill are mixed, as it is more convenient than a daily pill but generally has more side-effects (Sek S et al., 1999). Known as 'the Chinese pill' among users, the instructions and contraindications are all in Chinese. A review of reproductive health commodities, undertaken by the United Kingdom Department for International Development for the Reproductive Health Supplies Coalition, including donors and procurement agencies, stated that "Some products are also imported from China. The only contraceptive found was the once-a-month pill. This product, about which WHO has expressed concerns on safety and efficacy, is widely available and because of its price for one month coverage, is used by many poorer women." (Hall, Chan Chhuong, 2006). The report recommended that "Chinese once-a-month pills should be removed from pharmacies because of safety

and efficacy concerns." Although international control mechanisms are being put in place, their impact on changing the availability of these pills may be minimal, according to some knowledgeable sources.

In Myanmar, HRP designed training materials for public sector and drug store personnel and other audiences, which emphasized that the Chinese once-a-month pills may be less safe than other oral contraceptives and should not be used. This information was also to be provided in Myanmar Medical Association courses on family planning for general practitioners. Subsequent comparison of pill usage in the 1997 and 2001 Fertility and Reproductive Health Surveys showed a decline in usage of these pills (Myanmar, Ministry of Immigration and Population, 1999; Myanmar, Department of Population, 2003).

UNFPA's country office in India supports a task force on contraceptive research, which includes scientists from Government, the Indian Council for Medical Research and UNFPA and provides technical advice on new contraceptive products. In 2005, the task force considered introducing China's once-a-month pill into India. The proposal was that India would begin importing the Chinese pill and that eventually an Indian company would start to produce it. The results of the review of the once-a-month pill by the Shanghai Institute of Planned Parenthood Research were considered (Ding Yong-gang et al., 2005; Fang Ke-juan et al., 2007), and on the basis of the review's findings and recommendations, the task force decided that the Chinese pill should not be introduced into India (personal communication, UNFPA country office). HRP-supported work contributed to this decision and is a public good with benefits for India.

At about the same time, Thailand was also considering importation of the Chinese once-a-month pill. The Institute of Health Research at Chulalongkorn University in Bangkok considered the evidence from the Shanghai Institute review. Subsequently, HRP information sources report, there has been no further discussion or reported formal importation of the pill into Thailand. It is unlikely that formal importation will occur in the future, given that the Thai Food and Drug Administration has applied for membership in the Pharmaceutical Inspections Cooperation Scheme and has begun implementing their recommendations on current good manufacturing practice for both national and imported products.

A once-a-month pill is also manufactured and has been used in the Dominican Republic for several years. Whether its development was linked in any way to the Chinese pill is unclear; however, the report by HRP in *Contraception* (Fang Ke-juan et al., 2007) that the Chinese once-a-month pill was no longer being provided to the Chinese family planning programme reportedly resulted in decreased promotion and advertising of the once-a-month pill in the Dominican Republic.

Regional and global public goods

The decision by the National Population and Family Planning Commission to stop providing the once-a-month pill to the national family planning programme definitely constitutes a national public good, with extension to the region. Collaboration and information-sharing by the HRP team was instrumental in the decisions not to introduce the once-a-month pill, especially in India and possibly in Thailand, and this also constitutes a global public good. Continued effort and influence will, however, be needed, given that once-a-month pills continue to be used in China and exported to South-east

Asia, formally or informally. Another indicator of HRP's contribution to the public good is that in at least one country, Cambodia, use of Chinese once-a-month pills has declined in the past five years (National Institute of Statistics, Directorate General for Health [Cambodia], and ORC Macro (2001, 2006).

Once-a-month injectable contraceptive No. 1

Monthly injectable contraceptives have been used in China for many years, the main product being Injectable No. 1. HRP observed that no well-designed comparative clinical trial on this product had been reported, although it had probably been used by one million Chinese women or more. In 1988, HRP supported a comparative phase III study to evaluate the efficacy and side-effects of Injectable No. 1. HRP interrupted the study because of the occurrence of an unexpectedly high pregnancy rate during the first two months of use in the group given Injectable No. 1. The injection schedule was modified and the study resumed and completed. The results showed that Injectable No. 1 was less effective than other monthly injectable products (Cyclofem and Mesigyna), that No. 1 was less suitable for monthly administration, and that side-effects resulted in high discontinuation rates (Sang Guo-wei et al., 1995a,b). HRP's toxicology group expressed its concern to Chinese decision-makers, including the State Pharmaceutical Administration. Injectable No. 1 is no longer supplied by the National Population and Family Planning Commission to the national family planning programme, although it reportedly continues to be manufactured, used and exported .

Injectable No. 1 was not among the contraceptives on which the systematic reviews were conducted, given HRP funding constraints at the time and the low prevalence of use of this product. Experts have since encouraged the Commission's Department of Science and Technology to work closely with the Shanghai Institute to continue systematic reviews of additional Chinese contraceptives, including Injectable No. 1.

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Annex 7. Terms of reference and HRP budget

This case-study was one of five conducted for the in-depth external evaluation of HRP, 2003–2007. The terms of reference for the overall evaluation, described below, led to the brief terms of reference for this case-study.

HRP was established by WHO in 1972 to coordinate, promote, conduct and evaluate international research in human reproduction. UNDP, UNFPA and the World Bank joined WHO as cosponsors of HRP in "coordination of the global research effort in the field of reproductive health". As the main instrument in the United Nations system for research in human reproduction, HRP brings together health-care providers, policy-makers, scientists, clinicians and consumer and community representatives to identify and address priorities.

One recommendation of the 1990–2002 external evaluation was:

> HRP should continue to focus on global public goods, and should try to document the contribution of its work to global public health. As a measure of efficiency, the cost to HRP of its contribution to health outcomes should be calculated. Estimates and projections of abortions averted, unwanted pregnancies prevented, and improved reproductive health through more effective contraceptive methods, emergency contraception, and service guidelines will help to demonstrate HRP's important contributions and cost-efficiency.

The international task force on global public goods gave the following definition:

> International public goods, global and regional, address issues that: (i) are deemed to be important to the international community, to both developed and developing countries; (ii) typically cannot, or will not, be adequately addressed by individual countries or entities acting alone, and, in such cases (iii) are best addressed collectively on a multilateral basis.

In the present evaluation, the evaluation team focused on five Programme achievements that fulfil the criteria of global public goods and lend themselves to an in-depth analysis of inputs, outputs, outcomes and, where possible, impacts on sexual and reproductive health and their contribution to achievement of the Millennium Development Goals, including poverty alleviation. In general, preference was given to Programme achievements in the recent past (approximately the last decade); however, this time limit made it difficult to demonstrate actual impacts on health outcomes, necessitating the use of proxy indicators and projections based on modelling.

Proposed global public goods for in-depth study

Case-study 2: Promoting family planning; improving quality of care in family planning in China

Since the late 1970s, and with combined WHO and UNFPA support, the Programme has collaborated with the Government of China to build domestic capacity for conducting research on sexual and reproductive health to the highest scientific and ethical standards. This has allowed Chinese scientists and institutions to participate in multinational research and thereby become familiar with 'western' contraceptive products and concepts, as well as to critically examine the safety and efficacy of domestic methods in common use. This research addressed, inter alia, Chinese once-a-month injectable contraceptives, the once-a-month oral pill, visiting pills and domestically produced IUDs.

Outputs of Programme-supported work include:

- withdrawal of locally produced, less effective IUDs (stainless-steel ring, copper ring) from the national programme;
- removal of the once-a-month pill from the national procurement list of contraceptive commodities;
- comparison of Chinese Injectable No. 1 with the Programme's once-a-month injectables (Mesigyna and Cyclofem); and
- critical assessment of gossypol for male contraception.

Other considerations:

- It was subsequently agreed with HRP that gossypol would not be included in the case-study as it was an older effort and not linked to the first three items.
- It was confirmed that the case-study would not cover all HRP contributions to improving quality of care in China but would focus on the above product-related support.
- The overall terms of reference designated that the case-studies would be carried out by five experts in the respective areas, assisted by a health economist commissioned to support the analyses of public goods.
- The budget shown in Table 1 was provided by HRP for HRP-supported activities and projects covered by the case-study.

Table 1. HRP budget for achieving the major outcomes specified in the terms of reference for this case study

Item	Amount (US$)
Strategic assessment Chongqing	
Agreement for performance of work with the Shanghai Institute of Planned Parenthood Research	33 450
Consultancy Simmons (45 days)	12 150
Travel	
Ruth Simmons (two trips)	11 000
Mary Broderick (two trips)	7 000
Peter Fajans (three trips)	10 500
Patrick Rowe	3 500
Wu Shangchun	934
Mary Broderick to Ann Arbor	3 500
Fang Kejuan to Ann Arbor	4 500
Subtotal Chongqing assessment	**86 534**
Plus 8 weeks of P3 HRP staff time and 5 weeks of P5 HRP staff time in 2000–2001	
Systematic reviews	
Agreement for performance of work with the Shanghai Institute of Planned Parenthood Research	41 230
Agreement for performance of work with Olav Meirik	8 750
Consultancy Olav Meirik	10 800
Expert working group, travel	
Patrick Rowe	3 500
Kate Curtis	4 500
Olav Meirik	7 260
Mary Broderick	3 500
Peters Fajans January 2004	4 760
Olav Meirik January 2004	7 260
Peter Fajans April 2004	4 760
Olav Meirik April 2004	7 260
Subtotal systematic reviews	**103 580**
Plus 2 weeks P3 staff time and 4 weeks P5 staff time	
Grand total (not including staff time)	**190 114**