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HRP Highlights 2008

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HRP Highlights of 2008

Department of Reproductive Health and Research
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UNDP · UNFPA · WHO · World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

UNDP/UNFPA/WHO/World Bank
Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Highlights of 2008

About HRP

HRP was established in 1972 by WHO. In 1988, the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), and The World Bank joined WHO as the Programme's cosponsors. The four cosponsoring agencies, together with the major financial contributors and other interested parties, make up the Programme's governing body, the Policy and Coordination Committee (PCC), which sets policy, assesses progress, and reviews and approves the Programme's budget and programme of work. Broad strategic technical advice on the Programme's work is provided by the Scientific and Technical Advisory Group (STAG). In 1999, STAG assumed the responsibility for reviewing, and advising on, the work of the whole Department. The Scientific and Ethical Review Group (SERG) Panel reviews all HRP projects involving human subjects and research in animals and contributes to ethical debate on matters relating to sexual and reproductive health. The Toxicology Panel is a complementary review body to the SERG Panel. It provides expertise in the evaluation of pharmacokinetic, metabolic, endocrinological, toxicological, teratogenicity, carcinogenicity and mutagenicity studies of drugs or devices developed or studied by HRP or referred to it for advice. In addition, the Programme has several strategic review committees and specialist panels that advise on detailed research strategies.

Sexual and reproductive health - general

- In 2005, HRP started funding research on quality of care in sexual and reproductive health services. As of 2008, 24 studies have been completed and more are ongoing. The completed studies examined various aspects of quality of care in the provision of services for family planning, maternal health, safe abortion, and sexually transmitted infections and HIV. Most studies involved provision of services through clinical settings, although a number of studies have also included outreach or community-based services. Taken together, these studies suggest that quality improvement strategies should: (i) seek to empower clients, especially marginalized groups; (ii) improve client–provider interactions; (iii) monitor equity in provision of quality care and test approaches that reduce disparities in health-care provision; and (iv) seek to optimize care, setting minimum essential standards. A synthesis of the findings from these studies will be published in 2009.

Promoting family planning

- A randomized, double-blind multicentre trial carried out in Nigeria compared the efficacy and side-effects of levonorgestrel when administered in two doses of 0.75 mg given 12 hours apart and when administered in a single dose of 1.5 mg up to 120 hours (5 days) after unprotected intercourse. In both groups, women treated later than 72 hours following unprotected intercourse had higher pregnancy rates than those treated within 72 hours. There were no significant differences in side-effects reported between the two groups. This study confirms the results from an earlier WHO multicentre trial showing that a single dose of 1.5 mg of levonorgestrel is effective for emergency contraception.
- A study was conducted in China to establish, among other things, the efficacy and side-effects of the TCu380A IUD as a method of emergency contraception among parous and nulliparous women. Overall, study results demonstrated that IUD insertion is safe and effective for emergency contraception in both groups of women.

Promoting family planning

- Insertion of quinacrine hydrochloride pellets into the uterus has been used to achieve sterilization. In the early 1990s, HRP's Toxicology Panel had recommended against conducting clinical research on quinacrine owing to lack of pre-clinical safety data. Prompted by the recent availability of pre-clinical toxicology and other safety data on quinacrine, HRP convened a technical consultation in 2008, in collaboration with Family Health International, to assess the relationship between quinacrine, when used for non-surgical sterilization in women, and safety endpoints, with an emphasis on cancer risk. The consultation recommended, inter alia, that until all safety, effectiveness and epidemiological data have been reviewed, quinacrine should not be used for non-surgical sterilization of women in either clinical or research settings. A final WHO statement on the safety of quinacrine for use in women for non-surgical sterilization will be developed in 2009 following a thorough review of human safety data.

Improving maternal and perinatal health

- A multicentre observational study entitled "Screening for pre-eclampsia: evaluation of the predictive ability of angiogenic factors" is being conducted to verify whether changes in serum and urinary angiogenic proteins during pregnancy, detected with an easy-to-apply screening test, can be used as an effective method for identifying women at high risk of developing pre-eclampsia. This study is under way in eight countries (Argentina, Colombia, India, Italy, Kenya, Peru, Switzerland, Thailand) with a total recruitment target of more than 12 000 women. Approximately 5000 subjects were recruited by December 2008.
- The results of the trial entitled "Vitamins in pre-eclamspia study" conducted in India, Peru, South Africa and Viet Nam were presented at several international congresses. The study showed that despite promising preliminary results, antioxidant supplementation during pregnancy with vitamins C and E does not reduce the risk of pre-eclampsia. These findings are in agreement with other large studies conducted at the same time.
- Collaboration was started with the University of British Columbia in Vancouver, Canada, to expand a study conducted in Australia, Canada, New Zealand and the United Kingdom to three developing countries (Fiji, South Africa and Uganda) in order to validate the universal applicability of a model consisting of maternal and fetal clinical variables that predict adverse maternal and perinatal outcomes in women with pre-eclampsia. This model aims at improving the definition of the clinical picture of women with pregnancy-related hypertensive disorders relative to existing classification systems.
- A large systematic review was conducted to evaluate the safety of human intrauterine exposure to ultrasonography. The electronic search identified 6716 citations and 63 were selected for full-text evaluation. Additionally, 19 citations were identified from secondary sources. A total of 58 references reporting data from 38 different studies were included. The results of the systematic review show that ultrasonography in pregnancy is not associated with adverse maternal effects, impaired physical or neurological development or increased risk for malignancies in childhood.
- The Programme conducted a multicentre, randomized, placebo controlled double-blind trial designed to compare the effectiveness of one-day versus seven-day nitrofurantoin treatment to eliminate asymptomatic bacteriuria during pregnancy. The rationale of the study was that, if proven effective, a one-day treatment would be more feasible and acceptable to women. The trial included centres in Argentina, the Philippines, Thailand and Viet Nam. Results showed that one-day nitrofurantoin treatment is significantly less effective than the seven-day regimen.
- Collaboration was initiated between HRP and the Perinatal Research Branch of the National Institute of Child Health and Human Development (PRB/NICHD), USA. Under this long-term agreement, HRP will collect biological samples and information from large cohorts of women and their infants worldwide according to well-defined methodological protocols and PRB/NICHD will analyse the samples according to pre-established research plans. This collaboration will allow HRP and PRB/NICHD to test rapidly new research hypotheses.

Controlling sexually transmitted infections (STIs) and reproductive tract infections (RTIs)

- HRP is conducting a large randomized controlled trial (the Kesho Bora study) to optimize the use of antiretroviral treatment during pregnancy to preserve the health of the mother, minimize side-effects and reduce the risk of vertical transmission of HIV. In 2007 recruitment was initiated in two new sites in South Africa (Durban and KwaMsane), and continued in Burkina Faso (Bobo-Dioulasso) and Kenya (Mombasa and Nairobi). Recruitment in all sites was completed in July 2008, with 826 women having been enrolled. First results are expected to be published in 2009.

Preventing unsafe abortion

- Using data from various sources, an analysis was undertaken to examine the relationship between contraceptive use and induced abortion. The analysis compared regional prevalence of use of reversible

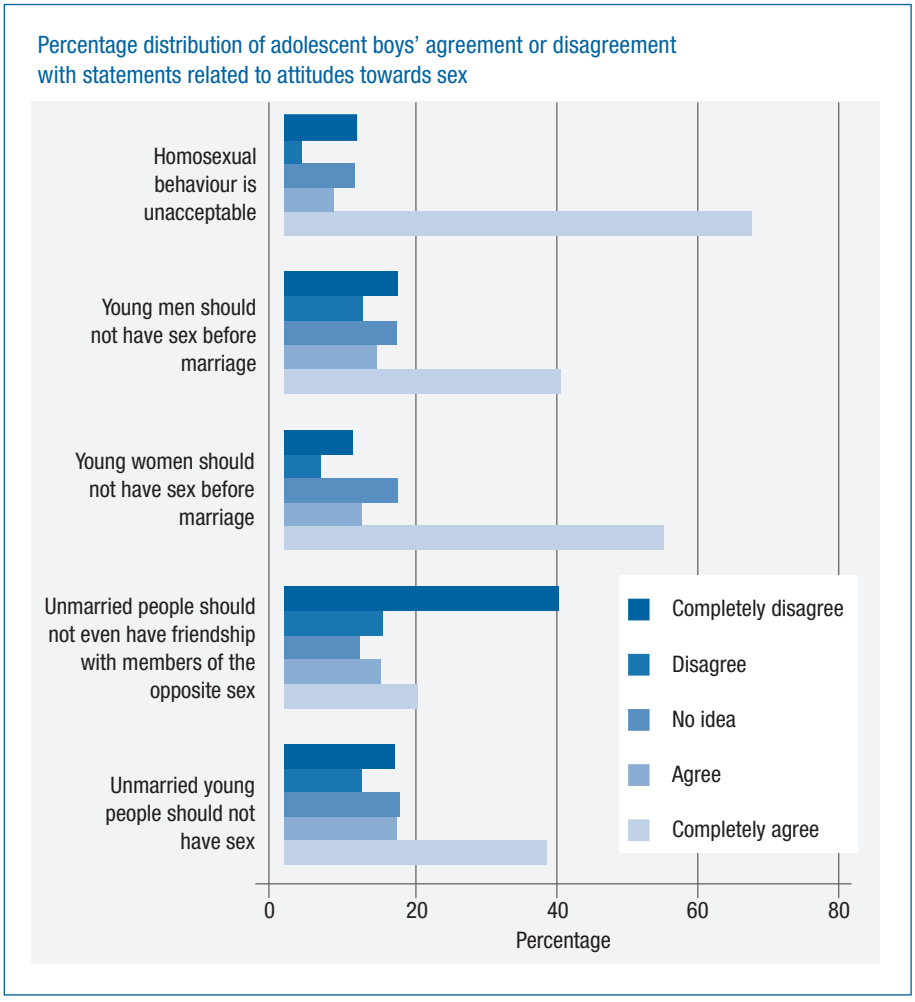
and terminal modern and traditional family planning methods with estimated unsafe abortion and all induced abortions rates. Among other findings, the analysis concluded that the lowest induced abortion rates are associated both with high contraceptive prevalence and with liberal abortion laws.

- A qualitative study in South Africa examined the role of health-care providers in improving access to safe abortion. The study concluded that, despite liberalization of abortion legislation in South Africa in 1996, barriers to safe abortion services still exist, including provider opposition to abortions and a shortage of trained and willing abortion-care providers.
- The optimal dose of misoprostol in the combined mifepristone–misoprostol regimen for abortions up to nine weeks' gestation was investigated in a trial launched in late 2006. In addition to comparing two misoprostol doses (0.4 mg and 0.8 mg), this trial also compared two routes of administration (sublingual and vaginal). Involving 3007 women, this trial was conducted in 15 centres in 11 countries. Two interim analyses suggest high efficacy for the sublingual administration. The final analysis is planned for 2009.
- A trial was conducted in seven countries to identify an effective misoprostol-only regimen for the termination of second-trimester pregnancy. Women requesting medical abortion at 13–20 weeks' gestation were randomly assigned to a vaginal or a sublingual treatment group, with both groups receiving 0.4 mg of misoprostol every 3 hours up to five doses. At 24 hours, the success rate was 85.9% in the vaginal group and 79.8% in the sublingual group. Misoprostol-alone regimens are clearly less effective compared with the combination of mifepristone followed by misoprostol.
- In 2008, HRP collaborated with Ipas to conduct a subregional workshop in French-speaking Africa on using the WHO Strategic Approach to address issues related to the provision of safe abortion. HRP also collaborated with Ipas to provide technical support to strategic assessments addressing unwanted pregnancy and unsafe abortion in Malawi and Zambia. In addition, HRP supported strategic assessments in the Russian Federation and Ukraine, and follow-up activities to strategic assessments in Bangladesh, The former Yugoslav Republic of Macedonia, Republic of Moldova and Mongolia.

Gender, reproductive rights, sexual health and adolescence

- *The WHO Multi-country Study on Women's Health and Domestic Violence against Women* has generated a database with information from over 24 000 women from 15 sites in 10 countries. In 2007–2008, the study team generated 16 published papers. In 2008, a meeting was convened of the multi-country study team to document how researchers have turned their findings into policy and programmatic actions in their respective countries. Some successes highlighted at the meeting included, inter alia, advocating for the creation of policies or expansion of existing laws to reduce violence against women and implementing programmes in the health sector to educate providers about violence against women.
- A study on female genital mutilation in the Gambia and Senegal confirmed that 70% of mothers felt they had little influence on the final decision taken for their daughters to be subjected to the practice. Grandmothers and paternal aunts had the most say in the decision. Factors contributing to abandonment of female genital mutilation were fear of HIV, fear of legal prosecution and personal experience with adverse outcomes.
- A synthesis of findings of studies supported under HRP's social science and operations research initiative on adolescent sexual and reproductive health was completed. This overview documents the perspectives and behaviour of adolescents on sexual and reproductive health and identifies policy and programmatic implications for promoting adolescent sexual and reproductive health.
- Nineteen papers were published in peer-reviewed national and international journals on adolescent sexual and reproductive health. In addition, two policy briefs (*Misperceptions among boys in the Islamic Republic of Iran about sexual and reproductive health* [Box 1 below] and *Perspectives on sexual violence during early years of marriage in Nepal: findings from a qualitative study*) were published by HRP.

Box 1. Extract from policy brief on misperceptions among boys in the Islamic Republic of Iran



Technical cooperation with countries

Africa and Eastern Mediterranean Region

- During 2007–2008, 14 centres were supported with long-term institutional development (LID) and service guidance centre or resource maintenance grants, and eight centres were involved in projects that addressed regional and national reproductive health priorities. Out of 41 studies, the highest number of projects were on maternal and newborn health and family planning. Most of the projects were implemented with support from national sources or from agencies other than WHO.
- In 2008, HRP supported 30 researchers from seven collaborating institutions in Nigeria to make presentations at the 42nd Scientific Conference of the Society of Gynaecology & Obstetrics of Nigeria (SOGON). The themes of the conference were reproductive cancers; prevention of mother-to-child transmission of HIV; and family planning and its contribution to the Millennium Development Goals 4 and 5. Some of the scientific papers presented at this meeting were based on the research results of projects that received financial support from HRP.

The Americas

- Activities to build country-level capacity in research ethics took place in Paraguay. More than 40 investigators, non-scientific personnel and members of ethical review committees of research and academic institutions in the country active in the area of health research participated; out of these, some 18 fellows also participated in a full two-day technical meeting to discuss the most important elements of the operational guidelines of the soon-to be-established National Health Research Ethics Committee. The first draft of these guidelines was presented to the HRP Secretariat in September 2008.
- A regional initiative to assess the feasibility of measuring indicators recommended in the implementation framework of *WHO's Global reproductive health strategy* was completed in 2008. Research groups from Argentina, Brazil, Guatemala, Panama and Peru, in coordination with their respective ministries of health, participated in this initiative. One of the case-studies showed that out of the 83 indicators recommended in the implementation framework, 51 could be calculated.
- Grants to strengthen research capacity and programme capacity were awarded to 15 countries in the Americas Region to support national sexual and reproductive health research, group learning activities for researchers and programme officers and to implement specific programmatic activities in the area of sexual and reproductive health.

Asia and Western Pacific

- Nine centres in the South-East Asia Region and 13 centres in the Western Pacific Region received research capacity strengthening grants. Three research project mentoring grants were awarded in 2008.
- A regional workshop on ethical issues in reproductive health research was held in Ho Chi Minh City, Viet Nam, in 2008 for 24 participants from nine countries who were chairpersons, secretaries and/or members of national ethics committees.
- In 2007–2008, 12 workshops on research methodology, ethical issues in reproductive health and scientific writing were supported at the national level.

Mapping best practices in reproductive health

- The number of Cochrane reviews included in *The WHO Reproductive Health Library* (RHL) reached 137 in 2008. Two new educational videos "Umbilical vein injection for retained placenta: why and how?" and "No-scalpel vasectomy technique" were added to RHL in 2008.
- A revamped version of RHL was published on the WHO web site (http://www.who.int/rhl). Monitoring of the Internet access showed that the number of sessions on the RHL web site increased from around 800 per day to 1400 per day between April 2008 and December 2008. Of the 212 WHO unique web addresses, RHL ranked 39th in terms of number of sessions per week. RHL is currently translated into Chinese, French, Spanish and Vietnamese. The first Russian translation of RHL was completed in 2008, and Russian Internet and CD publications are planned for the first half of 2009.
- A national training workshop on 'Evidence-based decision-making in reproductive health' was conducted in Monrovia, Liberia, on 4–6 February 2008 with the participation of 15 health workers, most of whom were midwives.
- A workshop was conducted in Khon Kaen, Thailand, on how to write a commentary for RHL. The participants were academic staff from the University. The overarching aim of this workshop was to make health-care practitioners aware about evidence-based medicine (in particular RHL) and to provide them skills for analysing systematic reviews and writing commentaries on clinical interventions evaluated in Cochrane reviews.

Communication, advocacy and information

- In 2008, 77 information materials were produced and distributed widely. Out of these, four were translated into Arabic, two into Chinese, 10 into French, nine into Spanish and five into Russian.
- During the period 1 January 2008 to 4 December 2008, some 1 640 000 downloads were made from the Department's web site – some 264 000 more than in 2007. This increase was largely due to an increased availability of publications in languages other than English on the web site.

Statistics and informatics support

- Decentralization or outsourcing of data management was further expanded in 2008, with HRP providing general oversight of the work.
- A new open-source data management system was adopted and used for three new projects and a software tool was developed for automated processing of electronic questionnaires.

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