



# Annual technical report 2013

Department of Reproductive Health and Research *including*  
UNDP/UNFPA/UNICEF/WHO/World Bank  
Special Programme of Research, Development and  
Research Training in Human Reproduction (HRP)



World Health  
Organization



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**UNDP · UNFPA · UNICEF · WHO · World Bank**  
Special Programme of Research, Development  
and Research Training in Human Reproduction



**World Health  
Organization**

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## Abbreviations

<b>AGH</b>	Adolescent and at-risk Populations (team)
<b>ALIRH</b>	Latin American Association of Reproductive Health Researchers
<b>AMR</b>	antimicrobial resistance
<b>ANM</b>	auxiliary nurse midwife
<b>BOLD</b>	Better Outcomes in Labour Difficulty (project)
<b>C4-GEP</b>	<i>Comprehensive cervical cancer control: a guide to essential practice</i>
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CEPEP</b>	Centre for Population Studies (Asunción, Paraguay)
<b>CIDES</b>	Centre for Research and Development in Sciences (La Paz, Bolivia)
<b>CIN</b>	cervical intra-epithelial neoplasia
<b>CIRE</b>	Continuous Identification of Research Evidence
<b>CREP</b>	Centro Rosarino de Estudios Perinatales (Uruguay)
<b>CRF</b>	case report form
<b>D&amp;C</b>	dilatation and curettage
<b>DECIDE</b>	Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (project)
<b>DHS</b>	Demographic and Health Surveys
<b>ECHO</b>	Evidence for Contraceptive options and HIV Outcome
<b>ECSA-HC</b>	East, Central and Southern African Health Community
<b>ELSI</b>	ethical, legal and social implications
<b>EMTCT</b>	elimination of mother-to-child transmission
<b>FCHV</b>	female community health volunteer
<b>FP2020</b>	London Summit on Family Planning initiative
<b>GAP</b>	Gender and Rights Advisory Panel Gentle Assisted Pushing (project)
<b>GASP</b>	Gonococcal Antimicrobial Surveillance Programme
<b>GCP</b>	Good Clinical Practice
<b>GFMER</b>	Geneva Foundation for Medical Education and Research
<b>GRADE</b>	Grading of Recommendations Assessment, Development and Evaluation
<b>GREAT</b>	Guideline-driven, Research priorities, Evidence synthesis, Application of evidence, and Transfer of knowledge ((Network)
<b>H4+</b>	UNFPA, UNICEF, WHO, World Bank, UNAIDS, UN Women
<b>HDI</b>	Human Development Index
<b>HPV</b>	human papilloma virus
<b>HRP</b>	UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction
<b>HRX</b>	Human Reproduction (team)

<b>HSV</b>	herpes simplex virus
<b>IARC</b>	International Agency for Research on Cancer
<b>IAWG</b>	inter-agency working group
<b>IBP</b>	Implementing Best Practices Initiative
<b>ICD</b>	International Classification of Diseases
<b>ICPD</b>	International Conference on Population and Development
<b>IHP</b>	International Health Partnership
<b>IM</b>	intramuscular
<b>IMPT</b>	Initiative for Multipurpose Technologies
<b>IPTp</b>	intermittent preventive treatment in pregnancy
<b>IT</b>	information technology
<b>IUD</b>	intrauterine device
<b>IVB</b>	Immunization, Vaccines and Biologicals (team)
<b>IVF</b>	in vitro fertilization
<b>IVR</b>	Initiative for Vaccines Research
<b>JTF</b>	James Tudor Foundation
<b>LID</b>	Long-term Institutional Development (grant)
<b>MDG</b>	Millennium Development Goal
<b>MEC</b>	<i>Medical eligibility criteria for contraceptive use</i>
<b>mHealth</b>	mobile health
<b>MiP</b>	malaria in pregnancy
<b>MMR</b>	maternal mortality ratio
<b>MPA</b>	Maternal and Perinatal Health and Preventing Unsafe Abortion (team)
<b>MPT</b>	multipurpose prevention technology
<b>MR</b>	menstrual regulation
<b>MSM</b>	men who have sex with men
<b>mTERG</b>	WHO mHealth Technical and Evidence Review Group
<b>MVA</b>	manual vacuum aspiration
<b>NGO</b>	nongovernmental organization
<b>NIH</b>	National Institutes of Health (USA)
<b>NSAID</b>	non-steroidal anti-inflammatory drug
<b>NSWP</b>	Global Network of Sex Work Projects
<b>OHCHR</b>	UN Office of the High Commissioner for Human Rights
<b>PATH</b>	Program for Appropriate Technology in Health
<b>PCC</b>	Policy and Coordination Committee
<b>PCR</b>	polymerase chain reaction
<b>PICOT</b>	Population, Indicator/Intervention, Comparator, Outcome, Time
<b>RCT</b>	randomized controlled trial
<b>RHL</b>	WHO Reproductive Health Library
<b>RHR</b>	Department of Reproductive Health and Research
<b>RMNCH</b>	reproductive, maternal, newborn and child health
<b>RP2</b>	Research Project Review Panel



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<b>SELMA</b>	Simplified, Effective, Labor-Monitoring Assistant
<b>SERG</b>	Scientific and Ethics Review Group
<b>SIS</b>	Statistics and Informatics Services
<b>SP</b>	sulfadoxine–pyrimethamine
<b>SPR</b>	<i>Selected practice recommendations for contraceptive use</i>
<b>SRH</b>	sexual and reproductive health
<b>STAG</b>	Scientific and Technical Advisory Group
<b>STEPMAG</b>	Simplified Treatment for Eclampsia Prevention using Magnesium sulphate (trial)
<b>STI</b>	sexually transmitted infection
<b>TAG</b>	Topic Advisory Group
<b>TFV</b>	tenofovir
<b>TFV ISC</b>	Tenofovir Gel Implementation Steering Committee
<b>THRIVE</b>	Technologies for Health Registries, Information, and Vital Events (consortium)
<b>TRC</b>	Technical Resource Team
<b>UK</b>	United Kingdom of Great Britain and Northern Ireland
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>UNDP</b>	United Nations Development Programme
<b>UNFPA</b>	United Nations Population Fund
<b>UNICEF</b>	United Nations Children’s Fund
<b>US</b>	United States
<b>USA</b>	United States of America
<b>USAID</b>	United States Agency for International Development
<b>VIA</b>	visual inspection with acetic acid
<b>WAHO</b>	West Africa Health Organization
<b>WHO</b>	World Health Organization
<b>WHO MCS</b>	<i>WHO multicountry survey on maternal and newborn health</i>



## Introduction

**“... We must do more for the teenage girl facing an unwanted pregnancy; for the married woman who has found she is infected with the HIV virus; and for the mother who faces complications in childbirth...”**

This impassioned and urgent call in September 2010 by the United Nations Secretary-General launched the Global Strategy for Women's and Children's Health and underscores the importance of WHO's and HRP's work in sexual and reproductive health.

The UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) is the main instrument within the United Nations for sexual and reproductive health research, bringing together policy-makers, scientists, health-care providers, clinicians and community representatives to identify and address priorities for research to improve sexual and reproductive health. HRP is a cosponsored Special Programme executed by WHO, which is part of the WHO Department of Reproductive Health and Research (RHR), based in the WHO cluster on Family, Women's and Children's Health (FWC).

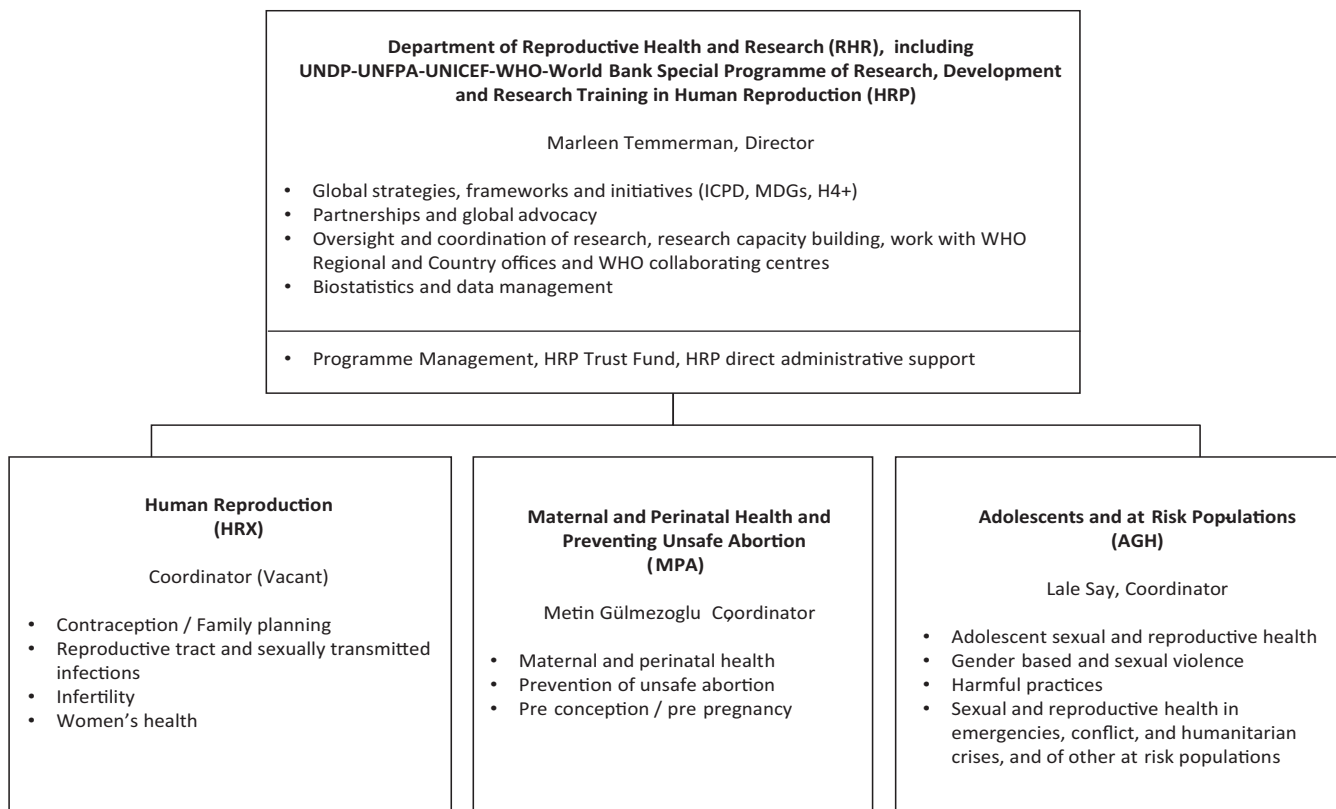
For RHR and HRP, the year 2013 represented a critical year of transition, marked by the appointment of a new Director and senior leadership team; the implementation of a programme of strategic planning and restructuring; and the completion of a five-year independent External Evaluation. This report describes these changes, whilst at the same time summarizes HRP's record of achievement in 2013 on the generation of new knowledge, synthesis of research evidence, strengthening of research and technical capacity, development of guidelines, and strengthening of research and policy dialogue on sexual and reproductive health and rights.

## Strategic planning and restructuring

In February 2013, a functional review of RHR was carried out which aimed to (i) review and revise the Department's priority functions and areas of work and ensure that these are relevant for, and aligned with, its overall strategic direction; (ii) rationalise the current structure of the Department, to make it more coherent and efficient in terms of its functional organisation; (iii) to redefine focus and clarity of HRP, and (iv) examine working practices and identify areas for improved and coordinated working across the Department, within WHO as a whole, and within the global sexual and reproductive health and rights community. The overall result of the review was a more focused programme, which is better aligned with changing global context and needs. The review concluded that while the work should continue in all key areas of sexual and reproductive health, including maternal and perinatal health, family planning, prevention of unsafe abortion, controlling sexually transmitted infections, gender and human rights related to sexual and reproductive health, and adolescent sexual and reproductive health, certain aspects should be further prioritized. Specifically, the review recommended that family planning, maternal and perinatal health and adolescent sexual and reproductive health should be prioritized, with a focus on research (biomedical, clinical, health systems, epidemiological and implementation research), guidelines, norms and standards, and monitoring and evaluation. At the same time, in view

of enhanced resources provided at the regional and country levels to technical support to countries, the functional review recommended a reduction in the relative contribution to this work, with a corresponding reduction in staffing. The present report of 2013 achievements has been structured under the new priority headings, which are also reflected the new structure of the department, shown in Figure 1 below.

**Figure 1. Organizational chart. Department of Reproductive Health and Research**



## HRP External Evaluation, 2008-2013

HRP is subject to periodic independent external evaluation, commissioned by its Policy and Coordination Committee (PCC), most recently in 2013 (2). This evaluation, covering the period 2008–2013, was requested by the World Bank at the 71st meeting of the standing committee in June 2011. At this meeting, the cosponsors agreed on draft terms of reference, elaborating an approach that would review the comparative advantage of HRP and its impact in improving outcomes and influencing evidence-based changes in sexual and reproductive health policies and programmes, as well as carrying out a number of case-studies cutting across all thematic areas. The results, which were presented at PCC in June 2013, concluded that:

“The HRP team in Geneva, though relatively small, is highly impressive in its capacity to identify and coordinate a large network of investigators, collaborators and experts, from academic and research institutions all over the world, capable of addressing and developing long-term solutions to global SRH challenges.

In the period 2008–2012, the Programme continued to produce many important global public goods in the area of SRH. This was largely due to three factors: the dedication and excellence of its staff; the leadership and determination of its

directors in making the necessary decisions to ensure that HRP continued to move forward; and its fundamentally sound governance and technical oversight systems. By helping to lead and guide global developments in SRH, and then adapting to the changing environment, HRP continues to demonstrate that its business model is robust, and that its work remains highly relevant to the needs of programme countries" (2)"

## Structure of this report

In the chapters that follow, HRP's achievements in 2013 are highlighted. They are structured under the new priority headings, which also reflect the new structure of the department, namely human reproduction, maternal and perinatal health, and adolescent and at risk populations. In addition, the department carries out a number of cross-cutting activities that underpin the work of all three thematic teams, relating to international partnerships, gender, rights and advocacy for sexual and reproductive health. These are described below.

## ICPD Beyond 2014: redefining the global agenda on sexual and reproductive health – WHO's role and strategy

### **Progress**

While significant progress has been made in many of the diverse goals of the ICPD Programme of Action, preliminary results from the Global Survey demonstrate that profound disparities persist. In this context, in 2013 RHR led an intra-organizational task team to identify priority topics to address, and developed a package of eight evidence briefs focusing on the core neglected topics of the Programme of Action for use by advocates and policy-makers at the Commission of Population and Development in 2014.

### **Planned activities**

To improve sexual and reproductive health globally, and thus to reduce inequality, there is a need to link the ICPD efforts with the Millennium Development Goals (MDGs). To advance health in the neglected topics of both agendas, there is a need to reach out to policy-makers, technical experts, and the communities affected. WHO headquarters, in collaboration with the Regional Office for Africa, will convene a regional workshop in spring 2014 that brings together countries with success in improving outcomes on a priority health topic, and countries committed to progress. This consultation will serve as an opportunity to facilitate south-to-south exchange of best practices learnt.

Lessons from these case examples will be distilled into suggested action items for community advocates on priority health topics, and published as a cohesive document. WHO will prepare a toolkit that combines the ICPD evidence briefs, relevant WHO technical guidelines, and the lessons from the case-studies. This toolkit will serve as an advocacy resource for countries as they engage in the work of the ICPD Programme of Action and the MDGs.

## High level advocacy for sexual and reproductive health

### Progress

RHR and HRP outputs were widely disseminated, and high-level advocacy for sexual and reproductive health was carried out at 36 different conferences, symposia and high-level international meetings (please refer to list in Annex 3).

One of the major events in 2013 was the Women Deliver Conference in Kuala Lumpur. This conference is one of the largest gatherings to date of government leaders, policy-makers, health-care professionals, researchers, nongovernmental organization representatives, corporate leaders, and global media outlets, focusing exclusively on women's health and empowerment, bringing together over 4500 participants from 149 countries. RHR participated in concurrent sessions, including high-level plenaries, skills-building workshops, and a ministerial and parliamentary forum; also, among other key presentations to share the latest updates on sexual, reproductive and women's health, RHR launched two new reports, the *Investment case for eliminating mother-to-child transmission of syphilis*, *Promoting better maternal and child health and stronger health systems*, and *Comprehensive cervical cancer prevention and control – a healthier future for girls and women*.

In 2013, RHR also engaged in another important global initiative, FP2020. Launched at the 2012 London Summit on Family Planning, FP2020 aims at expanding access to family planning information, services, and supplying contraception to an additional 120 million women and girls in the world's poorest countries by 2020. RHR has actively contributed to the FP2020 initiative, chairing the Performance, Monitoring and Accountability Working Group, together with the Population Council. In November 2013, FP2020 launched its first progress report, *Partnership in Action 2012–2013*, at the International Conference on Family Planning in Addis Ababa. The report details successes and progress made since the 2012 London Summit on Family Planning, highlighting commitments, accountability, innovation, collaboration and ways to measure FP2020's progress. In the lead up to the 20th anniversary of the International Conference on Population and Development (ICPD) Programme of Action, RHR and WHO has supported the work of UNFPA in reviewing progress and identifying remaining gaps in the implementation of the Programme. Within WHO, HRP led an intra-organizational task team to develop eight evidence summaries on neglected priority areas for use by policy-makers and advocates at the advocacy events, including at the Commission on Population and Development.

RHR has also been working with the Inter-Parliamentary Union (IPU) and other thematic and regional parliamentarian such as the European Parliament and the Pan Africa Parliament to advocate for the uptake of sexual and reproductive health issues. In particular, in 2013, the Director of RHR has been appointed as WHO focal point for IPU and other parliamentarian activities. In 2013, RHR supported IPU in the draft of a resolution on demographic trends and natural constraints, and the Pan African Parliament in the finalization and endorsement of a resolution on gender-based violence, including recommendations on legislation to address child marriage.

## Planned activities

For 2014, RHR plans to continue to advocate for improved sexual and reproductive health and rights at conferences, symposia and high level international meetings, such as at the 13th Congress of the European Society of Contraception and Reproductive Health, which will take place in Lisbon from 28 to 31 May, 2014, at the Third Global Symposium on Health Systems Research which will be held in Cape Town, South Africa, from 30 September to 3 October 2014.

## United Nations H4+ joint support to countries advancing Millennium Development Goals 4 and 5

H4+ (UNFPA, UNICEF, WHO, World Bank, UNAIDS, UN Women) works with countries to support the implementation of commitments to the United Nations Secretary-General's strategy on Every Woman, Every Child (46), to accelerate progress towards Millennium Development Goals (MDGs) 4 and 5. Action focuses on effective high-impact interventions in RMNCH, by strengthening the health systems and by improving equity in accessing quality services. Bilateral donors like the Swedish International Development Agency, the Canadian International Development Agency, and the French Muskoka Initiative have considered the partnership as a valuable platform to operationalize their support for the Every Woman Every Child strategy. HRP/RHR and other departments in the Family, Women's and Children's Health Cluster have contributed to the planning and implementation of these initiatives.

### *Progress*

The 2013 H4+ report includes an assessment of the support provided by H4+ teams in 58 countries to help them reach their RMNCH goals (47).

The partnership has become a "one-stop shop" for countries to access technical and financial support for the entire spectrum of RMNCH issues; 57% of countries have established their H4+ country teams, which have supported strategic activities, such as in preservice training curriculum development, training of trainers, and engaging community health workers in service delivery in countries like Benin, Côte d'Ivoire, Mali and Togo. Countries have also used evidence-based planning and costing tools, e.g. the OneHealth examples of achievements in Benin, Democratic Republic of the Congo, Niger, Sierra Leone and Togo. At least 12 country teams have mobilized additional resources to support the implementation of H4+ joint plans among international agencies and national partners.

### *Planned activities*

- Develop a joint, rapid multi-stakeholder synthesis of the RMNCH landscape that brings together the various RMNCH-related plans, subplans and initiatives.
- Strengthen country engagement to align and coordinate funding streams to support implementation of prioritized interventions, such as family planning, maternal health and adolescent SRH services.
- Increase efforts to integrate RMNCH service with HIV and malaria prevention/treatment, and support equitable access to quality services for all women and children, including those in deprived and hard-to-reach areas.

## Sexual and Reproductive Health and Human Rights

### Progress made

During 2013, the Department continued to contribute to the work of United Nations Treaty Monitoring Bodies. This included ongoing support to the Committee on Economic, Social and Cultural Rights in the development of its draft general comment on the right to sexual and reproductive health. The Department also developed technical guidance on the application of a human-rights-based approach to the implementation of policies and programmes to reduce preventable maternal morbidity and mortality. This represented a significant contribution to the implementation work of the UN Office of the High Commissioner for Human Rights (OHCHR). The Department is working closely with OHCHR on the application of this guidance in four countries in southern Africa (Malawi, South Africa, Uganda, and the United Republic of Tanzania).

The Department also disseminated *Safe abortion: technical and policy guidance for health systems* to UN treaty monitoring bodies. A successful meeting was organized for the UN Committee Against Torture and the recommendations of WHO are reflected in its recent concluding observations in relation to conscientious objection.

During 2013, the Department worked on developing guidelines on ensuring human rights in the provision of contraceptive services and information and an analysis of existing quantitative indicators in relation to contraceptives based on human rights (see Human Reproduction chapter for further details). Also in 2013, the *Sexual and Reproductive Health and Human Rights: a Tool for Examining Laws, Regulations and Policies* and a WHO/joint UN agency statement on forced sterilization was finalised.

Finally, the Department has been working on the integration of human rights into the WHO International Classification of Diseases (ICD 10) revision process in connection to sexuality issues which are currently classified under mental health. Proposals were developed that are currently being field tested in five low- and middle-income countries.

### Planned Activities

Planned activities for the work on sexual and reproductive health and human rights include: development of a research agenda on sexual and reproductive health and human rights; integration of human rights in the key areas of work of the Department; contribution to the development and interpretation of human rights standards and developing guidance on the implementation of sexual and reproductive health standards based on a human rights-based approach.

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# Human Reproduction

## Summary

### Key objectives

The workplan in the area of human reproduction is progressively expanding its focus on implementation into the areas of research, guidelines and partnership. Research studies planned at present are developed to address research priorities that have important programmatic implications. Currently, the available WHO guidance on human reproduction primarily addresses “what to do” in providing quality services. However, the Human Reproduction team has already started to collaborate with its partners to enhance this work by including evidence on “how to do it” – and to use this guidance to provide WHO recommendations for key interventions to expand high-quality services, as well as for how best to implement them in the field.

### Major achievements

#### *Research*

In line with the distinguished trajectory of the Programme in contraceptive research, HRP/RHR completed a multicountry study comparing the safety and effectiveness of two contraceptive implants. The results of the study, which will be published early 2014, will inform global implementation efforts such as the London Summit on Family Planning (FP2020) initiative and the United Nations Commission on Life Saving Commodities for Women and Children’s Health. In addition, the Programme invested in the protocol development and implementation plans of the International Contraceptive Choice Study (which will ensure a rights-based approach in ensuring quality family planning services offering a good method mix) and the ECHO (Evidence for Contraceptive options and HIV Outcome) trial (to determine the risk of HIV acquisition in women using hormonal contraception), which will be two of the most important international research efforts in the area of family planning in the next 4–5 years and will generate results with significant health-policy and programmatic implications. In the area of sexually transmitted infection (STI), the Programme secured funds and international support to start several new studies on evaluation and implementation of screening and diagnostic tests.

#### *Guidelines*

The Continuous Identification of Research Evidence (CIRE) system continues to work effectively to constantly update WHO guidance in contraceptive use, with ongoing preparations for the next revision in 2014. Work will also start on implementation of the guidance document on family planning and human rights recently submitted to peer review. The new *WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention* was published and launched and received huge success. In addition, the Programme launched in 2013 the guide *Programming strategies for postpartum family planning*, to help programme planners and managers identify opportunities to offer family planning/contraception to postpartum women within existing health systems. The new sexuality counselling guidelines for health care were completed and

the Programme secured funding and international technical support to start the processes of developing guidelines for the management of STIs, as well as guidelines for topical pre-exposure prophylaxis for woman-controlled HIV prevention; the sexual and reproductive health of women living with HIV; and the diagnosis, management and treatment of infertility/subfertility.

### ***Dissemination, advocacy and partnerships***

The team has participated in important international partnerships and supported global initiatives to support the increased interest in promoting reproductive health and contraception, such as the H4+ initiative (WHO, UNFPA, UNICEF, The World Bank, Joint United Nations Programme on HIV/AIDS [UNAIDS], UN Women joint country support for Millennium Development Goals [MDGs] 4 and 5); the Muskoka Initiative; Implementing Best Practices Initiative (IBP); Africa Build; Global Fund; United Nations Commission for Life Saving Commodities, where RHR led the Technical Resource Team for Emergency Contraception; and the Initiative for Multipurpose Prevention Technologies. Activities ranged from providing technical assistance to countries; disseminating key information in family planning, infertility, STIs, including HIV, and women's health; supporting implementation of evidence-based guidelines and tools; and providing advocacy for policy development. The team actively participated in numerous conferences, including the International Conference for Family Planning (November, Addis Ababa), Women Deliver, the International Union against Sexually Transmitted Infections, and the European Society of Contraception and Reproductive Health (ESCRH), through high-level side events and plenary sessions, oral and poster presentations, and IBP workshops and panel sessions. Finally, WHO guidelines for (i) *Ensuring human rights in the provision of contraceptive information and services* and (ii) *Responding to intimate partner violence and sexual violence against women* were developed.

## 1. Introduction

The Human Reproduction (HRX) team of the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) carries out activities in:

- research and development
- norms, standards and tools
- research capacity-building
- monitoring and evaluation
- dissemination, advocacy and partnerships.

The team's activities focus upon the following thematic areas within a consolidated and comprehensive approach to sexual and reproductive health (SRH):

- family planning/contraception
- sexually transmitted infections (STIs), including HIV/AIDS
- women's health, including cancers of the reproductive tract
- infertility.

The following areas of SRH, including bidirectional linkages between the areas, underlie some of the most critical global health challenges that need to be effectively addressed to improve health and foster socioeconomic development worldwide.

- An estimated 222 million women in low- and middle-income countries would like to delay or stop childbearing but, because of lack of access and knowledge, are not using any method of contraception; improving access to contraception could reduce maternal mortality by 30% worldwide.
- There are 499 million new infections of curable STIs (syphilis, gonorrhoea, chlamydia and trichomoniasis) each year and drug resistance, especially for gonorrhoea, is dangerously increasing, posing a major threat to STI control globally.
- An estimated 1.4 million pregnant women are infected with syphilis each year and, as a result of insufficient testing, there are over 300 000 stillbirths or neonatal deaths per year.
- HIV is now the leading cause of mortality of women of reproductive age, with an estimated 60% of people living with HIV being female; HIV-related maternal mortality rates in sub-Saharan Africa have increased and surpassed other causes.
- One in every four couples in low- and middle-income countries have been found to be affected by infertility, and a 2012 WHO study estimated that levels and trends have not improved from 1990 to 2010 (1).
- Cervical cancers are increasingly recognized as one of the major causes of mortality for women, in both low- and middle-income countries and high-income countries, and globally more women are dying from breast and cervical cancer than from maternal mortality.

The team conducted an extensive prioritization exercise effort with internal and external partners, to answer important research questions and to address vital implementation challenges through the most cost-effective strategies. Building on the convening power and scientific/technical excellence of the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children's Fund (UNICEF)/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), the team has established large international collaborative networks to generate innovative approaches to deal with the major unmet needs in SRH.

To achieve this objective, the team is implementing a collaborative, science-driven approach, the key components of which are:

1. identification and conduction of priority research activities to strengthen the evidence base on priority needs;
2. development of normative guidance that addresses the needs;
3. identification of research gaps and elaboration of funding strategies to meet these gaps;
4. research synthesis and updating of the guidance in a timely fashion;
5. support for utilization of evidence in countries through systematic introduction of science-driven solutions to inform health policies.

The HRX team's plan of work shows how this approach translates into concrete and coordinated activities toward achieving the ultimate goal of improving SRH.

## 2. Research and development

### Research and development in family planning/contraception

#### 2.1 Global research priority setting in family planning

In 2011–2012, the Department conducted a research priority-setting exercise, using the methodology of the Child Health and Nutrition Research Initiative to identify global research needs in contraceptive research and to guide investment in effective interventions to satisfy the large and currently unmet need for modern methods of family planning.

##### *Progress*

Through a global survey, experts on contraception were invited to identify and rank the research priorities that would address knowledge gaps on reducing the unmet need for family planning in the next decade, on the basis of five criteria: (i) being deliverable, affordable and sustainable; (ii) leading to a substantial reduction in the unmet need for contraceptives; (iii) being effective and efficient in improving health systems; (iv) being addressed in an ethical way; and (v) having an equitable effect on the target population. The overall scores were then ranked.

The survey prioritized research on the following relevant issues: implementation of the health systems and policies relevant to family planning; integration of services – to address barriers to contraceptive use; and interventions targeted at underserved groups, such as adolescents. These observations will inform decision-makers, researchers and funding agencies in developing a clear and focused research approach to satisfying the global need for family planning and reaching the target set by the London Summit on Family Planning (FP2020) initiative.

An article presenting the results of the survey was published in the *Bulletin of the World Health Organization* (2).

##### *Planned activities*

- Future activities will be related to planning research and alignment of study groups to the priorities stated.

#### 2.2 ECHO (Evidence for Contraceptive options and HIV Outcome): research studies on the risk of HIV acquisition in women using hormonal contraception

Historically, HRP has played a major role in assessing the safety of contraceptives, as it led the scientific efforts that contributed to decreasing concerns about links between contraceptive use and cancer and cardiovascular risk.

Nowadays, the potential risk of HIV acquisition associated with the use of various hormonal contraceptives is the issue generating concerns within the international community. Recent published studies have suggested a possible increased risk of acquiring HIV among women using progestin-only hormonal contraceptives, most notably injectables. This concern has important health policy implications, as many of the countries most affected by HIV are also those with the fewest contraceptive options, and many rely heavily on the provision of injectable progestin-only contraception. Further complicating matters are the competing risks women must weigh in settings where foregoing family planning puts them at significant risk of maternal morbidity or mortality.

### ***Progress***

To address this knowledge gap, a multicentre randomized clinical trial to compare the rate of HIV acquisition between women using depot medroxyprogesterone acetate injectables, the copper-bearing intrauterine device (IUD), and another possible method (either norethisterone enantate injectable or a hormonal implant) in African settings is being planned. Women will be followed for one year, after randomization to one of the two or three methods, and will undergo HIV testing at 3, 6, 9 and 12 months after enrolment. Because the incidence of HIV at the study sites is unknown at this time, an adaptive study design will be pursued, to ensure that the number of seroconversions observed in the study is sufficient to distinguish a clinically meaningful difference. The study protocol has been approved by WHO's scientific and ethics review boards. This protocol is being discussed with other international partners and experts, to consider harmonization with other research plans aimed at addressing similar research questions.

### ***Planned activities***

- The study will be conducted at clinics in East London, Cape Town and KwaZulu-Natal in South Africa, and in Mombasa, Kenya.

## **2.3 Expanding the choice of contraceptive methods through the International Contraceptive Choice Project**

Extensive prioritization efforts conducted by HRP, in collaboration with internal and external partners, indicated that the most pressing need in terms of research in family planning is to determine how to expand the use and choice of contraceptive methods in low-resource settings. In order to identify factors to facilitate expansion of the method mix and integration of provision of contraceptives into antenatal, safe abortion, post-abortion and post-partum services, to inform health policies at national level, the recently published cohort study, the Contraceptive Choice Project (3), will be used as a model for expansion and adaptation to low-income countries in Africa (International Choice project). The Contraceptive Choice Project, conducted in the city of St Louis, Missouri, United States of America (USA) has shown that use of long-acting contraceptive methods could be effectively promoted by acting on three dimensions:

- appropriate information for providers and clients;
- availability of methods free of charge;
- reducing delay and unnecessary procedures/barriers in delivering the method.

Importantly, Choice has shown that this approach resulted in increased uptake of contraceptives, fewer unintended pregnancies and reduced abortion rates.

The Choice cohort study protocol will be adapted to include strategies for recruitment that are feasible in low-resource settings, focusing on post-abortion/postpartum approaches in integration with reproductive maternal, neonatal and child health (RMNCH) services. There will be a need to look into strengthening health systems, capacity-building for local human resources, and community mobilization, as well as considering local policies as part of the adaptation process in low-income countries.

**Progress**

A series of consultative meetings has been convened by HRP with the University of North Carolina, FHI 360, and Washington University at St Louis, USA, to develop the project, which has received preliminary approval from the Bill and Melinda Gates Foundation, for a planning grant to be implemented in Zambia. Discussions with other potential funding agencies to expand the project to other countries are ongoing. The European CHOICE study looked at the important role of counselling in the uptake of various hormonal contraceptives. An application has been made to the European Union (EU) for adaptation of the International Contraceptive CHOICE Project in another site.

## **2.4 Multicentre randomized clinical trial of two implantable contraceptives for women: 2-rod levonorgestrel implant (Jadelle) and 1-rod etonorgestrel implant (Implanon)**

**Progress**

HRP/RHR recently completed a multicentre, randomized clinical trial to assess the 3- and 5-year safety, effectiveness and acceptability of two hormonal contraceptive implants: 2-rod levonorgestrel implant (Jadelle) and 1-rod etonorgestrel implant (Implanon). The study was conducted in seven countries: Brazil, Chile, Dominican Republic, Hungary, Thailand, Turkey and Zimbabwe. A total of 2963 women have been randomized to one of the two implants (with 971 women on the TCU380A IUD enrolled in an age-matched cohort). An article presenting the baseline characteristics of the two study groups was published in *Contraception* in 2013 (4). A manuscript describing the 3-year follow-up of clients in the implant study is in preparation and will be submitted to a peer-reviewed journal by end of January 2014.

**Planned activities**

- The main paper on the 5-year analysis of the study will be submitted in 2014.

## **2.5 Study on sperm suppression using norethisterone ethantate and testosterone undecanoate**

**Progress**

To expand contraceptive options for men, HRP/RHR initiated a phase II trial of a combined progestin (norethisterone ethantate) + androgen (testosterone undecanoate), as this product has been shown to determine sperm suppression. However, the high number of side-effects such as depression and emotional side effects reported in the trial led to discontinuation of recruitment in 2012. While the early termination of the study will compromise the precision of a final estimate of the contraceptive failure rate of this regimen, other analyses linking the serum hormonal levels to the clinical effects are planned. The study participants have been followed up until the end of the recovery phase (when sperm levels are observed to return to normal levels). All study sites have completed follow-up of recruited subjects.

**Planned activities**

- Data cleaning and analysis are ongoing and the analysis of the serum hormone levels is expected to be completed in 2014.

## 2.6 Pericoital oral contraceptive use of levonorgestrel 1.5 mg

This is a study to provide a “proof of concept” for the use of a levonorgestrel oral contraceptive pill that can be taken 24 hours before or after sexual intercourse (pericoital use), up to six times a month. The study will provide preliminary data to justify a pivotal phase III study to establish efficacy and safety and to inform policies and programmes worldwide, as well as for regulatory purposes.

### *Progress*

A total of 320 participants in four countries have been recruited, in a prospective, open-label, single-arm, multicentre study to evaluate whether oral levonorgestrel (1.5 mg), taken around the time of sexual intercourse, can offer an acceptable level of safety and contraceptive efficacy. Follow-up has been completed in Singapore and Thailand and is under way in Brazil and Hungary, to end in mid-2014.

### *Planned activities*

- Analysis is expected to be completed in late 2014, with a technical report and scientific publications prepared.

## 2.7 Evaluation study of the feasibility, utility and effects of the use of family planning counselling tools at the community level

The positive role of counselling tools in communicating high-quality and correct information to family planning clients is well established. However, counselling tools for use at the community level by health workers with limited education and training (6 weeks or less) have not been developed until recently. Therefore HRP/RHR, in collaboration with the Population Council, conducted an evaluation determining the relative utility and acceptability of three simplified counselling tools designed for community health workers – the WHO publication, *A guide to family planning for community health workers and their clients* (5), the Population Council *Balanced Counseling Strategy* tool (6), and a hybrid version with key features common between the two, as compared with the usual information material provided to community health workers in India.

### *Progress*

The evaluation, conducted with 142 community health workers, has shown that in almost all cases (90% to 100%), there were no major variations between various counselling tool groups and the control group, and that community health workers were able to perform their counselling tasks appropriately and effectively when using the simplified tool, including facilitating choosing an appropriate method and providing it, if available.

### *Planned activities*

- The full technical report and scientific publications will be prepared in 2014.
- Discussions on how to improve the various counselling tools or the respective adaptation guides based on the study reports is planned for early 2014.



## 2.8 Measuring the need for family planning among women attending HIV services: a comparison of data-collection methods

There is an established need to identify more accurate methods for measuring the unmet need for family planning among persons living with HIV. Therefore, HRP/RHR conducted a study to compare how the use of a simplified questionnaire adapted from Demographic and Health Survey (DHS) questions determined unmet needs when used by health-care providers during their interaction with the clients at the HIV clinic, or by external interviewers conducting exit interviews among women attending HIV care and treatment services.

### *Progress*

Using a cross-sectional study design, 1186 women aged 15 to 49 years were interviewed only once, either during the provider contact or during the exit interview at selected HIV care and treatment facilities with large client loads in Kenya, Uganda and Zambia. Data collection took place between March 2012 and February 2013. The study showed that providers' use of this brief tool in allocating family planning need status is statistically equivalent to the allocations made by external, non-clinical interviewers. This implies that the tool can be used to collect routine data on family planning need status, which may be aggregated at the facility level and higher up the health information system, in order to monitor progress in reducing unmet need for contraception among women living with HIV.

### *Planned activities*

- The results of this study will be submitted for publication in 2014.

## 2.9 Reviewing and generating evidence on financing mechanisms for sexual and reproductive health services and commodities including family planning

### *Progress*

Lack of access to affordable contraceptive services and commodities is contributing to unmet needs for family planning in many low- and middle-income countries. Evidence on the best mechanisms to provide these affordable services and commodities using financial schemes is limited. Therefore, HRP/RHR is conducting a series of systematic reviews to identify the current gaps in knowledge and potential research topics in health-care financing in contraception. In addition, HRP/RHR is collaborating with Marie Stopes International and other organizations to implement and evaluate two projects that aim at reducing barriers to SRH services, including family planning, among women living in one of the poorest regions of the Philippines and in Pakistan. These evaluations will contribute to generating evidence on the effectiveness of reducing barriers to health services by using vouchers programmes, integrating supply and demand components of health, and increasing enrolment into social insurance schemes.

### *Planned activities*

- The systematic reviews will be conducted in 2014. The projects in Pakistan and Philippines have begun in 2013, with the Pakistan project expected to be completed by 2014. Two manuscripts describing the baseline data and the research protocol of the Pakistan project have been finalized and submitted to peer-reviewed journals in 2013. Evaluation of the Philippine study site will be conducted after recovering from the effects of the typhoon.



## Sexually transmitted infections, including HIV/AIDS

Recently, several studies have been initiated by HRP/RHR to advance knowledge on implementation of cervical cancer screening and human papilloma virus (HPV), dual HIV/syphilis testing, behaviour-change communication, and STI diagnostics. However, there are still gaps in the evidence required to ensure effective STI prevention and management. STI guideline management which will highlight the key gaps in STI research. These research gaps will be published with the guidelines and will support a future research agenda.

### 2.10 ESTAMPA: a multicentre study of cervical cancer screening and triage with HPV testing

ESTAMPA is a multicentre screening study among 50 000 women in selected Latin American countries, to compare visual, cytological and molecular triage methods, or combinations of these methods, in terms of performance and cost effectiveness, among HPV-positive women participating in HPV-based screening programmes and a sub sample of HPR negative women. In each participating centre, at least 5000 women aged 30–49 years who are attending clinics for cervical screening will be invited to participate in the study. The combined number of histologically confirmed diagnoses of cervical intra-epithelial neoplasia CIN3+ (estimated  $n = 500$ ) will be the outcome of primary interest for evaluation of the performance of the various triage modalities. The effectiveness and costs of each alternative strategy will be assessed under various scenarios of feasibility, cost and effectiveness. The study is a great opportunity to develop a model for organized screening intervention in the selected sites, and to define the target population, in order to evaluate factors associated with implementation – participation rates, follow-up completeness, psychosocial factors etc. WHO partners that are supporting this study include the International Agency for Research on Cancer (IARC), WHO headquarters, and the Pan American Health Organization, with the National Institutes of Health (NIH) of the USA.

#### *Progress*

Ten centres in six countries have initiated the study. Out of these, two centres in Colombia have started the recruitment (770 as of December 2013). All the other centres/countries are now ready to start between January and March 2014.

#### *Planned activities*

- Additional sites are planning to carry out the study: earlier planning phases include Chile, Costa Rica (two sites), Guatemala, Panama, Peru, Puerto Rico and Venezuela. These sites should be ready by September 2014. In February 2014, the Data Safety and Monitoring Board will meet to review data and progress.
- To address issues specific to Africa with the introduction of HPV testing, and also of a visual inspection with acetic acid (VIA)-based algorithm, WHO and IARC are developing another joint protocol for a randomized cluster trial to evaluate different algorithms for cervical cancer screening in Africa. Algorithms currently considered as study arms include HPV test and treatment; VIA and treatment; HPV test followed by VIA and treatment; and HPV test followed by colposcopy and treatments. Potential participating countries are Cameroon, Malawi and the United Republic of Tanzania. The identification of study coordinators is ongoing and, at the end of February 2014, a principal investigator meeting will be held by WHO to review the study protocol.

## 2.11 Implementation research on the introduction of HPV testing in the United Republic of Tanzania

In 2005, WHO, with the Ministry of Health and Social Welfare in the United Republic of Tanzania and partners implemented a pilot programme of cervical cancer screening and treatment based on VIA and cryotherapy at the primary, district and regional levels of the health-care system. These demonstration sites and others identified by the Ministry of Health and Social Welfare are ideal as the basis for conducting operational research to introduce new rapid HPV DNA-based screening tests for cervical cancer (careHPV) to improve cervical cancer and prevention programmes at health facility level. The objective of the study is to assess the reproducibility, feasibility and acceptability of careHPV at each level of the health system and to determine whether it is able to perform as intended to improve the national cervical cancer-prevention programme based on screening with VIA.

### **Progress**

In November 2013, a field visit is taking place to evaluate the capacity of the site for the research and plan the implementation of the study starting in 2014.

Planned activities

- In January 2014, the test kits will be shipped and training will start in the different sites and at the national level. The study will start at the end of February 2014, and the recruitment will last for 3 months. It is expected that the results will be available before the end of 2014.

## 2.12 Road map for development of STI vaccines

Although progress has been made in the control of STIs, recent global estimates have found that nearly 500 million adults are infected, without counting viral infections. The limitations around existing approaches for prevention, screening, diagnosis and treatment of STI has motivated HRP/RHR and the Immunization, Vaccines and Biologicals (IVB)/Initiative for Vaccine Research (IVR) teams to revisit, in collaboration with partners, progress in STI vaccine development. During the last decades, significant advances in vaccine technology have resulted in the development and widespread use of two valuable STI vaccines, for hepatitis B and HPV. However, progress in vaccine development to prevent other critical STIs, i.e. gonorrhoea, chlamydia, syphilis, trichomoniasis, and herpes simplex virus (HSV), has lagged behind.

### **Progress**

A technical consultation to develop a STI vaccine road map was held in 2013. Several background papers were prepared for the technical consultation, and were accepted for publication in a special issue of *Vaccine*, co-edited by WHO/RHR, WHO/IVR and NIH, addressing: (i) the pressing needs for STI vaccines and the theoretical impact; (ii) key immunological issues for the development of STI vaccines; (iii) the state of the art on the development of vaccines against HSV, *Chlamydia trachomatis*, *Neisseria gonorrhoea*, *Trichomonas vaginalis* and *Treponema pallidum*; (iv) the programmatic issues linked to the introductions of these vaccines, as well as barriers and challenges from the manufacturer perspective to development of such vaccines; and (v) the way forward to develop such vaccines and a call for action with the STI vaccine road map. The special issue of *Vaccine* will be published in January 2014.

### ***Planned activities***

WHO, the United States (US) Centers for Disease Control and Prevention (CDC) and NIH will organize a workshop during the meeting of the International Union against Sexually Transmitted Infections in Atlanta in 2014, to review progress and future plans for implementation of the road map. Three major issues will be discussed:

- by HRP/RHR: the follow-up work with regard to all STI epidemiologic data, burden of diseases and impact of interventions, as per the road map;
- by IVR: the target product profiles for each of these vaccines;
- by NIH: the basic research needs for development of the vaccines.

## **2.13 Accelerating introduction of dual HIV/syphilis rapid diagnostic tests to eliminate mother-to-child transmission of HIV and syphilis**

Global and regional initiatives have been launched for dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. One critical component of these initiatives is early detection and timely intervention with pregnant women infected with HIV and/or syphilis. Innovative strategies are needed to improve the number of pregnant women tested and treated, as coverage is currently inadequate. At least three manufacturers have developed dual HIV/syphilis rapid diagnostic tests, which hold potential to improve the coverage of syphilis and HIV testing, efficiency of services, and quality of laboratory testing. To date, there are no independent data on the laboratory performance, field performance, or operational implications of these dual HIV/syphilis rapid diagnostic tests.

### ***Progress***

WHO has worked with countries and other partners (PATH [Program for Appropriate Technology in Health], the London School of Hygiene and Tropical Medicine, University of Bristol, CDC, The Bill and Melinda Gates Foundation, etc.) to prepare a comprehensive package of studies to evaluate dual HIV/syphilis rapid diagnostic tests to provide data for future WHO recommendations on appropriate use of these tests. Laboratory evaluations in China and Nigeria have been approved by the Research Project Review Panel (RP2). Protocols for evaluation of field performance in Zambia and introduction studies of dual rapid diagnostic tests in China and Colombia have also been approved by RP2. Another introduction study protocol in Nigeria is being finalized. A mathematical modelling exercise has been initiated to evaluate the diagnostic and cost implications of using different syphilis-testing strategies.

### ***Planned activities***

- WHO prequalification of three dual rapid diagnostic tests is scheduled for early 2014.
- The approved studies of new dual HIV/syphilis rapid diagnostic tests in China, Colombia, Nigeria and Zambia, and complete modelling exercises, will be initiated in 2014.
- Data from studies and modelling exercises are to be prepared for review within the ongoing WHO STI guidelines process.

## 2.14 Assessment of adverse outcomes of syphilis in pregnancy and the impact of timing of maternal treatment in Mozambique

Antenatal syphilis screening and treatment has been shown to be a highly cost-effective intervention to reduce fetal and infant morbidity and mortality associated with maternal syphilis infection. However, it is unclear how early screening should be done, and what the impact on different adverse outcomes is. In addition, diagnosis of congenital syphilis is extremely difficult, even in settings with substantial laboratory capacity.

### *Progress*

HRP/RHR support was provided to Mozambique National Health Institute and Health Alliance International, to conduct a retrospective cohort study of the effectiveness of syphilis treatment administered at different times during pregnancy, and the utility of polymerase chain reaction (PCR) in diagnosis of congenital syphilis. Enrolment of 16 812 women was finalized in March 2013. Preliminary analysis has been conducted, and final analysis is pending finalization of laboratory processing of specimens.

### *Planned activities*

- Finalization of laboratory assessment is anticipated by January 2014, and final analysis and dissemination by June 2014.

## 2.15 Advancing STI control and prevention through new innovations for STI testing technology – integrated point-of-care tests for sexually transmitted infections

Between 80% and 90% of the global burden of STIs occurs in low- and middle-income countries, where there is limited or no access to appropriate diagnostics. In such settings, syndromic management is used, which results in over diagnosis of STI among women with vaginal discharge for example, and under diagnosis of STI among symptomatic women and men. In both developed and developing countries, STI-related stigma and ostracism negatively affect health-seeking behaviours, therefore limiting opportunities for diagnosis. The absence of reliable, affordable and private diagnostic tests is therefore a major obstacle to effectively reducing the burden of STIs. This barrier could be overcome by developing reliable, low-cost, point-of-care tests, which could offer immediate results to patients, allowing them to receive immediate diagnosis and treatment while protecting their privacy. Therefore, HRP is developing a research project to contribute to ensuring universal access to high-quality STI testing through the development and implementation of low-cost point-of-care tests for STIs.

### *Progress*

A systematic review of studies and a landscape analysis have been conducted to identify the most promising point-of care diagnostics tests for different STIs (syphilis; trichomoniasis; chlamydial, gonococcal and HPV infection). The results of the systematic review will be discussed at a meeting of experts to be held in March 2014.

### *Planned activities*

- The systematic review and expert meeting will inform the development of a research proposal for a multicountry validation study of the most promising diagnostic tests to determine both analytical and operational performances in the field.

## **2.16 Advancing STI prevention through new evidence-based behaviour-change interventions**

Behaviour-change interventions have consistently been seen as an essential part of comprehensive STI/HIV prevention. Current understanding of prevention combines structural changes, such as access to commodities (condoms, information) and services (testing, treatment and care), within a human rights framework focusing on promoting relevant behaviour-change interventions, such as delay in sexual debut; consistent condom use; partner reduction strategy; STI/HIV testing; and promotion of sexual well-being through increasing self-esteem, self-regulation and a positive attitude towards one's own and other's sexuality. Sexual behaviour is very much driven by local norms, traditions and culture; thus, behaviour interventions have to conform to local contexts.

HRP/RHR will implement a research project to establish the validity of specific behaviour-change interventions that are proven in their effectiveness in high-income settings, to address the needs of low- and middle-income settings, especially on combination prevention strategy among key populations such as adolescents and young people. The goal of the project is to produce solid scientific evidence to promote the most up-to date and effective behaviour-change interventions to prevent STI/HIV in both key populations and the general population in low- and middle-income countries.

### *Progress*

A systematic review of available techniques of brief behaviour-change interventions used for STI/HIV prevention was conducted in 2013.

### *Planned activities*

- The results of the systematic review will inform the development of a multicountry study to validate the most promising identified techniques of brief behaviour-change interventions in both targeted populations and the general population.

## **2.17 SIALON II – multicountry integrated bio-behavioural survey, among men who have sex with men**

Additional efforts are needed to strengthen HIV/STI prevention, diagnosis and treatment in men who have sex with men (MSM). Data from 23 European countries show that the annual number of HIV cases in MSM increased by 86% between 2000 and 2006. To address this challenge, the European Commission is funding the integrated project SIALON II, which aims to implement innovative surveillance methodologies for hard-to-reach populations like MSM. These innovative surveillance methodologies are intended to be an effective tool in implementing ongoing and systematic behavioural surveillance in the participating countries. HRP/RHR actively participated in developing the conceptual framework of the project, which identifies which behaviours should be monitored and in which populations. This surveillance approach enables accurate monitoring of at-risk

groups and understanding of whether and how the rates of HIV/STIs are changing over time, as well as measuring the impact of implemented prevention activities.

### ***Progress***

Formative research was carried out in order to identify specific conditions and methods for data collection among MSM, according to local contexts and for prevention-needs assessment in participating countries: Armenia, Belgium, Bulgaria, Germany, Italy, Lithuania, Moldova, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland (UK). The data collection has been completed in most of the study sites.

### ***Planned activities***

- The primary analysis of the data collected by the surveillance system will be carried out in 2014. The final analysis and development of series of articles are planned for the end of 2014.

## HIV Linkages

### **2.18 Temperature-recording vaginal ring device for accurate measurement of user adherence**

Vaginal rings are already marketed for various clinical indications, including contraception, hormone replacement therapy and luteal phase support, and are being actively developed as HIV microbicide and multipurpose prevention technology (MPT) products. To date, all microbicide clinical trials, including the CAPRISA-004 (Centre for the AIDS Programme of Research in South Africa), VOICE (Vaginal and Oral Interventions to Control the Epidemic) and FEM-PrEP (Pre-exposure Prophylaxis Trial for HIV Prevention among African Women) studies, have relied on self-reporting questionnaires as a measure of user adherence. However, the reliability and validity of these adherence data are questionable; participants are likely to report good adherence, given the expectation to comply with the study protocols. More objective, quantitative and accurate methods for assessing adherence are needed.

### ***Progress***

A study proposal was finalized with Queen's University Belfast, Northern Ireland, UK to evaluate a temperature-recording device for vaginal rings, to improve measurement of user adherence. Preliminary experiments are ongoing at Queen's University Belfast, to establish proof-of-concept in a non-clinical setting. A prototype ring design has been proposed to permit the programming and insertion of the nano-temperature device after manufacture and prior to the start of a trial.

### ***Planned activities***

- Initial development work to produce a prototype ring with a temperature device will be developed, and a phase I study planned to evaluate adherence with two different vaginal rings.
- HRP/RHR will support as co-investigator and partly finance the 3-year project at the School of Pharmacy, Queen's University Belfast, Northern Ireland, UK, to develop simple and inexpensive injectable-type MPT products, with the potential to provide simultaneous long-term hormonal contraception and antiretroviral-based protection against HIV infection. Two different



formulation strategies will be assessed, involving reformulating Depo-Provera (medroxyprogesterone acetate) to include an antiretroviral agent, in which the polymer component precipitates to form a depot implant upon injection.

## 2.19 Evaluating national assessments on sexual and reproductive health/HIV linkages using the rapid assessment tool

HRP/RHR, in collaboration with the International Planned Parenthood Federation (IPPF), UNFPA, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Global Network of People living with HIV (GNP+), the International Community of Women with HIV/AIDS (ICW) and Young Positives, developed the *Rapid assessment tool for sexual and reproductive health and HIV linkages* (8), to assess national bidirectional linkages between HIV/AIDS and SRH, identify gaps, and contribute to the development of country-specific action plans. This initiative was launched by HRP/RHR in 2008 with the initial implementation of the tool in Botswana. To date, over 48 countries have completed implementation of the assessment tool. HRP/RHR is currently supporting countries and partners to share the process, findings, recommendations, and lessons learnt from this implementation.

### *Progress*

In 2013, HRP/RHR co-convened the SRH/HIV Linkages Indicators Specialists Symposium, which led to the development of a draft *SRH/HIV linkages indicator compendium*. Pilot testing for the three new integration indicators is currently under way in Botswana, Lesotho, Namibia, Malawi, Swaziland, Zambia and Zimbabwe, in collaboration with the Joint UNFPA/UNAIDS regional project on linking SRH and rights and HIV in Southern Africa. In addition, following the implementation the Rapid Assessment Tool, 20 country case summaries have been finalized and are available in the SRH & HIV Linkages Resource Pack (9) (see Fig. 1).

**Fig. 1. Countries that have implemented the SRH/HIV Rapid Assessment Tool since 2008**



**Planned activities**

- The *SRH/HIV linkages indicator compendium* will be finalized. The review of key findings from the implementation of the rapid assessment tool in 25 countries, and the report of pilot testing of SRH/HIV indicators are expected to be completed in the last quarter of 2014.

## Infertility/subfertility

**2.20 Development of a rapid assessment tool to assess existing health policy, systems and services for fertility care**

It is the choice of each individual and couple, within their own sense of conscience, to determine whether they intend pregnancy, and, if so, the size of their family unit and the timing of when to have a child or children. If fertility problems arise, interventions for the woman and man can be attempted, from simple fertility-awareness methods to more advanced methods associated with in vitro fertilization (IVF). Many of these problems can be avoided or addressed, through affordable interventions with timely help seeking. HRP/RHR wishes to support the operations and implementation research required to introduce affordable fertility interventions into health systems.

**Progress**

HRP/RHR convened a meeting in 2013 to scope the requirements for successful infertility care integration into existing health-care systems. A draft country rapid assessment tool to assess existing health policy, systems and services – which will facilitate the ability at country level for decision-makers to determine how, what and where to introduce various levels of fertility care – was developed.

A research proposal, *Plan with the end in mind: targeting the preconception period for a healthy pregnancy* has been drafted and submitted for funding. It includes the development and adaptation of a fertility-awareness tool for community health workers.

**Planned activities**

- The rapid assessment tool for integration of infertility care into policy, systems and services will be field-tested. A second consultation with mobile health (mHealth) experts, to adapt the rapid assessment tool for use on tablets is planned for Spring 2014. Funding has been secured through a special grant from the Australian Institute for Innovation.

**2.21 Research in infertility and subfertility for neglected and at-risk populations**

Better understanding of the prevalence of infertility/subfertility in all countries, trends over time, and also research to assess the prevalence of infertility/subfertility in all individuals, including at-risk populations, such as HIV-positive individuals, has been limited. As HIV-positive individuals are living longer, healthier and more productive lives, with the advent of more affordable antiretroviral therapies, their reproduction needs increase. This is especially true within cultures where great emphasis is placed on childbearing. While engaging in sexual activity, HIV-serodiscordant couples knowingly risk HIV transmission to their uninfected partner in order to achieve pregnancy. This can be a contributing factor in the HIV epidemic, particularly in countries with a high HIV burden – and within settings



where the integrity of pharmaceutical products and management of their usage, are less reliable. Although assisted reproductive services may be considered for HIV-serodiscordant couples, these innovative technologies are often dismissed in some settings, owing to barriers to access within health sectors in either high or low- and middle-income countries.

### ***Progress***

In collaboration with the WHO Department of Health Statistics and Information Systems, several papers have been published to present data on infertility prevalence and trends covering the analysis of fertility surveys in 190 United Nations Member States (10–14). A paper on the algorithm defining a specific measure for infertility was discussed; a paper on measuring the prevalence of infertility; and also several papers on trends to address needs for access to infertility care, owing to an unmet desire for a pregnancy, have been published and presented at two regional, as well as country and international, conferences in 2013.

Research to measure the prevalence of infertility was conducted using DHS data in three high-burden HIV sub-Saharan African countries, published as an abstract and presented at the XXVII International Union for the Scientific Study of Population, Korea in August, 2013.

### ***Planned activities***

- The three recent WHO papers on prevalence data for infertility/subfertility (10, 12, 13), have contradicted some of the prevalence values and estimates that WHO had previously published in 1984 (15) and 2004 (16). Research is ongoing to utilize a statistical model that has been generated to reconcile the differences. A manuscript is in preparation.
- The DHS research analysis had shown an extended time to pregnancy in HIV-positive women attempting pregnancy and not using any form of contraception. Additional research is under way using DHS data, modifying and extending this analysis to 11 high-burden HIV countries worldwide. In addition, a unique detailed community dataset from the United Republic of Tanzania is being cleaned to address similar information and assess trends over time. This work will result in multiple manuscripts for publication in a peer-reviewed journal in 2014 and 2015.
- A research grant was written and supported through a competitive call to assist with a consultation and workshop to be conducted in December 2014, for the development of operations research protocols which include an ethical, legal and social implications (ELSI) dialogue, in the dedicated area of infertility/subfertility and at-risk populations. Following two-side consultations for protocol development at the European Society of Human Reproduction and Embryology and the American Society for Reproductive Medicine, the second research randomized controlled trial (RCT) proposal has been finalized, which addresses researching options of fertility/subfertility interventions for HIV-serodiscordant couples, entitled *A child wish granted – addressing ZERO transmission to partner and child*. These research protocols seek funding and will be submitted to competitive funding calls for this area of work in 2014 and 2015.

### 3. Norms, standards and tools

#### Family planning/contraception

Effective dissemination of evidence through WHO guidelines is critical, to be sure that research results will inform the actions of governments and organizations committed to expanding contraceptive choices for women, especially in low-resource settings.

#### **3.1 Continuous Identification of Research Evidence and the family planning guidelines – revision of the *Medical eligibility criteria for contraceptive use* and *Selected practice recommendations for contraceptive use***

In partnership with the US CDC/WHO Collaborating Centre for Reproductive Health, HRP/RHR uses the Continuous Identification of Research Evidence (CIRE) system to assure that WHO's global family planning guidance is created – and maintained – based upon the best available published evidence since 2002. The PubMed bibliographic database regularly searches for newly published evidence (in any language) relevant to the recommendations of *Medical eligibility criteria for contraceptive use* (MEC) (17) and *Selected practice recommendations for contraceptive use* (SPR) (18). Citations are uploaded and discussed for relevance and a systematic review is prepared (or updated) as needed and later submitted for expert peer review. Experts advise WHO on whether: (i) the current recommendations remain consistent with the body of evidence and no action is needed; (ii) the current recommendation is inconsistent with the body of evidence but the inconsistency is insufficient to warrant interim guidance; or (iii) the current recommendation is strongly inconsistent with the body of evidence and interim guidance should be issued.

#### ***Progress***

The Guidelines Steering Group met in May 2013 to review the scoping questions for the guidelines. A guideline development group will convene in March 2014 to review evidence summarized within systematic reviews and Grading of Recommendations Assessment, Development and Evaluation (GRADE) system summary of finding tables to formulate recommendations. The guideline development group comprises an external, multidisciplinary, gender- and regionally balanced membership with a WHO Secretariat.

#### ***Planned activities***

- Efforts to finalize the revisions of the MEC (17) and SPR (18) are targeted for late 2014. The revisions will be published on HRP/RHR's website. Related counselling tools and job aids will be updated accordingly.
- WHO has received requests from its Member States, as well as professional organizations, to offer information within the SPR in a more user-friendly, simplified format. A job aid (or tool) for health-care providers, tentatively titled "The Contraceptive Service Delivery Tool", based upon the SPR guideline, will be prepared and field-tested for usability during Summer 2014. Tentatively, field-testing is planned in Bangladesh, Congo and Kenya.

### 3.2 Programming strategies for postpartum family planning

Following childbirth, women often lack the support they need to space and limit future pregnancies. By addressing the unique needs of these women, postpartum family planning can help improve maternal, neonatal and child health. *Programming strategies for postpartum family planning (19)* outlines the important elements of a postpartum family planning intervention, to help programme planners and managers identify opportunities to offer family planning to postpartum women within existing health systems.

#### *Progress*

A working group comprising experts in international family planning convened at WHO in September 2012 to prepare the document. Decision-making was through consensus and informed by a synthesis of the peer-reviewed and grey literature. The document was purposefully organized to offer a variety of approaches to support postpartum family planning programme development. Strategies can be applied towards comprehensive programming or to strengthen a single (or multiple) component(s) of a programme. Considerations for design include: examining the local context; applying a health-systems framework to identify needs, challenges and opportunities for strengthening services; and identifying opportunities for integration (i.e. antenatal, labour and delivery, postpartum and postnatal, infant health and immunization). Examples of programme models are offered throughout and supported by a summary of the evidence and country case-studies to guide programme design efforts.

The final document was launched during the 3rd International Conference on Family Planning in Addis Ababa in November 2013, and is available on the WHO website (19).

### 3.3 Contraceptive services delivery in the OptimizeMNH guidance document on task shifting/sharing

#### *Progress*

The WHO OptimizeMNH guidance (20) contains evidence-based recommendations for the safe provision of key maternal and neonatal health interventions by different cadres of health workers. This document also summarizes the WHO recommendations on the cadres, ranging from lay health workers to mid-level providers that may be trained and supported to provide the following contraceptive methods safely: tubal ligation, vasectomy, IUD, implants and injectables, as well as promotional activities. The process of enabling additional cadres to provide a specific health intervention is referred to here as “task shifting” but is also widely known as “task sharing”. This guidance document, and its accompanying policy brief (21), were presented in a special side event at the International Conference on Family Planning in Addis Ababa.

### 3.4 Training Resource Package for Family Planning

The *Training Resource Package for Family Planning (TRP) (22)* is a comprehensive set of up-to-date online training materials on family planning/contraception, based on WHO’s cornerstones for family planning guidance. It includes the components and tools needed to design, implement and evaluate training for both clinical and community-level providers, for pre-service and in-service training.

***Progress***

Nine modules (Benefits of Family Planning, Combined Oral Contraceptives, Male Condoms, Female Condoms, Contraceptive Implants, Family Planning Counseling, IUDs, Progestin-only Injectables, and WHO Family Planning Guidance and Job Aids) include PowerPoint presentations, lesson plans, evaluation tools and job aids, and are currently available online (22), with two more soon to be released. WHO/RHR and the Implementing Best Practices Initiative (IBP) have conducted dissemination activities during the East, Central and Southern African Health Community (ECSA-HC) Best Practices Forum, and the UNFPA regional meeting on Family Planning for five South-east Asian/Western Pacific countries, workshops in francophone Africa in October 2013, and at the International Conference on Family Planning in Addis Ababa in November 2013. All PowerPoint presentations of the modules and one facilitator manual have been translated into French. The remainder will be translated into French and Spanish in early 2014.

***Planned activities***

- RHR is currently completing the development of the new module on Emergency Contraception, as part of the workplan for the United Nations Commission on Life Saving Commodities.
- Follow-up dissemination activities in either French or English will continue. An evaluation survey of all countries that have participated in dissemination activities will be conducted in 2014.

### **3.5 Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations**

***Progress***

A need for guidance, focused at the service-delivery level, on how to ensure that human rights are respected, protected and fulfilled was identified, and a needs scoping conducted. A guideline development committee was created, and spoke monthly by telephone. Systematic reviews of the literature were conducted. Two technical consultations were convened to develop the guidelines. The guidelines have been written and have received conditional clearance by the WHO Guidelines Review Committee.

A need for indicators to monitor accountability to human rights in contraceptive programmes was also identified. A methodology was developed by a WHO-led advisory group, and draft quantitative indicators identified. A draft report has been written, and is being circulated for peer review.

***Planned activities***

- A launch for this guideline is planned in early 2014. Dissemination will also occur as part of the Department's contributions to the ICPD Beyond 2014 agenda.
- Publication of the report on indicators to ensure accountability in contraceptive programmes is also planned for early 2014. Furthermore, the group will continue to develop this body of work through adding policy and qualitative measures to the piece, and identifying where the creation of new indicators is needed.

## Sexually transmitted infections, including HIV/AIDS

### 3.6 Guidelines for the prevention, management and control of sexually transmitted infections

The *Guidelines for the management of sexually transmitted infections (23)* are being updated to provide evidence-based guidance and assist Member States to develop standardized guidelines. A stepwise approach is being proposed, owing to the numerous issues that need to be addressed for various STIs, the cost implication, and the methodological challenges required by the WHO Guideline Review Committee. Phase I will address important STI issues, namely treatment of major STIs, syndromic management, and syphilis screening. Phase II will focus on prevention. As new information becomes available, phase III will address other STIs and phase IV will focus on STI screening.

#### **Progress**

HRP/RHR initiated activities to update the 2003 WHO *Guidelines for the management of sexually transmitted infections (23)* based on the new WHO *handbook for guideline development (24)* approved by the WHO Guideline Review Committee. A STI Guideline Steering Committee meeting was organized in September 2013, to define the scope of the guideline. The first STI Guideline Development Group meeting was convened in December 2013, with the scoping document submitted to the Guideline Review Committee for approval.

HRP/RHR also developed the STI and SRH section of the operational tool *Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions (25)*.

#### **Planned activities**

- Systematic reviews and modelling studies will be completed for the guidelines review meetings for phase I in 2014. Phase II will be initiated next year.
- HRP/RHR will continue to work with the WHO HIV department to develop the comprehensive guidelines on HIV and STIs among key populations.

## Women's health, including reproductive tract cancers

### 3.7 Development of WHO normative guidance on topical pre-exposure prophylaxis

HRP/RHR has been involved in the development and evaluation of microbicides for STI and HIV prevention. The guideline development process is being started, while the late-stage clinical studies to confirm the safety and effectiveness of 1% tenofovir (TFV) gel and the dapivirine ring are under way, in anticipation of successful results. While the first licensure decisions are not expected before 2016, the guidance is being planned and developed in advance, so that the WHO recommendations can be issued soon after licensure. WHO normative guidance is critical to accelerating expansion of a new product in countries and facilitates the use of public funds to support country programmes. The development of the WHO normative guidance on topical pre-exposure prophylaxis will be closely coordinated with other guidance on the strategic use of antiretroviral drugs for treatment and prevention, as well as SRH, gender-based violence, and adolescent HIV testing and counselling.

**Progress**

The Department maintained and updated the inventory of ongoing research related to the regulatory process on TFV gel, continuing the liaison with the TFV Development Group and the TFV Regulatory Group, supported the European Medicines Agency in application of the Article 58 process to involve developing country regulators in the review of registration dossiers, and participated in European Medicines Agency consultative meetings on technologies for HIV prevention. The Guidelines Steering Committee meetings for the TFV gel were convened in June and November 2013. Extensive discussions have taken place with partners in the HIV Department and the International Partnership for Microbicides, to ensure that the guidance on topical pre-exposure prophylaxis and the planning, design and implementation of the introductory and demonstration studies can be built upon experience with developing similar projects for the delivery of oral pre-exposure prophylaxis.

**Planned activities**

- A stakeholder consultation on topical microbicides and Guidelines Development Group meetings is planned for March 2014 in South Africa. The criteria for prioritization and mapping of countries for pre-licensure pre-introductory studies' consideration for TFV gel and/or the dapivirine ring will be completed.

**3.8 Reproductive health commodities in essential medicines**

HRP/RHR has continued to work in collaboration with UNFPA and the Reproductive Health Supplies Coalition on activities aimed at improving access to and quality of reproductive health essential medicines and commodities. This includes conducting the review process to develop and publish technical guidance that defines the quality-assurance processes, specifications, testing procedures and requirements for prequalification and procurement processes for male latex condoms, female condoms and the copper-bearing intrauterine device (TCu380A IUD).

**Progress**

A technical review meeting in September 2013 of 10 technical experts addressed the updating and development of the WHO/UNFPA specifications, prequalification scheme and procurement process for male latex condoms, female condoms and copper-bearing IUD. Initiating this technical review process required a consultation to revise the advisory note on the bulk procurement of personal lubricants for male and female condoms. In addition, a technical consultative process with key stakeholders was started, to guide incorporating the United Nations Policy on Green Procurement, which requires that environmental performance considerations be embedded into the decision-making process, in the same manner as price, performance, quality and availability, for the manufacturing, prequalification and procurement process for contraceptives.

**Planned activities**

- A technical consultation will review and finalize the update of the specification, prequalification and guidance on procurement for the three commodities. This revision will include the implementation and monitoring of practical approaches that enhance the eco-production of these devices.

- Efforts to support the eco-production of products will undertake relevant technical and cost-benefit analysis to make these less restricting and allow possible use of biodegradable materials in packaging.
- A technical consultation to review the evidence and formulate guidance on the bulk procurement of personal lubricants will be planned with partners.

### 3.9 Development of a core set of sexual health indicators

In 2010, WHO convened an expert consultation on sexual health, to make recommendations on strategic directions for work in this area. One specific recommendation of the consultation was to develop, operationalize and promote sexual health indicators, in order to strengthen monitoring and evaluation of sexual health-related activities at national level. Since the establishment of the WHO International Advisory Group on Sexual Health Indicators in July 2011, a working version of the *Core set of sexual health indicators* has been developed. The proposed indicators cover the following areas of sexual health: healthy sexuality, sexual well-being, sexual dysfunction, sexual vulnerability, sexual violence, harmful practices, and adolescent sexual health. The document recommends 15 outcome/impact and determinants indicators as well as a National Commitments and Policy Instrument tool to assess the policy context and environment.

#### *Progress*

Some outcome survey-based indicators have been integrated into ongoing surveys and studies in 2013, including the Integrated Bio-behavioral Surveys among injecting drug users in Russia and in Spain; and the multisite (in 21 EU, Eastern European countries) Integrated Bio-Behavioural Surveys on sexual behaviour. Some of these have also been included in the SIALON II study. The above surveys should assess the validity and feasibility of the indicators in these various settings. The working version of the document was reviewed in WHO regional offices and by the main technical partners, and will be available in electronic format by the end of 2013.

#### *Planned activities*

- Results of the previously mentioned surveys will be monitored to assess how these indicators were used and what results were obtained, for possible revision, if needed.
- HRP/RHR will explore other opportunities to pilot the core set of sexual health indicators into other population groups and in various settings.

### 3.10 Sexuality counselling guidelines for health-care providers

In 2010, WHO convened an expert consultation on sexual health, to make recommendations on sexuality counselling guidelines for health-care providers, to be used for incorporating counselling into primary health-care services and in SRH services. The ultimate goal of this initiative is to ensure access to SRH services for all, and promotion of sexual health. The development of this guideline followed the WHO Guidelines Review Committee's standards (24) and was initiated in 2012.



**Progress**

The main scoping topics included the effectiveness of brief sexuality counselling applied to adolescents and adults, compared to usual standard of care, in addressing various sexual health-related concerns, including preventing HIV/STIs, unplanned pregnancy and abortion, or sexual violence, and promoting sexual well-being, and the identification of which elements of programmes (such as sensitization training) for primary health-care providers increase knowledge and skills on sexuality counselling/communication. Systematic reviews on these various questions were prepared to inform the committee. The guidelines have been drafted and are undergoing review.

**Planned activities**

- The final version of the sexuality counselling guideline for health-care providers will be made available in the first quarter of 2014.
- This process will help to initiate development of a training module on sexual health/sexuality for WHO staff.

### **3.11 Development of WHO normative guidance on the sexual and reproductive health of women living with HIV**

The SRH of women living with HIV/AIDS is fundamental to their well-being and that of their partners and children. The 2006 guidelines on *Sexual and reproductive health of women living with HIV/AIDS: guidelines on care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings* (26) address their specific SRH needs and contain recommendations for counselling, antiretroviral therapy, care and other interventions. Since then, there have been new developments in treatment and on the relationship between HIV and SRH, including contraception, which would have to be updated in this document.

**Progress**

The steering committee meeting to discuss the plans to revise the document was held in September 2013. Key PICOT (Population, Indicator/Intervention, Comparator, Outcome, Time) scoping questions were identified, and a mapping document was prepared to compile other relevant WHO recommendations, documents and publications, and to identify other existing sources of evidence for potential topics to be covered in the updates.

**Planned activities**

- In the interests of ensuring that the priority issues of women living with HIV are addressed through the guidelines, and to ensure broad-based support for, and engagement with, the product, an e-consultation with women living with HIV will be conducted in the first two quarters of 2014. This will be followed by a meeting of the Guideline Development Group in quarters 2 and 3 of 2014.

### **3.12 Updating cervical cancer guidelines for the *Comprehensive cervical cancer control: a guide to essential practice***

*Comprehensive cervical cancer control: a guide to essential practice* (C4-GEP) (27) was first published in 2006 by RHR and the Department of Chronic Diseases and Health Promotion of WHO, and other partners, to provide a single, easy-to-use



publication that puts together existing experience and evidence-based knowledge for the prevention and treatment of cervical cancer. Since then, new evidence and guidelines are available in preparation for the next edition of the CC4-GEP.

### **Progress**

A number of documents have been published this year, in order to provide the background information and evidence to update C4-GEP.

- *Monitoring national cervical cancer prevention and control programmes: quality control and quality assurance for visual inspection with acetic acid (VIA)-based programmes (28)*: this guide outlines quality-control and quality-assurance considerations, to support introduction or scale-up of VIA as a screening test for cervical cancer, within the context of national comprehensive cervical cancer prevention and control programmes. The guide proposes a framework for quality control and quality assurance, including a core set of indicators, and provides examples for how the indicators can be set, measured and used to strengthen programme implementation.
- *Comprehensive cervical cancer prevention and control – a healthier future for girls and women: WHO guidance note (29)*: this WHO guidance note advocates for a comprehensive approach to cervical cancer prevention and control and is aimed at senior policy-makers and programme managers. It describes the need to deliver effective interventions across the female life-course, from childhood through to adulthood. These include community education, social mobilization, HPV vaccination, screening, treatment and palliative care.
- *WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention (30)*: this guideline provides recommendations for strategies for a screen-and-treat programme. It builds upon the existing WHO guidelines: *Use of cryotherapy for cervical intraepithelial neoplasia* (published in 2011) (31) and on the new WHO guidelines for treatment of cervical intraepithelial neoplasia 2–3 and glandular adenocarcinoma in situ (forthcoming).
- *WHO guidelines for treatment of cervical intraepithelial neoplasia 2–3 and glandular adenocarcinoma in situ: cryotherapy, large loop excision of the transformation zone (LEEP/LLETZ), and cold knife conization (CKC)* (forthcoming): this guideline builds upon the WHO guidelines: *Use of cryotherapy for cervical intraepithelial neoplasia (31)* published in 2011, and provides recommendations for the use of cryotherapy versus loop electrosurgical excision procedure (LEEP) versus cold knife conization (CKC) for the treatment of histologically confirmed CIN2+, and additional recommendations for the treatment of histologically confirmed adenocarcinoma in situ.

### **Planned activities**

- The new edition of the C4-GEP will be finalized, compiling the document described above. The comprehensive guide will be published, translated and disseminated in 2014. Implementation plans are already being prepared, in collaboration with WHO regional offices.

## 4. Infertility/subfertility

### 4.1 Development of comprehensive evidence-based guidelines for the diagnosis, management and treatment of infertility and subfertility

Within the mandate of provision of reproductive health care, are the newly prioritized areas of diagnosis of infertility or an inability to become pregnant or maintain a pregnancy; and service interventions for subfertility – fertility care for desired pregnancy, awareness, support and management. Therefore HRP/RHR has started new activities in this area of work, to develop evidence-based guidelines and to update and expand the guidance provided within existing publications: the *WHO Manual for the standardized investigation and diagnosis of the infertile couple* (1993) (32); and the *WHO Manual for the standardized investigation, diagnosis and management of the infertile male* (1999) (32), as well as the *WHO laboratory manual for the examination and processing of human semen* (2010) (33).

#### **Progress**

Initial steps for the development of new and updated comprehensive infertility/subfertility care guidelines require a significant amount of research through systematic reviews in multiple topics. A Guidelines Development Group scoped the field into 26 areas, which covered all aspects of comprehensive fertility care for males and females. Through a global prioritization process in 2013, PICOT questions were developed and systematic reviews commissioned in the following: male (including semen) subfertility diagnosis and management, female subfertility diagnosis and management, controlled ovarian stimulation, intrauterine insemination (IUI), IVF–ICSI (intracytoplasmic sperm injection), polycystic ovary syndrome, endometriosis and provision of reproductive medicine interventions to HIV-positive and HIV-discordant couples desiring pregnancy. In 2013, there have been three Guideline Development Group subgroup consultations held as side meetings during two regional and international congresses.

#### **Planned activities**

- In the next year, WHO will complete the systematic reviews and modelling studies to inform the recommendations on the comprehensive guidelines. Additional side meetings/consultations will be held during 2014, with regional congresses in July and October. The main Guideline Development Group and Expert Group meeting will be held in November 2014, to assess the evidence, make recommendations and identify research gaps. A draft set of guidelines will be submitted in late 2014 or early 2015 for Guidelines Review Committee approval. The next set of priority topics from the 26 scoped areas will be addressed in late 2014.

## 5. Monitoring and evaluation

### Sexually transmitted infections, including HIV/AIDS

#### 5.1 Antimicrobial resistance to *N. gonorrhoeae*

Antimicrobial resistance (AMR) to *N. gonorrhoeae* is increasingly acquiring the dimension of a major public health problem globally, with fewer antibiotics available to treat the infection. In 2012, 36 countries reported increasing the minimum inhibitory concentration to third-generation extended spectrum cephalosporins, with 10 countries reporting treatment failure. HRP/RHR works to expand the Gonococcal Antimicrobial Surveillance Programme (GASP) and implement the *Global action plan to control the spread and impact of antimicrobial resistance in Neisseria gonorrhoeae* (35).

##### **Progress**

More countries now report to GASP, from 50 in 2011 to 67 in 2012. Annual mapping of patterns of gonococcal AMR are available on the HRP/RHR website (36) (see Fig. 2).

WHO reference panel strains are regularly updated to ensure availability of valid, comparable data on gonococcal AMR and to standardize definition of resistance to cephalosporins in *N. gonorrhoeae*. HRP/RHR continues to coordinate the regional GASP network through regular meetings and teleconferences.

The Institute Pasteur in Cote d'Ivoire and the Medical Microbiology Department of University of Nairobi, Kenya were selected as subregional reference centres to support GASP-in-Africa, with training conducted on monitoring of gonococcal AMR.

Work was initiated with the Prince of Wales Laboratory, WHO Collaborating Centre for STIs to support China and the Philippines in developing enhanced surveillance systems for PCR molecular typing in 2014.

Laboratory capacity-building for gonorrhoea diagnosis and AMR monitoring was done in eight countries in the WHO Region of the Americas, 19 Pacific Island countries, two countries in the WHO South-East Asia Region, three countries in the WHO African Region, and five countries in the WHO European Region.

Programmes to integrate strengthening of STI surveillance and GASP were carried out in Indonesia and Zimbabwe.

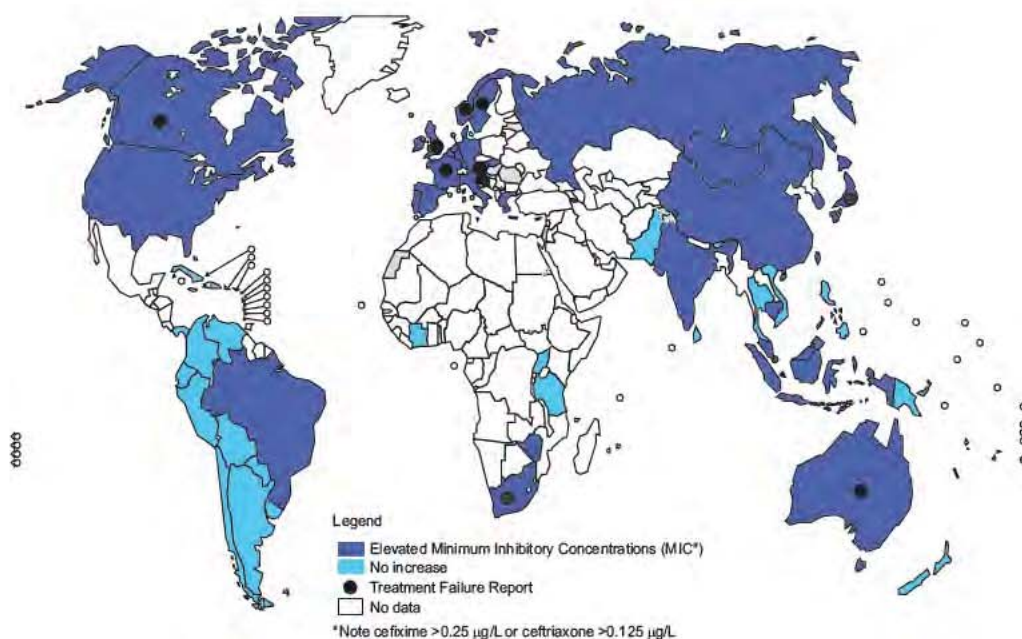
An online training module on gonococcal antimicrobial surveillance, and an operational tool on surveillance, were developed for dissemination starting in 2014.

A supplement on gonococcal AMR was published in the *BMJ* journal *Sexually Transmitted Infections*, in December 2013 (37).

##### **Planned activities**

- HRP/RHR will support GASP-in-Africa to expand countries conducting AMR monitoring, to integrate GASP into overall STI surveillance. In addition, HRP/RHR will organize global and regional GASP network meetings, to review progress and facilitate implementation of the global action plan (35).

Fig. 2. Proportion of strains of *N. gonorrhoeae* with increasing minimum inhibitory concentrations to cefixime and ceftriaxone reported in countries (2010)



## 5.2 The road map for strengthening STI surveillance

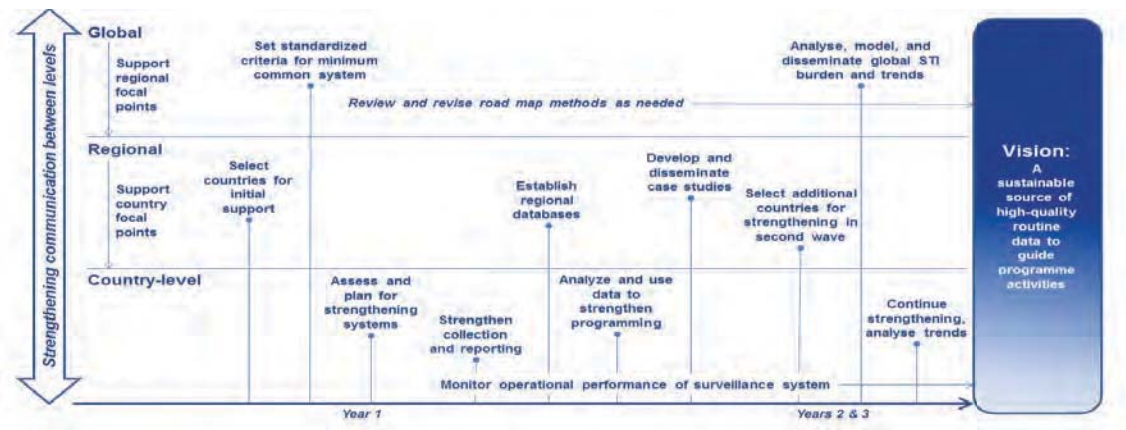
Strengthening surveillance, monitoring and estimation of the burden of STIs at a global, regional and country level is a critical component of WHO's *global strategy for the prevention and control of sexually transmitted infections: 2006–2015* (7).

### Progress

In 2013 RHR published a roadmap for improving STI surveillance (see Fig. 3) and a baseline report on global surveillance (38), which demonstrated that although STI surveillance is being conducted in many countries around the world, there is an urgent need for improved data quality and collection. In response, WHO established a global system of STI reporting through the Global AIDS Response Progress Reporting System, incorporated STI data into the WHO Global Health Observatory Data Repository (39), and worked with regions to conduct STI surveillance-strengthening exercises in eight countries. Global STI surveillance guidance was translated into French, Spanish and Russian, and STI surveillance training modules have been drafted in collaboration with the WHO Regional Office for Europe.

A global consultation on methods for improved global STI estimates was held, at which preliminary work on estimates for chlamydia, gonorrhoea, HSV2, syphilis, adverse outcomes of syphilis in pregnancy, and trichomonas for 2012 were presented. Recommendations were made on how to finalize 2012 estimates and work towards improved estimates in the medium and long term, through establishing national centres of excellence for STI surveillance, and working at a global level to identify a model for how to utilize routine surveillance data for STI estimates.

Fig. 3. Road map for strengthening STI surveillance



Source: Baseline report on global sexually transmitted infection surveillance 2012. Geneva: World Health Organization; 2013 (38).

#### *Planned activities*

- Release a 2014 global STI surveillance report using data collected through the HIV Global AIDS Response Progress Reporting System, and case-studies from pilot exercises
- Publish peer-reviewed manuscripts on the 2012 global burden of syphilis in pregnancy and associated adverse outcomes, 2012 global burden of curable STI, 2012 global burden of HSV2, and lessons learnt from the eight-country STI-strengthening exercises.
- Work with regional offices to establish national centres of excellence for STI surveillance.
- Work with global partners to identify modelling strategies for incorporating routine STI surveillance into global estimation processes.

### 5.3 Monitoring progress in elimination of mother-to-child transmission of HIV and syphilis

EMTCT of HIV and syphilis has been endorsed as a dual initiative in the Americas, Asia Pacific, and Africa, and targets have been set for 2015 and beyond. However, it is critical to have criteria and processes for how to validate that EMTCT has occurred, as well as credible systems to collect data at a global level to assess progress toward EMTCT of HIV and syphilis.

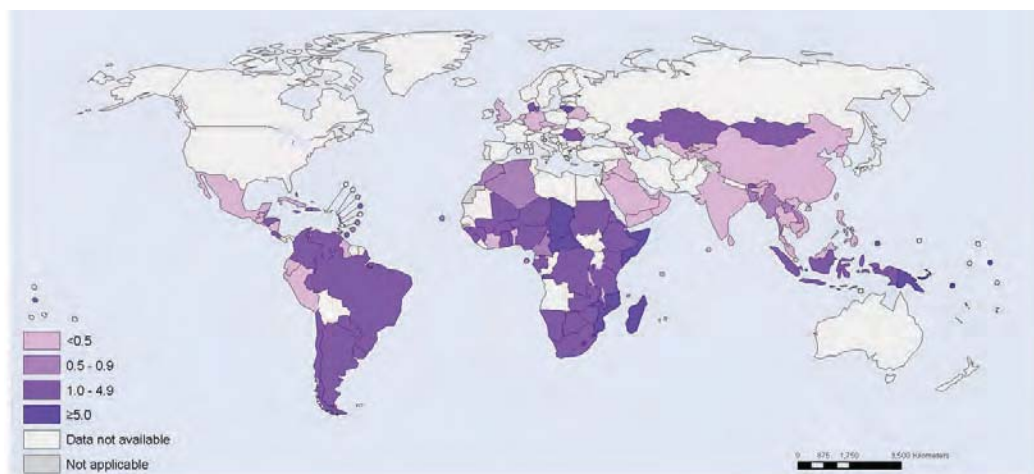
#### *Progress*

WHO worked jointly with UNAIDS, UNFPA and UNICEF to finalize guidance on criteria and processes for validation of EMTCT of HIV and syphilis, intended to help countries improve monitoring, harmonize standards, and celebrate successful country efforts.

Tables and maps of data on syphilis testing and seropositivity in pregnancy, collected through the Global AIDS Response Progress Reporting System were made publicly available through the Global Health Observatory Data Repository (39), to encourage use of the data (see Fig. 4).



Fig. 4. Percentage of antenatal care attendees positive for syphilis (latest available data since 2005)



Source: Global Health Observatory Data Repository (39).

Global estimates of syphilis in pregnancy and associated adverse outcomes were published in *PLOS Medicine* (40), as well as an accompanying meta-analysis of expected adverse outcomes in the *Bulletin of the World Health Organization* (41) in 2013. Estimates for 2012 have been drafted and methodological improvements reviewed and approved by external technical advisers in November 2013.

#### **Planned activities**

- Convene the first global EMTCT of HIV and syphilis validation committee in June 2014, and review evidence for validation of elimination for at least one country.
- Publish a summary of global progress in EMTCT in the 2014 WHO global STI report, and finalize global estimates of syphilis in pregnancy and associated adverse outcomes for 2012.
- Work with PATH to finalize the investment case for dual EMTCT of HIV and syphilis in India, Nigeria and Zambia.

## 6. Dissemination, advocacy and partnerships

### Family planning/contraception

#### **6.1 RHR contributions to the United Nations Commission on Life Saving Commodities for Women and Children's Health**

Under the auspices of the United Nations Secretary-General's Every Woman Every Child initiative, the Commission on Life-Saving Commodities for Women and Children was established to advocate at the highest levels for the increased availability, affordability and accessibility of essential but underutilized commodities, including contraceptives. Within the Commission, RHR leads the Technical Resource Team (TRT) for Emergency Contraception and participates in the TRTs for the Female Condom and for Hormonal Implants.

### **Progress**

A review of the literature on best practices for increasing access to emergency contraception identified mostly studies on knowledge, attitudes and practices of providers and of users, on service provision, and on policy governance. This review will inform the development of operational research proposals on improving access to emergency contraception. This work started in 2013 with a workshop on technical assistance on emergency contraception programmes and on operation research methodology, organized by the International Consortium on Emergency Contraception for representatives of five African countries (Ethiopia, Malawi, Nigeria, Senegal and Uganda) that requested support from the Commission to expand access to emergency contraception. In addition, a module on emergency contraception for the WHO/USAID/UNFPA Family Planning Training Resource Package was developed and is being prepared for field-testing.

For female condoms, HRP conducted the desk review of completed surveys on knowledge, attitudes and practices of female condom users and non-users in various countries with different levels of use of the female condom.

### **Planned activities**

- A report on the review of the literature on best practices for increasing access to emergency contraception will be prepared for journal publication.
- The operations research proposals will be reviewed and approved for funding for implementation in 2014.
- An adaptation of the Family Planning Training Resource Package on Emergency Contraception for pharmacists will be developed and disseminated.
- Development and field-testing of an assessment-monitoring tool and a step-by-step guide for introduction at country level of new types of female condom.

## **6.2 French Muskoka grant in support of reproductive, maternal and child health**

HRP/RHR is implementing the French Muskoka grant to strengthen family planning services in francophone Africa. The grant is implemented by HRP/RHR, in collaboration with the WHO Maternal Newborn Child and Adolescent Health Department and three other United Nations agencies.

### **Progress**

In its second year, the initiative has supported six francophone countries (Cote d'Ivoire, Democratic Republic of the Congo, Guinea, Mali, Senegal and Togo) in the adaptation and dissemination of RHR norms and guidelines, especially the WHO publication, *A guide for family planning for community health workers and their clients* (5) and the Family Planning Training Resource Package (22). All countries also conducted a situation analysis on RMNCH services and various capacity-building workshops for family planning service providers, with emphasis on long-acting methods. In Guinea, 1000 new users of long-acting methods of contraception were reported. National strategic plans were also developed and disseminated in Cote d'Ivoire and Guinea.

***Planned activities***

- In the forthcoming third year of the grant, the focus will be on high-impact interventions in RMNCH, such as scaling up community-based services, making available a wider range of contraceptive methods in clinics, and ensuring informed choice for family planning. The initiative will be expanded to two new countries (Benin and Niger).

**6.3 Activities of the Implementing Best Practices Initiative**

Since 1999, the IBP Initiative has worked at the global, regional and country levels to foster collaboration, reduce duplication, and harmonize approaches among several organizations implementing family planning programmes, to support the identification, implementation and scaling up of effective technical and managerial practices to improve reproductive health.

***Progress******Partnership and knowledge management***

Last year, Futures Group, Plan International, Population Media Center, Hesperian Health Guides, and the West Africa Health Organization (WAHO) joined the IBP Consortium, which now has 41 partners.

In 2013 IBP started implementing its current 5-year strategy and its accompanying results framework. The objectives of the strategy are to increase the scale-up of effective practices in reproductive health, strengthen the ability and commitment of IBP partners to actively work towards expected results, support sustained collaboration at the country level, and enhance knowledge sharing.

IBP partners and the larger reproductive health community keep connected through the Knowledge Gateway, which is a reliable, consistent knowledge-management platform with over 350 000 users worldwide, of which 30 000 focus on reproductive health/family planning, through discussion groups or “communities of practice”. In 2013, new communities were created, including one on “Systematic approaches for scale-up of best practices in family planning/reproductive health”, hosted by the Evidence2Action project, and another by the Alliance for Reproductive Maternal and Child Health on “Family planning research priorities for donors”, in December, 2012.

In addition, IBP established task teams addressing specific activities in the plan of action. The Fostering Change task team has worked with K4Health to finalize the newly updated online Fostering Change tool. The Monitoring and Evaluation task team has finalized a matrix of indicators, in order to evaluate the IBP strategy. The High Impact Practices task team has been created to focus on the dissemination and implementation of high-impact practices. A task team was created to address sharing effective practices in the Latin America and Caribbean region.

***Promoting fostering change for scale-up of effective reproductive health practices in countries and with regional bodies***

The IBP publication, *A guide for fostering change to scale up effective health services (42)* was designed to reinforce the synergy between using proven change-management practices and the introduction, adaptation, use and scale-up of clinical or programme practices, such as in the activities described next.

IBP has supported the ECSA-HC to co-facilitate a workshop in fostering change for scaling up effective practices in Harare, Zimbabwe, for five Member States,



building on successful local experience, which developed a programme to offer nursing students peer-provided reproductive health services in their dormitories.

IBP partners also assisted in organizing and implementing the ECSA 7th Best Practices Forum in the United Republic of Tanzania in August 2013, with pre-conference workshops on family planning technical updates, population, health and environment, SRH and persons with disabilities, and SRH and adolescents.

A new IBP member, WAHO, worked with IBP and ECSA-HC to initiate a process for holding its own Best Practices Forum for the Economic Community of West African States, now being planned for next year.

Finally, Zambia, IBP's first focus country, began activities in October with requested support for documentation of best practices in family planning, to identify practices in the implementation and scale-up of their new 8-year family planning strategy.

IBP hosted 28 sessions at the International Conference on Family Planning in Addis Ababa. The main track of eight interactive sessions focused on overcoming obstacles to scale-up, and on using a systematic approach to scale-up, using practical, tested programmatic tools and approaches. IBP partners also organized smaller workshops to share tools and resources and allowed targeted discussions on implementation of evidence-based practices, expanding on discussions from the IBP main track, and on how to engage at national and regional levels.

IBP partners widely distributed the document, *From Kampala to Dakar and on to Addis (43)*, to capture the lessons learnt from actual implementation of effective practices at the country level, presented during the IBP interactive sessions in the International Conference on Family Planning in Dakar in 2011.

#### ***Planned activities***

- IBP partners will continue to work with ECSA to plan their 2014 Best Practices Conference and to follow up countries on their scale-up activities. The IBP secretariat and partners will continue to work with WAHO to plan and document their first Best Practices Forum in Reproductive Health for the end of 2014.
- Activities will continue with Zambia as an IBP focus country. Validation and dissemination of the document on best practices in family planning will be conducted in early 2014. Another focus country may be identified during 2014. In addition, the IBP main secretariat and partners will follow up regional family planning tools workshops, by supporting countries that have requested technical assistance in documentation and scale-up of effective practices.

## **6.4 The Africa Build EU project: building a research and education infrastructure for Africa**

Africa Build is a coordination action involving eight partners, aiming to support and develop advanced centres of excellence in health care, education and research in the African countries, through information technology (IT).

#### ***Progress***

WHO carried out a survey among the Africa Build users during August to October 2013, to evaluate the Africa Build portal. The report will be completed by January 2014. Two pilot courses in HIV/AIDS research and evidence-based medicine, and in writing recommendations and guidelines and research protocols, were conducted.

Interactive communities of practice have been developed on the Africa Build portal, for exchange and sharing of knowledge between users. In addition, 145 dissemination activities have been completed to date, from the beginning of the project, such as: scientific presentations, newsletters, fact sheets, meetings and conferences. Several interactive communities of practice have been developed and published on the Africa Build portal, to facilitate exchange and sharing of knowledge. As a concrete output, 19 scientific peer-reviewed papers have been published, based on collaborative research work fostered by the project.

#### ***Planned activities***

- HRP/RHR is responsible for the dissemination of activities and will develop the final report of activities carried out during the execution of the project. A meeting with the Africa Build expert committee was held in Cameroon on 25 November 2013, mainly to discuss a roadmap on how the Africa Build portal can continue to be sustained for an effective and shared use.

### **6.5 The cartography of controversies on family planning/contraception**

Family planning has often been at the centre of scientific, political and cultural debates, with major ramifications for individuals and societies. These debates have focused on four main topic areas: demographic factors, health benefits/risks, human rights, and religious and cultural beliefs. The ongoing global effort to increase the supply of, and demand for, contraceptive methods could benefit from an exhaustive analysis of all the issues and actors involved in contemporary discussions of family planning. To contribute to this analysis, the cartography of controversies methodology was applied to the complex debates surrounding family planning. The cartography of controversies, developed by sociologist of science Bruno Latour, is a set of methodologically sound techniques to explore and visualize controversial issues, which is based on analysis of website content, including sites that foster active debate on specific subjects.

#### ***Progress***

The results of the analysis were presented at the International Conference on Family Planning in Addis Ababa 12–15 November 2013, where they generated positive interest. Interesting and unexpected results of the analyses include the very central position in the debate of issues related to religion and pregnancy prevention in young populations. Deserving further analysis is the very limited and marginal presence of the concept of “population growth”, which seems to have lost its centrality in debates on family planning.

#### ***Planned activities***

- Further in-depth analysis will continue in 2014, as preliminary results show how the cartography of controversies approach can help elicit keywords, hot issues and relevant actors shaping the family planning debate. This information can be used to define the best strategies/approaches to interact with/influence this debate and to defuse potentially sensitive issues that can result in negative reactions to the introduction or scale-up of family planning services.

## Sexually transmitted infections, including HIV/AIDS

### 6.6 Partnerships to eliminate mother-to-child transmission of HIV and syphilis

EMTCT of HIV and syphilis will require engagement of global, regional and in-country partners. RHR is working jointly with the WHO Department of HIV to engage partners to attain dual EMTCT of HIV and syphilis.

#### *Progress*

WHO initiated a project called “Dual Testing for Elimination of Congenital Syphilis”, with PATH (funded by the Bill and Melinda Gates Foundation), with a goal to develop investment cases for dual EMTCT of HIV and syphilis in India, Nigeria and Zambia. As part of this project, WHO developed an online tool for countries to estimate the burden of syphilis in pregnancy and associated adverse outcomes (44), and conducted estimation exercises in four countries. These estimates are now being used to guide discussion around national policy, programmatic focus, and improved monitoring strategies, and engage in-country partners.

In 2013 at Women Deliver, RHR launched the *Investment case for eliminating mother-to-child transmission of syphilis: promoting better maternal and child health and stronger health systems* (45), in order to engage global maternal and child health partners. In order to reinvigorate the engagement of the STI and HIV community, it also highlighted dual EMTCT of HIV and syphilis at the International Society for Sexually Transmitted Diseases Research/International Union against Sexually transmitted Infections (ISSTD/R/International Union against Sexually transmitted Infections (ISSTD/R/IUSTI) conference in Vienna, Austria and at the International Conference on AIDS and STIs in Africa (ICASA) in Cape Town, South Africa. WHO is also working with priority countries such as Madagascar, Indonesia and Papua New Guinea, on strategies to accelerate EMTCT.

WHO continued to keep over 100 partners supporting EMTCT of syphilis updated on a routine basis, through the Battling Against Syphilis, a Team Approach (BASTA) newsletter.

#### *Planned activities*

- Work with PATH to finalize the investment case for dual EMTCT of HIV and syphilis in India, Nigeria and Zambia, to improve the evidence on the burden of mother-to-child transmission of syphilis.
- Work with ministries of health in 12 priority countries to create country profiles that summarize the data necessary to engage countries and partners in EMTCT of syphilis.

### 6.7 Contributions to work with the Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund to Fight AIDS, Tuberculosis and Malaria *Strategy Framework 2012–2016* (48) seeks to improve its business model by investing more strategically, to have greater impact on these diseases and to align with the broader MDGs. This new business model has offered Global Fund partners an opportunity to rethink about how grants impact the health outcomes of women and children, through the following areas of support:

- contributing to increased health expenditures at a macro level;

- supporting gender equality and creating an enabling environment for women and young girls;
- supporting health interventions that impact the health of women and children;
- strengthening health systems.

It was designed to enable strategic investment for maximum impact, and central to this is support for RMNCH.

### ***Progress***

HRP/RHR, in coordination with other relevant unit in the Family, Women's and Children's Health Cluster, has been instrumental in identifying challenges and opportunities to maximize the impact of the Global Fund's investments on women and children. Through the promotion of interventions such as malaria in pregnancy (MiP) and the prevention of mother-to-child transmission, HRP has encouraged integration of services as a priority for the New Funding Mechanism. Specific activities in 2013 included: (i) working closely with the Global Malaria Programme, HIV and Global TB Programme departments in WHO, and with UNAIDS, Roll Back Malaria, and Stop TB partnerships, to ensure that areas of RMNCH are included in their Global Fund-related documents and activities; (ii) representing RHR in the interagency working group on Global Fund issues; and (iii) update of the RMNCH technical guidance (49) for inclusion of RMNCH in Global Fund proposals.

### ***Planned activities***

- Assist 5–6 countries during the process for the application to the New Funding Model, ensuring linkages/integration with RMNCH interventions.

## **6.8 Tenofovir Gel Implementation Steering Committee for woman-controlled HIV prevention**

RHR manages the Tenofovir Gel Implementation Steering Committee (TFV ISC), which has been created to steer, coordinate, and accelerate delivery of this new HIV-prevention tool. The committee is a mechanism for coordination, sharing information and ensuring that key stakeholders work together and are accountable for the key decisions needed to ensure timely availability and delivery of this product.

### ***Progress***

At present, the Steering Committee includes representatives of the licence and sub-licence holders and manufacturer (CONRAD and the South Africa Technology Innovations Agency respectively); the representatives of a cooperation agreement to manufacture and distribute TFV gel; possible commercialization vehicle companies; donors for product development; and global and national health authorities and civil society members.

The TFV ISC meetings (Washington, DC, United States of America, March 2013 and Cape Town, South Africa, September 2013) prioritized actions to ensure TFV gets to market after clinical research confirms product safety and effectiveness. These actions include defining implications for: (i) ongoing and planned clinical, social and operations research; (ii) introductory strategies in countries; (iii) listing requirements for how to support effective, safe and sustained product use; and (d) targeting key user populations. A web presence was developed to share information on pre-exposure prophylaxis (50).

### ***Planned activities***

- Plans include maintaining an inventory of the regulatory process in different jurisdictions, progress in relevant research activities, development of alternative formulations to deliver TFV vaginally, impact and cost-effectiveness modelling, demand forecasting, and developments in financing product implementation.
- A stakeholders' consultation is planned (March 2014, Durban, South Africa) to identify and prioritize issues in programme implementation and research on novel topical HIV-prevention products.
- Web content on topical microbicides is to be updated.

## **6.9 The inter-agency working group on sexual and reproductive health and HIV linkages**

The international community has reiterated calls for integrating and strengthening linkages between strategies and services for SRH and for the prevention and treatment of HIV/AIDS. Key challenges are lack of collaborative approaches by technical and funding agencies, vertical donor priorities, and poor communication. In order to overcome these barriers, and to advance, accelerate and harmonize approaches, an inter-agency working group (IAWG) on linkages between SRH and HIV was established by RHR.

RHR co-convenes the IAWG with UNFPA and continues to support a variety of tools and approaches to strengthen SRH and HIV linkages including the SRH and HIV linkages resource pack (51), which is an adaptable set of resource materials targeted to national governments, and international and national nongovernmental organizations, United Nations agencies, and donors. This material is updated prior to the International AIDS Conference and World AIDS Day each year, and widely disseminated through the IAWG and other partners.

### ***Progress***

An overview document to promote the work of the SRH/HIV IAWG has been finalized and the website for SRH and HIV linkages reconfigured and updated (51).

### ***Planned activities***

- The next SRH/HIV IAWG meeting is planned for early 2014, to bridge dialogue and activities related to multipurpose prevention technologies (MPTs).

## **6.10 Initiative for Multipurpose Prevention Technologies**

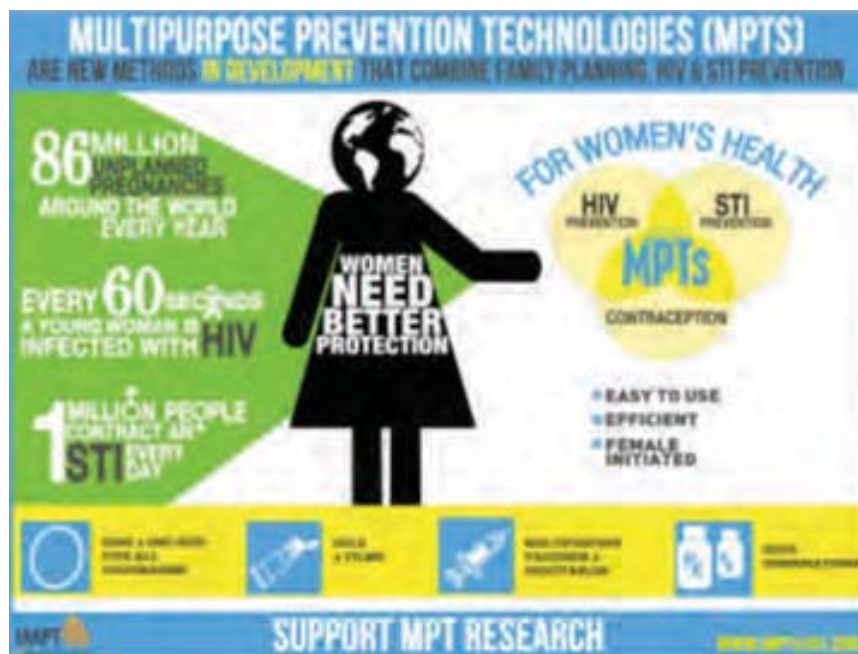
MPTs are products that address multiple threats to SRH – unintended pregnancy, HIV and other STIs. HRP/RHR plays an active role in the Initiative for Multipurpose Technologies (IMPT) as steering committee member, provides technical support to the Scientific Advisory Working Group of the IMPT, and co-chairs the committee with the National Institutes of Health and the STI sub-working group of the IMPT.

### ***Progress***

HRP/RHR provided support to IMPT to identify lead products, establish target product profiles and assess the most efficient pathways for clinical evaluation, and in extensive advocacy and communication efforts (e.g. Fig. 5). While condoms do prevent both pregnancy and STIs if used correctly and consistently, new methods have been identified and prioritized, including (i) devices – SILCS diaphragms and condoms; (ii) vaginal rings; (iii) matrix rings versus reservoir rings; (iv) vaginal tablets; and (v) vaginal film.

HRP/RHR submitted two funding proposals on MPTs to the Bill and Melinda Gates Foundation, in collaboration with CONRAD and the University of Ghent, Belgium.

Fig. 5. MPT infographic developed in collaboration with partners in the IMPT



#### Planned activities

- A special supplement on MPTs will be published in *BJOG: An International Journal of Obstetrics and Gynaecology* in 2014.

## Infertility/subfertility

### 6.11 Activities for infertility/subfertility programmes

A growing body of evidence is showing that pre-pregnancy care can increase the health and well-being of women and couples and improve subsequent pregnancy and child health outcomes. The evidence has shown that, in addition to addressing stigmatization, misconceptions and a gap in the continuum of care, those who require assistance to achieve pregnancy – especially those from low- and middle-income countries and in low-resource settings – require greater clinical and programmatic support.

#### Progress

The WHO global consensus document on preconception care (52) identified immediate pre-pregnancy as an important period to address within the strategy to prevent maternal and childhood mortality and morbidity. Infertility/subfertility-related health problems, behaviours and risk factors that contribute to mortality/morbidity have been described, as well as evidence-based interventions for delivery of public health care.

The first WHO dedicated pages on infertility/subfertility care were developed and first published in 2013 (53).



### **Planned activities**

- With the present nongovernmental organization partners – the International Federation for Fertility Societies (IFFS) and the International Committee for Monitoring Assisted Reproductive Technologies (ICMART), new plans of work (2014–2016) have been completed. These include generating a joint country-level surveillance of assisted reproductive technology policy, services and practices; and revision and expansion of the infertility/subfertility glossary (54, 55).
- In collaboration with the University of Sheffield (UK) Departments of Communication/Reproductive and Developmental Medicine, a commissioned plan for a communication strategy for infertility/subfertility will be developed and implemented.
- To address the environment and effects on reproductive health fitness, a congress has been planned for January 2014, with technical support from two departments in the Family, Women's and Children's Health Cluster – RHR and Public Health and the Environment. In addition, symposia (with side meetings, multiple guidelines, and a Semen Manual) are planned for two major regional meetings on infertility/subfertility in 2014; a plenary in May 2014 for the International Consultation on Men's Health and Infertility; and, an ELSI summer course on all aspects of infertility care, Summer 2014.

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# Improving Maternal and Perinatal Health

## Summary

Despite significant progress in reducing maternal mortality globally, many important challenges remain. As countries increase institutional births and reduce the number of deaths, issues relating to quality of care and equity become more visible and pertinent. For maternal and perinatal health, poor quality of antenatal and intrapartum care, over medicalization during pregnancy and childbirth, with overuse of technologies such as ultrasound and caesarean section, have become important. On the other hand, access to safe and high-quality abortion services continues to be restricted and challenging in most countries. For both maternal health care and prevention of unsafe abortion, disrespect and abuse of women at health-care facilities have become important public health issues. These issues are relevant to most low- and middle-income countries and it is therefore essential for the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) to focus on all Member States with such problems.

As recommended by the Scientific and Technical Advisory Group (STAG) in 2013, the Department has increased its focus on quality of intrapartum care and caesarean section, and the work on these areas will expand in 2014. Similarly, the Department continues to focus on access to safe abortion services, through its work on midlevel providers and, in particular, expanding the use of medical abortion methods.

### Key objectives

The RHR/MPA (Maternal and Perinatal Health and Preventing Unsafe Abortion) team is responsible for research and normative work on maternal and perinatal health. The team has a large portfolio of activities based on its rich collaboration within the HRP research network, to answer questions that can be addressed through large, multicountry projects. Specifically, the team strives to generate new knowledge and develop evidence-based recommendations to promote quality and respectful care for pregnant women. The RHR/MPA team has special interest and focus on developing new research methodologies and improving the science of implementing evidence-based practices based on WHO recommendations. In 2013, the team has increased collaborative activities with academic institutions as well as nongovernmental organizations (NGOs), and with private institutions through public–private partnerships.

### Major achievements

- The *Lancet* publication of the *WHO multicountry survey on maternal and newborn health 2010–2012* in March 2013, together with the *British Journal of Obstetrics and Gynaecology* supplement, including 12 secondary analyses. This study provided the largest international evidence base in the area of severe maternal morbidity and mortality in facilities and confirmed that, while coverage of effective interventions is high, it is not sufficient to reduce avoidable morbidity and mortality.

- Completion of the short-term catheter stay trial following simple vesicovaginal fistula repair. This non-inferiority, randomized controlled trial is the largest trial in this field and demonstrated that a 7-day catheter stay is the recommended practice following surgery.
- Two large-scale research projects, namely the fetal growth study and the implementation research on antenatal care in Mozambique, have regained momentum after suffering delays in earlier years, and will be completed in the 2014–2015 biennium.
- The large multi-year multicountry research initiative on medical abortion has been completed. Although several results still need to be written, 21 studies in 30 countries on clinical, health systems and social science evidence on this topic have been completed.
- The WHO publication *Safe abortion: technical and policy guidance for health systems* was translated into seven languages and is one of the most in-demand publications of the Department.

## 1. Introduction

In recent years, several trends in maternal and perinatal health and preventing unsafe abortion have emerged. These include significant reductions in maternal deaths globally, although the progress is largely uneven between regions and countries and within countries. With the reduction in deaths, two issues have become important. First, is the increasing focus on severe maternal morbidity, which could serve as a proxy for high-quality and humane maternity care. The second is the changing patterns of causes of maternal death. Indirect causes are becoming increasingly important, although understanding of how that works in specific settings is not adequate. These changes could represent an “obstetric transition”, which is conceptually similar to the so-called “epidemiologic transition” that describes the shift from a pattern of high prevalence of communicable diseases to a pattern of high prevalence of noncommunicable diseases (1). In anticipation of these changes, the World Health Organization (WHO) Department of Reproductive Health and Research (RHR)/Maternal and Perinatal Health and Preventing Unsafe Abortion (MPA) team has been working on maternal severe morbidity and near-miss mortality for some time. In addition, it has identified new priority areas such as intrapartum care (including caesarean section), which were endorsed by the Scientific and Technical Advisory Group (STAG) in 2013. In addition, in the 2014–2015 biennium, the team plans to expand the work to cover antenatal care, and disrespect and abuse during childbirth.

The same concepts express themselves in a slightly different way in the area of preventing unsafe abortion. While the proportion of deaths due to unsafe abortion is likely to be smaller – probably due to increased use of medical methods – significant problems remain and new challenges emerge in the provision of safe abortion services. Stigma, disrespect and abuse are prevalent, while conscientious objection by health-care providers as a barrier to provision of abortion services is an emerging issue.

The team will continue to focus on research and normative work on best practices in this area. Concurrently, it will focus on developing and assessing the value of new methodologies in both research and research synthesis, and developing research capacity through the newly formed Academic Alliance.

## 2. Research and development

### 2.1 Care during pregnancy

#### *Progress*

##### *Implementation of the WHO antenatal care model in Mozambique*

Implementation bottlenecks and health-system constraints often limit the full availability and accessibility of antenatal care services at health-facility level. To address these constraints, a multi-year implementation research project in Mozambique aiming to increase the delivery of evidence-based antenatal care practices by midwives, and promoting the integration of key interventions into routine antenatal care, is being undertaken. On the basis of the formative research undertaken in 2012–2013, an intervention package that is tailored to the local service context, and acceptable to local pregnant women and health-care providers, will be implemented, following a facility-based cluster randomized controlled trial (RCT), with a stepped-wedge design. The intervention includes provision of antenatal kits, a storage system, a tracking system, and training sessions for health-care providers. In 2013, four types of kits were designed and ordered. The protocol has been published and baseline data collection has commenced.

##### *Multicountry study to develop fetal growth standards*

The United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children's Fund (UNICEF)/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)/RHR is implementing a multicountry study to develop fetal growth standards for international application, by assessing fetal growth under nutritionally unrestricted conditions in populations of different ethnic and geographic backgrounds. The study is ongoing; 10 countries are participating and 806 pregnant women had been recruited by 31 October 2013. The study aims to achieve a sample size of 1400 women by July 2014.

#### *Planned activities*

- Ten facilities in different regions of Mozambique, selected by the Ministry of Health to implement the antenatal care project, will start receiving the intervention in 2014.
- Recruitment to the fetal growth study will be completed in July 2014 and the results will be available by mid-2015.

### 2.2 Severe maternal morbidity, maternal near-miss and maternal mortality

#### *Progress*

##### *WHO multicountry survey on maternal and newborn health*

The WHO multicountry survey on maternal and newborn health (WHO MCS) (2) was a cross-sectional, facility-based survey conducted from May 2010 to December 2011. The survey aimed to assess the management of severe maternal complications and the prevalence of maternal near-miss. It captured information on over 314 000 women in 359 facilities across 29 countries in five WHO regions.



The primary findings of the WHO MCS were published in *The Lancet* in May 2013 (3), concluding that, to achieve a substantial reduction in maternal mortality, a comprehensive approach to emergency obstetric care, and overall improvements in the quality of maternal health care, will be needed. In parallel, the WHO MCS network collaborators conducted several global analyses of the dataset, including social determinants of health, major causes of maternal mortality and morbidity, neonatal care, and other aspects of maternal and perinatal health. Twelve scientific papers have been accepted for publication in a *British Journal of Obstetrics and Gynaecology* special supplement dedicated to maternal and perinatal health (January 2014).

#### **Planned activities**

- The team is coordinating several lines of secondary analysis of the WHO MCS on preterm birth in low- and middle-income countries, in cooperation with the Preterm Birth International Collaborative (PREBIC).

## **2.3 Hypertensive disorders of pregnancy**

### **Progress**

#### *Screening for pre-eclampsia: evaluation of the predictive ability of angiogenic factors*

The objective of this multicentre observational study is to evaluate whether changes in serum and urinary angiogenic proteins, substances potentially involved in the genesis of hypertension in pregnancy, can be used as an effective method for identifying women at high risk of developing pre-eclampsia. Recruitment is finished and blood/urine samples have been analysed. Results of the study are going through statistical analysis. The final results will be submitted for publication in January 2014.

#### *Long-term calcium supplementation in women at high risk of pre-eclampsia: a multicountry, double-blind, randomized controlled trial*

Calcium supplementation has been shown to reduce the severity of pre-eclampsia, maternal morbidity and neonatal mortality when the supplementation starts around mid-pregnancy, particularly in women with low calcium intake. Current WHO guidelines recommend 1.5–2.0 g daily elemental calcium supplementation in pregnant women, from 20 weeks' gestation until the end of the pregnancy. However, calcium supplementation in the second half of pregnancy may be too late to affect pre-eclamptic processes, which could be addressed by earlier supplementation. HRP/RHR is conducting a multicountry randomized, double blind, placebo-controlled trial to assess whether calcium supplementation before, and in the first half of, pregnancy reduces the incidence of recurrent pre-eclampsia more effectively than supplementation starting at 20 weeks. The trial started in 2011 and, as of November 2013, 1093 women have been screened; 472 have been recruited and 141 pregnancies have been recorded in sites in Argentina, South Africa and Zimbabwe. The required sample size (1440 women) will be reached in 2015. The Data and Safety Monitoring Board met in February 2013 and the second steering committee meeting was held in East London, South Africa, in March 2013.



*Simplified Treatment for Eclampsia Prevention using Magnesium Sulfate: a multicentre randomized non-inferiority trial (STEPMAG trial)*

Magnesium sulfate is widely accepted as a life-saving drug for preventing the progression of pre-eclampsia to eclampsia and avoiding associated complications. There is compelling evidence that it halves the risk of eclampsia and probably reduces the risk of maternal mortality in women with pre-eclampsia. While coverage relating to the use of magnesium sulfate as prophylaxis and treatment for eclampsia seems to be improving worldwide, its use is still largely limited to hospitals where skilled health workers are available to provide care. A technical consultation was held in June 2013, where international research partners identified a clear need for a randomized trial of a simpler magnesium sulfate regimen for treating women with pre-eclampsia/eclampsia. The first meeting of the project technical working group was held in October 2013, to review evidence and research plans. The key outcome of the meeting was an agreement on a stepwise approach to identify a simpler regimen that is not inferior to the current standard regimens.

**Planned activities**

- **STEPMAG trial:** a pharmacokinetic–pharmacodynamic modelling activity will be conducted, led by experts from Merck in collaboration with HRP/RHR staff. Two new systematic reviews, a Cochrane review update and protocols for an international survey of hospital practices are being developed. The next meeting of the technical working group to review the findings of the ongoing work will be in April/May 2014. Once this formative work is completed, it is anticipated that the trial will commence in 2015.

## 2.4 Intrapartum care and obstructed labour

**Progress**

*Non-inferiority of short-term catheterization following fistula repair surgery*

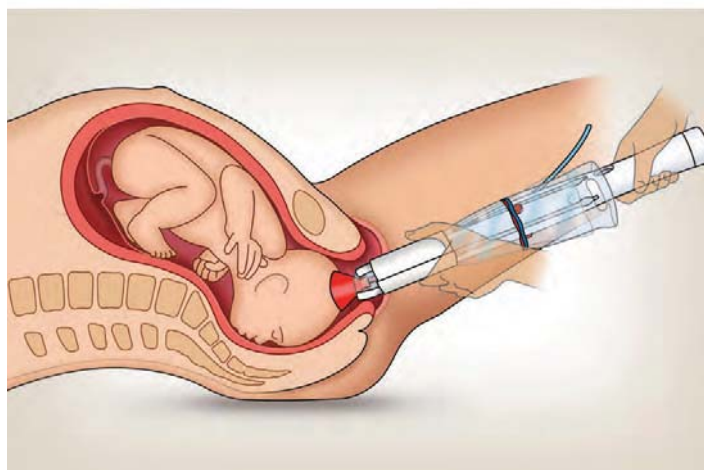
HRP/RHR, jointly with EngenderHealth, coordinated and implemented the non-inferiority of short-term catheterization following fistula repair surgery trial. The trial's main objective was to evaluate whether short-term (7-day) catheterization is not inferior to longer-term (14-day) catheterization, in terms of incidence of fistula repair breakdown. Eight facilities across eight African countries (Democratic Republic of the Congo, Ethiopia, Guinea, Kenya, Niger, Nigeria, Sierra Leone and Uganda) participated in the study. The trial started in December 2011 and completed recruitment in August 2013, achieving a sample size of 524 women with simple fistula. The trial showed that 7 days' catheterization is not inferior to 14 days' catheterization after fistula repair surgery. The results of the trial will be submitted for publication in December 2013.

*Feasibility and safety study of a new device (Odón device) for assisted vaginal delivery: phase I trial*

The objective of this study is to evaluate the safety and feasibility of the Odón device (see Fig. 1) in assisting vaginal delivery in singleton term pregnancies during the second stage of labour, under normal conditions. This study is a hospital-based, multicentre prospective phase I cohort study with no control group. One-hundred and thirty pregnant women will be recruited in tertiary care facilities. The protocol was published in 2013; data are available for the first

30 women recruited in Argentina and a manuscript describing the results and the experience with this innovative proposal is in preparation. In 2013, HRP/RHR signed a partnership agreement with Becton Dickinson to ensure technical optimization, large-scale manufacturing and global distribution of the device, at affordable prices for low-resource countries.

**Fig. 1. The Odón device**



#### *Disrespect and abuse of women during childbirth in facilities*

Increasing skilled birth attendance during childbirth is required to improve maternal care and reduce maternal mortality at birth worldwide. However, disrespectful and/or abusive treatment of women by skilled attendants in facilities is a significant barrier to increasing skilled birth attendance. A 2010 landscape analysis by the United States Agency for International Development (USAID)–TRACTION project identified physical abuse, non-consented care, non-confidential care, non-dignified care, discrimination based on specific patient attributes, abandonment of care, and detention in facilities as occurring in facilities during childbirth globally. However, there is a lack of clear, universally accepted definitions of what constitutes disrespectful and/or abusive care in these settings, as well as a lack of operational definitions, of validated measurement methods that encompass basic human rights principles, and of reliable prevalence estimates. A mixed methods systematic review is being conducted to provide a comprehensive synthesis of qualitative and quantitative evidence on disrespect and abuse in facilities during childbirth. This review is informing a technical consultation of international experts (including researchers, clinicians, advocacy groups and other stakeholders) on disrespect and abuse, being held in Geneva in November 2013. At the consultation, the current evidence on definitions, measurement and prevalence of disrespect and abuse were reviewed and a disrespect and abuse research strategy was developed.

#### *Planned activities*

- **Better Outcomes in Labour Difficulty (BOLD) project:** following several technical consultations and bilateral discussions with the Bill and Melinda Gates Foundation, a 2-year planning grant for an intervention trial was received in October 2013. The project aims to develop tools that will (i) facilitate monitoring of the woman and the baby during childbirth and (ii) create demand for good-quality and respectful care in the facility. The project is a

partnership between HRP, M4ID (a social enterprise leveraging communication technology for development and health based in Finland), the University of São Paulo, Brazil, Ibadan University, Nigeria, and Makerere University, Uganda. The team will conduct a cohort study to develop and validate labour-management algorithm, tentatively named SELMA (Simplified, Effective, Labor-Monitoring Assistant), formative research to assess the quality of care in district-level facilities, and community-level work to develop a “Passport to Safe Childbirth”, which will be carried by the women when they come to the facility for birth.

- **Gentle Assisted Pushing (GAP) trial: a three-arm randomized controlled trial of GAP and/or upright posture compared with current routine practice (recumbent/supine posture) to reduce prolonged second stage of labour.** A prolonged second stage of labour is hazardous for the baby; therefore, fundal pressure is frequently applied to expedite delivery. However, there is very little objective evidence of the effectiveness or safety of applying fundal pressure. The recumbent/supine posture for the second stage of labour has become routine in health services in low-resource settings. There is some evidence that upright postures may have advantages for mother and baby, but more evidence is needed. This trial aims to evaluate a gentle, innovative method of applying fundal pressure (GAP), and/or postural variations, to reduce the incidence of prolonged second stage of labour and the risk of associated maternal and neonatal complications, at all levels of care.
- **iDeliver – Developing a Scalable Solution to improve the Quality of Care for Institutional Deliveries in Low-Income Settings – moving beyond contact to content:** HRP will collaborate with Merck for Mothers to develop an eHealth tool that supports both measurement and delivery of quality intrapartum care. The project will take advantage of existing mobile health (mHealth) platforms that the department has developed, and the BOLD project, specifically the SELMA tool.
- **Feasibility and safety study of a new device (Odón device) for assisted vaginal delivery – phase I trial:** phase I will be completed in 2014, with the recruitment of 100 additional women, both multiparous and nulliparous, in Argentina and South Africa.

## 2.5 Postpartum haemorrhage

### *Progress*

#### *Carbetocin room temperature stable (RTS) for preventing postpartum haemorrhage: a randomized non-inferiority controlled trial*

This trial, which is a hospital-based, multicentre, double-blind, randomized, non-inferiority, active controlled trial, will be implemented in collaboration with Merck for Mothers and Ferring Pharmaceuticals, who manufacture carbetocin. The main objective of this trial is to evaluate whether carbetocin RTS 100 µg intramuscular (IM) is non-inferior to oxytocin 10 IU IM, as a uterotonic during the third stage of labour, in preventing postpartum haemorrhage in women delivering vaginally. Centres from 12 countries are expected to recruit 29 000 women over a period of

12 months. The trial will start in July 2014. If carbetocin is shown to be non-inferior (or superior) to oxytocin, the findings of this trial will facilitate registration and wider access to carbetocin in low- and middle-income countries.

#### ***Planned activities***

- During 2013, preparatory activities with Ferring and Merck for Mothers were conducted. The trial protocol was developed and a presentation was made to the United Kingdom of Great Britain and Northern Ireland Medicines and Health Regulatory Authority. The trial recruitment will start in the second half of 2014.

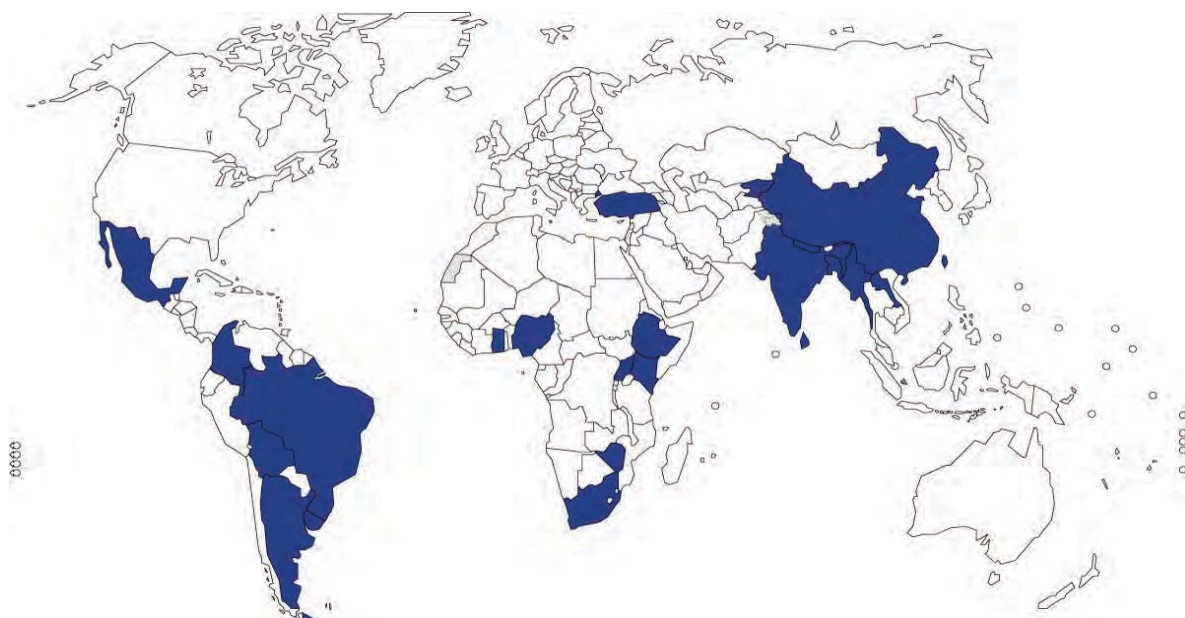
## **2.6 Preventing unsafe abortion**

### ***Progress***

#### ***Research to expand access to medical abortion***

The 5-year project on “Social Science and Operations Research to Expand Access to Medical Abortion” drew to a close. However, while no new projects will be taken up, several of the research studies that were developed or supported as part of this initiative are still in the implementation or analysis phase. Thirty research projects, covering 21 countries and spanning most of WHO’s geographic regions, were supported through this initiative. Fig. 2 shows the geographical distribution of the projects. Results from some of the studies are under review in journals, and a special supplement in *Reproductive Health Matters* highlighting the study findings is also under development.

**Fig. 2. Countries where studies were conducted as part of the initiative to expand access to medical abortion**



The countries included Argentina, Bangladesh, Bolivia (Plurinational State of), Brazil, China, Colombia, Ghana, India, Kenya, Kyrgyzstan, Lao People’s Democratic Republic, Mexico, Myanmar, Nepal, Nigeria, South Africa, Turkey, Uganda, Uruguay and Zimbabwe.

The earlier years of the grant period (phase 1) focused on studies that examined the perspectives and attitudes of potential and current providers to using medical abortion. These have been reported on in previous years. More recently, the grant has focused on exploring the roles of non-physician providers, or of supportive technology like mHealth to expand access, or on documenting the health impacts of moving from unsafe to safe abortion.

Specific research projects included are presented next.

#### **Nurse provision of medical abortion: Mexico**

A non-inferiority RCT was conducted in three public sector clinics in Mexico City. A total of 1017 women with gestational age <70 days were randomized to receive medical abortion by a physician or a nurse. The rate of successful medical abortion without the need for surgery was 98.7% for physician-led care and 97.7% for nurse-led care, which is well within the predetermined margins of non-inferiority. Contraceptive acceptance was similar in the two arms and both physicians and nurses estimated gestational age as well as estimates made with ultrasound. In this study, nurses provided medical abortion to 10 weeks and successfully managed the process using a protocol that allowed home use of misoprostol.

#### **Midwife management of incomplete abortion: Uganda**

A two-sided equivalence RCT comparing the safety and efficacy of incomplete abortion management using misoprostol, between midwives and physicians in primary care settings, is ongoing. A total of 880 women presenting for treatment of incomplete abortion at the six facilities (district hospitals and level IV health centres) were randomized to management by a physician or a midwife. The pilot study showed a 98% success rate for midwives (similar to physicians) in correctly diagnosing and managing incomplete abortion. The acceptability of the task shifting was high among women, as well as among the providers themselves. There were no serious adverse events. Early results from the main trial (based on analysis of the first 260 cases) show a similar pattern. The final results are expected by March 2014.

#### **Primary care, midlevel provision of medical menstrual regulation in Bangladesh**

This feasibility study is being conducted in collaboration with the Directorate General of Family Planning, Population Council, Bangladesh and Marie Stopes Bangladesh. A total of 1882 women received menstrual regulation (MR) with medications at 11 public primary care facilities and two NGO facilities outside of the capital. A total of 1882 women received medical abortion during the study period; care at all the government facilities was offered by auxiliary health workers. Ninety-two per cent of the women returned for follow-up and, of these, 95% had a successful MR without needing surgical intervention. No serious adverse events were reported and the referral system functioned well. Medical MR was found to be acceptable to women as well as providers.

#### **Feasibility of nurse provision of medical abortion in rural Kyrgyzstan**

Following a national situation assessment, the Kyrgyz Ministry of Health requested technical support from HRP/RHR to design a feasibility study to train midwives to provide medical abortion, in order to extend safe abortion care to women living in rural, underserved areas. The study is being conducted in collaboration with the Kyrgyz Alliance of Midwives at one reproductive health centre, a maternity hospital, and 28 primary care Felsher Obstetric Points (primary care centres). Midwives provide pre-abortion counselling, assess gestational age and eligibility



for medical abortion, provide combination mifepristone and misoprostol to 9 weeks' gestation, and assess the woman at the follow-up visit. Safety and acceptability are being monitored over a 9-month observation period. Data-collection forms have been finalized and training in data management is being held. Study enrolment is expected to commence in January 2014.

#### **Pharmacy workers: Nepal**

A quasi-experimental design was used to test the effects of a training intervention with pharmacy workers. Staff from 214 pharmacies selected through cluster sampling in the intervention district received baseline and refresher training on providing accurate information about medical abortion drugs and referral. Baseline and end-line data were compared to similarly selected pharmacies from a neighbouring control district. There were significant increases in the accuracy of knowledge among the intervention group. However, despite the emphasis placed in the training on the importance of client referral to safe abortion facilities, only one fifth of the intervention pharmacies made such referrals. It is likely that the profit margin involved in the sale of these drugs was a deterrent to making referrals. Those who did make referrals were most often staff from pharmacies that did not themselves stock or sell mifepristone/misoprostol.

#### **Pharmacy workers: Kenya**

Based on a mapping of pharmacy shops in the urban slum areas of Nairobi and its outskirts, 135 pharmacies were randomized into intervention and control groups. Pharmacy workers from the intervention pharmacies received 8 hours of training on the national laws, post-abortion care, misoprostol, contraceptives and the referral of clients for reproductive health services. Monitoring data were collected for 6 months, using structured questionnaires and log books, and by simulated clients. At the end-line interviews, providers in the intervention group (71.4%) were more likely to offer information on when to seek help after dispensing misoprostol, compared to 39.3% in the control group. The intervention group was also more likely to offer information on, and to dispense, medication and contraceptive technologies when compared with their counterparts in the control group; however, referrals to safe providers did not increase significantly.

#### **Medical abortion provision with auxiliary nurse midwives: Nepal**

This quasi-experimental study studied the effectiveness of engaging female community health volunteers (FCHVs) and auxiliary nurse midwives (ANMs) in enhancing clients' accessibility, acceptability, confidence and satisfaction with medical abortion. ANMs (see Fig. 3) at 16 public sector primary care sites in the intervention district were trained to provide medical abortion. Community health volunteers in the catchment areas of these facilities were trained to administer urine pregnancy tests and to provide accurate information and referral to women with an unintended pregnancy, as well as to raise awareness about safe abortion in the community at large. At the end of one year, 304 women had received medical abortion from auxiliary nurses stationed at health posts, with complete abortion without surgical intervention in 98.6% of cases. There was a significant increase in FCHV knowledge about medical abortion, and also in their ability to correctly use urine pregnancy-testing kits. However, referral patterns did not change significantly and most women who reached the health posts did so as a result of direct contact with the auxiliary nurses in the community.

**Fig. 3. Auxiliary nurse midwives at the launch of medical abortion services**



#### **Medical abortion eligibility assessment by community health workers in Ethiopia, India and South Africa**

The extent to which community health workers can use simple evaluation checklists to accurately determine eligibility for medical abortion, and to identify women who need follow-up care after a medical abortion, is being conducted in three diverse countries where, despite liberalizations to the law, major challenges in access to safe abortion, and a shortage of trained providers in the public sector, persist (see Fig. 4). All three countries have an interest and potential to expand the role of community-level workers to abortion-related care. Data collection is complete in Ethiopia and South Africa but still ongoing in India. Preliminary results from the first 461 cases show that there is close agreement between physician and community health worker assessments using the checklists. The final results are expected in January 2014.

**Fig. 4. Community health worker assessing eligibility for medical abortion at a clinic in India**



### **mHealth for supporting women having medical abortion: South Africa**

This study evaluated the role of text messaging (SMS) support for women having a medical abortion. A total of 469 women undergoing a medical abortion at four Cape Town clinics were randomized to receive usual care or intervention in the form of mobile messaging support. The SMS messages were written to coach women through medical abortion, with timed reminders to take medication and information on managing side-effects or potential problems, as well as providing family planning information through the iChooseWhen mobi-site. Members of the intervention group felt considerably more satisfied and had less stress and anxiety over the medical abortion process than did the individuals in the control arm. The intervention did not alter contraceptive uptake rates, which were high in both groups, nor did the text messages reduce unscheduled calls to the provider.

### **Assessment of the cost of abortion care provision: Colombia**

Data were obtained from 1411 unlinked anonymous hospital billing records from three hospitals in Cartagena and Medellin. The average cost of an uncomplicated manual vacuum aspiration (MVA) at a clinic was nearly half the cost of the same procedure at a hospital (US\$ 197 versus US\$ 374). The cost of an uncomplicated, clinic-based MVA was nearly one third of the cost of a hospital-based dilatation and curettage (D&C; US\$ 197 versus US\$ 657). Post-abortion care with complications cost more to treat than legal induced abortion. The health systems could save costs by increasing existing medical abortion services and switching from D&C to MVA. If all of Action Research and Training for Health (ARTH); Udaipur; India the current post-abortion care cases could be replaced with legal abortion (medical or surgical), the health system would save an additional US\$ 163 000 dollars. The health system could potentially save an additional US\$ 177 000 (per 1000 women) from baseline, by replacing D&C with medical abortion or MVA.

### **Misoprostol availability and the changing the nature and severity of unsafe abortion (Ghana, Lao People's Democratic Republic, Myanmar, Nigeria and Sri Lanka)**

This multicountry study is a descriptive hospital-based study in five countries that is attempting to test the hypothesis that the increasing the availability of misoprostol, even in restrictive legal environments, is decreasing the severity of abortion complications. Data collection includes a 5-year retrospective case record review to determine whether the volume and nature of abortion complications has changed, as well as structured interviews with 4000 women (800 per country) presenting with abortion complications, in order to determine the nature and severity of complications and possible linkages to the methods of abortion used. In-depth interviews with a subset of women who admit to using medical abortion are also being carried out, in order to understand their information sources and care-seeking pathways.

#### ***Planned activities***

- Development of a proposal on using community-based information and vouchers to increase access to safe abortion: planning is under way to conduct research to examine the feasibility of increasing access to safe abortion through the use of community-based information, referral and vouchers. The research, including both a formative and implementation component, would address several of the research gaps – evaluation of the role of provider incentives and identification of how women pay for abortions – identified in the 2010 safe



abortion consultation that preceded publication of the second edition of the *WHO Safe abortion technical and policy guidance for health systems (4)*.

- Sex selection and abortion: as a follow-up to the interagency statement on *Preventing gender-biased sex selection (5)*, a consultation was held to discuss the effectiveness of policies to reduce sex selection and the relative roles of restrictive policies (like bans on sex-determination tests or on legal, safe abortion) versus proactive policies that address issues of discrimination. A paper looking at these issues in five Asian countries (China, India, Nepal, the Republic of Korea and Viet Nam) is under preparation. An in-country consultation in Nepal is planned for November 2013 and one in India in 2014.
- Study on pain control in medical abortion: WHO recommends the use of non-steroidal anti-inflammatory drugs (NSAIDs) during medical abortion with mifepristone and misoprostol. Previous studies have shown that NSAIDs, particularly ibuprofen, reduce pain once uterine cramping has started, and are superior to paracetamol; however, they do not appear to be effective at preventing or minimizing the moderate to severe pain of medical abortion when administered prior to pain onset. As pain is often cited as one of the worst features of medical abortion, and given that inadequate pain management may motivate some women to seek unnecessary clinical care, there is a clear need to identify the most effective methods of pain control in this setting. A proposal has been developed for a RCT to evaluate two novel strategies to address pain associated with early medical abortion. The proposal is currently undergoing technical review; however, it is anticipated that technical and ethical approval will be achieved in the next several months, with a goal of study initiation in 2014 across three sites in Nepal, South Africa and Viet Nam.
- A systematic review on the use of medical abortion medications without direct medical supervision is ongoing.

### 3. Norms, standards and tools

#### 3.1 Care during pregnancy

##### *Progress*

##### *Antenatal care*

Since the publication of the *WHO antenatal care randomized trial (6)* and *Integrated Management of Pregnancy and Childbirth* manual on normal antenatal care (7), many countries have implemented antenatal care models, commonly known as focused antenatal care or basic antenatal care, which rely heavily on delivering antenatal care services with a four-visit model. However, a recent Cochrane review on models of antenatal care (8), and a secondary analysis of the WHO trial, suggested that the fewer-visit model may be associated with increased fetal death. Furthermore, in several countries demographic and health survey studies suggest declining antenatal care attendances, probably due to poor quality of care. RHR is a partner in the "Antenatal care: adding content to contact" project, funded by the Bill and Melinda Gates Foundation and led by the Woman and Health Initiative, based at Harvard University, and has started working on a comprehensive antenatal care guideline.

***Planned activities***

- Two technical consultations in 2014 will determine the scope of this guideline. The recommendations will be issued in 2015.
- A technical consultation to discuss the evidence base and research needs and measurement of antenatal, intrapartum and postnatal care will be convened in April 2014.

**3.2 Intrapartum care and obstructed labour*****Progress****WHO recommendations for augmentation of labour*

Prolonged labour is an important cause of maternal and perinatal mortality and morbidity. Augmentation of labour has commonly been used to treat delayed labour when poor uterine contractions are assessed to be the underlying cause. While interventions within the context of augmentation of labour may be beneficial, their inappropriate use can cause harm, and unnecessary clinical intervention in a natural birth process undermines women's autonomy and dignity as care recipients and may negatively impact their childbirth experience. The primary objective of this guideline was to consolidate the guidance for effective interventions that are needed to reduce the global burden of prolonged labour and its consequences. The guideline panel meeting was held in September 2013 at WHO in Geneva. The guideline document and evidence tables have been completed according to the WHO Guideline Review Committee guidelines, and were submitted for final review in November 2013. It is anticipated they will be published by early 2014.

*WHO recommendation on optimal caesarean section rate*

Since the 1985 publication by WHO of a proposed ideal caesarean section rate of 5–15%, what constitutes best practice has been debated. This is especially pertinent since many low- and middle-income countries have caesarean section rates around 30–40%. In 2013, RHR conducted several activities to issue normative guidance on this issue in 2014:

- **Implementation of the Robson classification for caesarean section:** what do users think? A systematic review: despite the lack of scientific evidence indicating any substantial maternal and perinatal benefits from increasing caesarean rates, and some studies showing that high rates can be linked to negative consequences, caesarean section rates continue to increase worldwide, particularly in middle- and high-income countries. In 2013, HRP/RHR conducted a systematic review of the literature to collect and synthesize the experience of users related to the pros and cons of the adoption, implementation and interpretation of the Robson classification for caesarean section, as well as their adaptations, modifications or recommendations on the use of this classification. Seventy-four studies were included, reporting on the use of the Robson classification in over 35 000 000 women in 31 countries. A manuscript for publication has been prepared and submitted to a peer-review journal. This review will assist facilities and countries as they work towards implementation of the Robson classification.

- **Secondary analyses of the WHO MCS (2) to develop an institutional benchmark for excessive caesarean sections:** a model to monitor caesarean section rates at facility level will help to determine whether the facility is performing excess caesarean sections for its institutional characteristics.

#### ***Planned activities***

- In 2014 WHO will issue guidance on facility-level caesarean section rates and monitoring of these rates. These will be based on (i) a caesarean section benchmark model developed using the WHO MCS (2) dataset; and (ii) a systematic review of the Robson classification system experience. In addition, a separate systematic review assessing the impact of population-level caesarean section rates on maternal and neonatal mortality in both developed and developing countries will inform acceptable country-/population-level caesarean section rates for individual countries.

### **3.3 Preterm birth**

#### ***Progress***

Preterm birth is the single most important cause of mortality and morbidity for the neonate. Providing guidance on the safety and effectiveness of interventions to prevent preterm birth, as well as supportive health-system characteristics, is crucial to improving maternal and neonatal outcomes. HRP/RHR and the MCA department are leading the development of a guideline that addresses questions relating to the effectiveness and safety of interventions and organization of care issues for management of both women in preterm labour and preterm newborn infants. Key questions relating to this guideline have been prioritized at an initial scoping meeting in April 2013, by a group of international stakeholders.

#### ***Planned activities***

- WHO recommendations will be published in 2014 following the guideline development panel meeting in early May 2014.

### **3.4 Postpartum haemorrhage**

#### ***Progress***

Since the 2012 *WHO recommendations for the prevention and treatment of postpartum haemorrhage (9)* were published, several areas of active research have been left without a firm recommendation. These are advance misoprostol distribution during pregnancy, use of a non-pneumatic anti-shock garment, and oxytocin in a compact prefilled auto-destructive device. RHR commissioned a review of advance misoprostol distribution programmes in 2013. The review is currently going through peer review.

#### ***Planned activities***

- The Department will issue a small update of the postpartum haemorrhage guidelines, focusing on the above-mentioned areas where new evidence has become available or will be available in 2014.

### 3.5 Birth spacing

#### *Progress*

In 2012, HRP/RHR and the Centro Rosarino de Estudios Perinatales (CREP), New Mexico, United States of America, conducted a systematic review on birth spacing intervals, including 117 studies from 57 different countries. It was found that although the available evidence seems to indicate that shorter and longer interpregnancy intervals are associated with poorer maternal and perinatal outcomes in general, the variety of definitions for outcomes and the heterogeneity in length of intervals make it impossible to make recommendations regarding the optimal birth interval. In 2013, HRP/RHR, the Latin American Centre for Perinatology and Human Development, Uruguay, and CREP conducted an analysis of the Perinatal Information System database (Montevideo, Uruguay), to evaluate how interpregnancy interval is associated with risks of adverse maternal and perinatal outcomes in Latin American women. The results indicate that women with short interpregnancy intervals (<12 months) are at increased risk of having a low-birth-weight baby, preterm delivery and neonatal death, but not fetal death. Moreover, intermediate and long interpregnancy intervals (>24 months) were associated with higher risks of preeclampsia, but not eclampsia, postpartum haemorrhage, puerperal infection or maternal mortality. A manuscript presenting the findings has been prepared and is currently under peer review.

#### *Planned activities*

- No new formal guideline work is planned for this activity.

### 3.6 Task shifting in safe abortion care

#### *Progress*

Work on a new task-shifting guideline for safe abortion care was initiated. This guideline will consider recommendations on options for shifting and/or sharing of tasks among health workers (including pharmacy workers and community workers) and the role of the woman herself. The preliminary scoping meeting, held in November 2003, outlined the scope of interventions and cadres that will be considered. Evidence retrieval and synthesis will be done in collaboration with the Norwegian Knowledge Centre. The guideline is expected in 2014.

#### *Planned activities*

- The evidence synthesis will be completed and the technical consultation to finalize the recommendations will be held in 2014.

### 3.7 WHO recommendations for the management of sepsis around childbirth

#### *Progress*

Work on a new guideline on prevention and management of maternal infections was initiated. Currently, the scoping work is being carried out by Department of Health Policy, National Center for Child Health and Development in Tokyo, Japan. The plan is to focus primarily on bacterial infections around the time of childbirth but the final scope will be determined after the electronic survey.

#### *Planned activities*

The systematic reviews, grading of evidence and the recommendations will be completed in 2014.

## 4. Monitoring and evaluation

### 4.1 Maternal mortality and morbidity

#### *Progress*

##### *Maternal mortality estimates*

The Department leads the collaborative effort with UNICEF, UNFPA and the World Bank to provide up-to-date estimates of global maternal mortality levels, as part of monitoring progress towards Millennium Development Goal (MDG) 5, target 5A (reducing the maternal mortality ratio [MMR] by three quarters, between 1990 and 2015). The MMR consultation process has served as a starting point to engage countries in improving the quality of data collection, and the processes in the estimation procedure have been recognized as transparent and a good example of how WHO estimates should be undertaken. In 2013, a preliminary revision was undertaken, with review of input data and draft estimates by Member States. With the addition of new data points and increased country engagement, it is now evident that the statistical model used to estimate maternal mortality will require additional refinement to better reflect good-quality country-level data. A document on the use of censuses to collect maternal mortality data was published online (10).

##### *Updates of global databases of maternal and perinatal health-care coverage indicators*

Annual updates of a range of global databases were continued and updated figures were published in the *World Health Statistics 2013* (11). They include: births attended by a skilled health professional (MDG 5.2), antenatal care coverage (MDG 5.5), caesarean section rates, and facility deliveries and coverage of postnatal care.

##### *Systematic reviews of epidemiological data on reproductive health conditions:*

##### **Pre-eclampsia and eclampsia**

A systematic review of the incidence of hypertensive disorders of pregnancy was conducted, with the objective of evaluating its magnitude globally and in different regions and settings (12). Using a logistic model, the global and regional incidences of hypertensive disorders of pregnancy were estimated using prespecified predictor variables. The systematic review includes nearly 39 million women from 40 countries. The overall estimates of hypertensive disorders of pregnancy are 4.6% (95% uncertainty range 2.7 to 8.2), and 1.4% (95% uncertainty range 1.0 to 2.0) of all deliveries for pre-eclampsia and eclampsia, respectively. Wide variation across regions was observed. The absence of data in many countries is of concern, however (see Fig. 5), and efforts should be made to implement data collection and reporting for substantial statistics.



Fig. 5. Countries reporting on pre-eclampsia and eclampsia, 2002–2010



### Causes of maternal death

An analysis of the global and regional causes of maternal death was conducted, using datasets identified in a systematic review of the literature (submitted for publication), in addition to vital registration data from the WHO Mortality Database. Based on prespecified criteria, country-specific estimates were obtained for maternal deaths, categorized according to *The WHO application of ICD-10 to deaths during pregnancy, childbirth and puerperium: ICD MM (13)*, using a Bayesian hierarchical model and constructed for MDG regions.

The paper has been submitted for publication. A total of 60 799 deaths from 417 datasets from 115 countries were included in the analysis. The main results of the analysis indicate that haemorrhage, hypertensive disorders and sepsis are responsible for over half of maternal deaths globally. Indirect causes have also become significant. These analyses should inform the prioritization of health policies, programmes and funding to reduce maternal deaths at regional and global levels. The study also highlights the limitations in analyses of cause of death, owing to inadequate and poor-quality data on cause of death from research studies, population-based surveys and vital registration.

### Planned activities

- Annual updates of maternal and perinatal health databases for the World Health Statistics will continue. Additional work will be carried out in provision of age-disaggregated data, with attention to the adolescent age group.
- A Maternal Mortality Estimation Interagency Group/Technical Advisory Group meeting will be convened to review the feedback to the maternal mortality estimates developed in 2013 and discuss methodological issues, needs for further methodological work (including subanalyses such as MMRs in specific populations, e.g. adolescents), and the timeline for the new round of estimates.
- A systematic review on cause distribution of maternal deaths will be published.

## 4.2 Maternal morbidity

### *Progress*

With reductions in maternal mortality, increased emphasis is being placed on maternal morbidity, although a common definition of what constitutes maternal morbidity does not exist. Accurate and routine measurement of maternal morbidity are needed to inform policy and programme decisions and resource allocations. The Department received a grant from the Bill and Melinda Gates Foundation for a project that aims to address this challenge and to improve the scientific basis for defining, estimating and monitoring the magnitude of maternal morbidity. A Maternal Morbidity Working Group has been established, with representation from all WHO regions and relevant technical expertise in quantitative and qualitative measurement of maternal morbidities and patient advocacy. The group drafted a working definition and framework upon which to ultimately develop a tool to measure maternal morbidity.

In 2013, the Maternal Morbidity Working Group continued to refine the maternal morbidity framework to develop the basis for a community-based tool for measurement of morbidity. Two papers, (i) discussing the rationale of the project and to invite collaboration (6), and (ii) describing the background scoping exercise conducted to inform the project (7) were published. A methodological paper has been submitted for publication.

## 4.3 Preventing unsafe abortion

### *Progress*

#### *Estimates of unsafe abortion*

In 2013, a comprehensive review of the methodologies used in producing estimates of unsafe abortion was conducted, which will feed into the work in 2014.

#### *Planned activities*

- The seventh edition of the unsafe abortion estimates will be produced in 2014. Current methods of estimation are being reviewed and approaches to enhance the estimates as well as nuance them, keeping in mind the changing nature of unsafe abortion, are being developed. An expert group consultation is planned for spring 2014. A systematic review of existing studies on the incidence of unsafe abortion is also under way.

## 5. Dissemination, advocacy and partnerships

### 5.1 Shaping the research agenda

#### *Progress*

#### *Global research prioritization in maternal and perinatal health and preventing unsafe abortion*

In 2013, a global research-prioritization activity was undertaken to identify priority themes in the area of maternal and perinatal health and preventing unsafe abortion, for the period 2015–2025. The exercise was based on the methodology of the Child, Health and Nutrition Research Initiative. A total of 339 stakeholders provided input to a consolidated list of 190 priority research questions. Most priority research questions (89%) were concerned with the implementation and



delivery of existing interventions, with research subthemes frequently concerned with training and/or awareness interventions (11%), and access to interventions and/or services (14%). Twenty-one questions (11%) involved the discovery of new interventions or technologies. Questions on abortion research constituted 25% of the 20 highest-scoring questions overall, followed by research on health systems (20%), obstetric haemorrhage (15%), neonatal care (15%), labour and delivery (10%), and other areas (15%). The results of this exercise were submitted for publication in November 2013.

#### *Conscientious objection to abortion as a potential barrier to access to safe abortion*

HRP/RHR staff contributed to an article on "Conscientious objection to provision of legal abortion care", for a special supplement of the *International Journal of Gynecology and Obstetrics*, focused on conscientious refusal of reproductive health care to be published in 2014. *Safe abortion: technical and policy guidance for health systems (5)* identifies conscientious objection to providing abortion services by health-care providers as a potential barrier to accessing safe abortion services. There is little evidence on the prevalence and impact of conscientious objection; RHR has committed to developing a collaborative research proposal to study the implications of conscientious objection for women, service providers and health systems, with a focus on South Africa.

#### **Planned activities**

- Global research prioritization: the activity has been useful in identifying global priority research themes. The team will continue to work on identifying concrete research questions that are a priority for HRP to undertake, based on STAG-approved priority areas, namely intrapartum care and caesarean section, which are detailed in specific sections.

## **5.2 Improving the science of implementation**

### **Progress**

#### *Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (DECIDE) activities*

HRP/RHR is a key partner in the DECIDE project. This collaborative project, funded by the European Commission's Seventh Framework Programme, aims to develop and evaluate communication strategies to inform evidence-based decision-making. As part of DECIDE, the Department has co-developed a framework for communicating evidence to inform decisions about health systems. In May 2013, it published the findings of an international survey of policy-makers and other stakeholders, supporting health policy decisions on the use and relevance of the DECIDE framework (14). A one-day workshop on the application of the DECIDE evidence to recommendation frameworks for WHO guidelines was held in June 2013. HRP/RHR contributes to the development of evidence-to-recommendations and recommendations-to-decision frameworks, in collaboration with the Norwegian Knowledge Centre for the Health Services. Evidence briefs from the OptimizeMNH guidance (see Fig. 6 for an example) (15) have been developed, to support the dissemination and use of the guidance on task-shifting approaches in maternal and neonatal health by policy-makers.

Fig. 6. One of the policy briefs from the OptimizeMNH guidance



### The GREAT Network

HRP/RHR is collaborating with the University of Toronto and Knowledge Translation (KT)-Canada on guideline-implementation research activities, through the GREAT Network (Guideline-driven, Research priorities, Evidence synthesis, Application of evidence, and Transfer of knowledge), funded by the Canadian Institutes of Health Research. The GREAT Network's objective is to facilitate the efforts of local stakeholders who are focused on enhancing maternal and perinatal health in low- and middle-income countries, through implementation of relevant evidence-based guidelines. The network completed a multiphased pilot study in Kosovo, published in *Implementation Science* in September 2013 (16). It explored the implementation of WHO maternal health guidelines in Kosovo, focusing on determinants of uptake and methods to contextualize them for local use, using a survey, individual interviews, focus groups and a consensus meeting with relevant stakeholders, including clinicians (obstetricians, midwives), managers, researchers, and policy-makers from the national Ministry of Health and the WHO office in Pristina, Kosovo. Particularly pertinent to maternal health guideline implementation in Kosovo were the effects of recent conflict and the resulting fragmentation of health-care and communication strategies among relevant stakeholders. The GREAT Network held its first international collaborators' meeting in Thailand in October 2013. Similar assessments of barriers to guideline implementation are being planned in Myanmar and three sub-Saharan African countries (see Section 5.2, "Planned activities").

**Planned activities**

- The DECIDE activities in 2014 will include workshops organized jointly by the WHO Guidelines Review Committee Secretariat and participation at the annual Grading of Recommendations Assessment, Development and Evaluation (GRADE)/DECIDE meetings. The Department is also discussing with the WHO Regional Office for Europe counterpart the organization of a research-to-policy workshop in 2014.
- The OptimizeMNH guideline (15) evidence synthesis and grading included the conduct of systematic reviews of qualitative studies and the development of a novel method of assessment of uncertainty in qualitative research synthesis. This approach, termed CerQUAL (certainty of qualitative research), will be developed further in partnership with the Norwegian Knowledge Centre for the Health Services in 2014, with participation and support from RHR.
- With support from the United Nations Commission on Life-Saving Commodities, the Department will conduct assessments of barriers and facilitators to the implementation of guidelines related to maternal health commodities (misoprostol, oxytocin and magnesium sulfate) in three sub-Saharan countries in Africa.
- At the 2014 Third Global Symposium on Health Systems Research (Cape Town, South Africa), the Department will present a workshop on its guideline implementation activities as part of the GREAT Network grant.

**5.3 Dissemination of WHO guidelines and derivative products****Progress***Evidence briefs on the OptimizeMNH guideline*

Two evidence briefs from the OptimizeMNH guidance (15) have been prepared and disseminated. These focused on the provision of effective reproductive, maternal and neonatal health interventions by lay health workers, and recommendations on the provision of contraceptives across health cadres.

*WHO Safe abortion: technical and policy guidance for health systems (4) translations*

This document has now been translated into French, Portuguese, Russian and Spanish, and all these versions are on the WHO website. In addition, unofficial translations have been completed in Japanese, Romanian and Ukrainian.

*WHO Safe abortion: technical and policy guidance for health systems (4) evidence briefs*

A series of evidence briefs based on recommendations from the 2012 *Safe abortion technical and policy guidance (4)* are being developed and will target policy-makers and programme managers. They cover the following topics:

- abortion before 12–14 weeks' estimated gestational age
- abortion after 12–14 weeks' estimated gestational age
- adolescents and abortion
- improving access to safe abortion through primary care and outpatient services
- post-abortion contraception
- abortion using misoprostol alone.

*WHO Safe abortion: technical and policy guidance for health systems (4) – The clinical practice handbook for safe abortion (17)*

The *Clinical practice handbook for safe abortion*, a derivative document of the *Safe abortion guidance (4)*, was finalized in 2013 and will be available in 2014. The document is on the WHO website at [http://www.who.int/reproductivehealth/publications/unsafe\\_abortion/clinical-practice-safe-abortion/en/index.html](http://www.who.int/reproductivehealth/publications/unsafe_abortion/clinical-practice-safe-abortion/en/index.html). This document summarizes the clinical recommendations for providing safe abortion and is intended as a handy reference tool to enable evidence-based practice for health professionals. It is hoped that the handbook will be useful to a range of providers in different settings and in varying legal and health service contexts. As part of the Department's dissemination activities, it also anticipates collaborating on two training-of-trainers workshops with introduction of this tool.

## 5.4 The WHO Reproductive Health Library

### Progress

The WHO Reproductive Health Library (RHL) (see Fig. 7) has been published by HRP since 1997. In 2013, it was felt that RHL needed to be made friendlier to social media tools (Facebook). This belief led to restyling of the older RHL Facebook page and the decision to replace the independently authored RHL expert commentary on systematic reviews with a short "RHL summary" of the included Cochrane reviews. The shift from commentaries to summaries was implemented in May 2013. Since May 2013, RHL has been updated each week with two new or updated Cochrane reviews and corresponding RHL summaries. This has speeded up the inclusion of new content in RHL. Initially, the summaries were also simultaneously being published on the RHL Facebook page, but traffic to the RHL Facebook was rather low and it appeared that RHL readers preferred to access RHL directly from the RHL website, which continues to attract high-volume traffic. Up to 15 November 2013, the total number of visits to all language sites of RHL was about 1.2 million, with 80% of visitors being new RHL readers.

Fig. 7. The RHL webpage



**Planned activities**

- In 2014, RHL will continue to be published, with further refinements and easy-to-access summaries in WHO official languages.

**5.5 Malaria in Pregnancy**

Despite clear gains in malaria control, MiP interventions still remain suboptimal, with intermittent preventive treatment in pregnancy with sulfadoxine–pyrimethamine (IPTp–SP) update and insecticide-treated net use far below global targets. There is a renewed interest among global and country-level stakeholders to improve MiP programmes, address missed opportunities, and increase coverage for all pregnant women.

**Progress**

The Malaria in Pregnancy Working Group, co-chaired by HRP/RHR and Jhpiego, has delivered key MiP interventions through: (i) dissemination of technical guidance and programmatic approaches; (ii) fostering partnership between national RMNCH and national malaria-control programmes; and (iii) engaging key partners at both global and country level, to help accelerate implementation and increase nationwide coverage.

In October 2012, the WHO Global Malaria Programme, with the support of HRP/RHR, issued an updated policy recommendation (49), encouraging increased uptake of IPTp–SP in all areas of Africa with moderate-to-high transmission of *Plasmodium falciparum* malaria, confirming the critical importance of increasing the frequency of IPTp–SP. In 2013, countries including Angola, Burkina Faso, Guinea, Kenya, Liberia and the United Republic of Tanzania, have initiated the process of discussing and implementing the new IPTp–Sp policy.

MiP was identified as a priority area for the annual review and planning meetings of the subregional Roll Back Malaria networks. National-level RMNCH and malaria-control managers participated jointly in the annual meetings, resulting in definition of key priorities for accelerating MiP programming.

A grant was secured for HRP/RHR from the Bill and Melinda Gates Foundation, to disseminate the updated WHO policy recommendation on IPTp–SP (49) and work to standardize global and country antenatal care and MiP guidelines. Increased awareness among the maternal and newborn health community is needed to prioritize MiP programming as a vital component of RMNCH services, and for successful resource mobilization.

**Planned activities**

- Support joint planning between RMNCH and national malaria-control programme communities, to strengthen the antenatal care platform for MiP interventions.
- Facilitate technical assistance as identified by RMNCH and national malaria-control programme representatives, during subregional Roll Back Malaria networks' annual review and planning meetings in 2013.
- Update tools and documents to reflect new strategies for MiP interventions and/or drugs for IPTp.
- Continue to include MiP as part of dialogue on essential drugs and commodities for maternal, infant and child health

## 5.6 Advocacy

### *Progress*

#### *Ending preventable maternal deaths by 2035*

In April 2013, a consultation on potential post-2015 targets hosted by WHO with the United States Agency for International Development, brought together stakeholders from four countries (Cameroon, India, Indonesia and Nigeria), professional organizations and associations, other multilateral participants, maternal health advocates and donors. The aim of the consultation was to consolidate strategies for accelerating progress towards ending preventable maternal deaths, and to explore related post-2015 targets. The consultation concluded that the future target post-2015 should continue to be the MMR but that the strategy should be flexible enough to handle various end dates (2025, 2030, 2035), because selection of the end date will depend on the overall development agenda. It is envisioned that both country and global goals will be elucidated and that each country's rate of progress would be measured by passing 5-year milestones that are consistent with its position on a "customized" predicted rate of reduction. For instance, countries with very high levels of MMR would have an even more ambitious goal, so that no country would have an MMR above a specific value (which depends on the end year), and countries with low levels of MMR would focus on any remaining subpopulations with high MMR.

#### *Briefing United Nations treaty-monitoring bodies on the WHO Safe abortion guidance (4)*

RHR/HRP staff provided a closed, in-session briefing on the WHO Safe abortion guidance (4) at the 51st session of the Committee Against Torture in October 2013. The presentation was well received, mainly generating committee member comments about particular country situations. The committee appreciated WHO's acknowledgement of their previous use of the WHO *Safe abortion guidance (4)* for concluding observations on Chile (2004) and Peru (2006), and agreed about the importance that human rights standards have for future WHO guidance on safe abortion, as well as the importance that future WHO health standards on abortion have for the generation of new human rights standards. Following the WHO briefing and inputs from NGOs and others, in the committee's concluding observations on Poland, they expressed concern about restrictions on access to abortion, especially for victims of rape, because of physicians and clinics refusing to perform legal operations on the basis of conscientious objection.

The Committee recommended that the State party ensure that women, especially rape victims who voluntarily decide to interrupt their pregnancy have access to safe lawful abortions. In accordance with World Health Organization technical and policy guidance for health systems on Safe abortion (2012), the State party should ensure that the exercise of conscientious objection does not prevent individuals from accessing services to which they are legally entitled. The State party should also implement a legal and/or policy framework that enables women to access abortion where the medical procedure is permitted under the law (18).



***Planned activities***

- Ending preventable maternal deaths by 2035: a meeting will be convened post 2015, to discuss with countries in order to understand their acceptance and commitment to a post-2015 MMR goal-setting process.

## 6. Technical cooperation

### **6.1 Supporting national policies and implementation**

***Progress******Dissemination of abortion-related work***

Country-specific dissemination activities were held for several of the studies, under the initiative on social science research in medical abortion. These included dissemination of the cost study in Colombia and a stakeholder meeting convened in Bangladesh by the Directorate of Family Planning, to discuss the implications of the feasibility study on MR with medications. Many of the studies were also disseminated at regional or global events. Notable among these were the regional meeting organized by the Latin American Consortium against Unsafe Abortion; the International Congress of Women's Health and Unsafe Abortion (IWAC) conference in Bangkok in January 2013; and Women Deliver in May 2013.

***Knowledge translation workshop on medical abortion***

A two-day knowledge translation workshop on medical abortion was held in Nairobi, Kenya, with study teams from Ghana, Kenya, Nepal and Zimbabwe that were part of the HRP/RHR medical abortion research initiative. The purpose of the meeting was to identify and discuss policy and programmatic options/strategies on promoting access to safe abortion services, using available evidence on medical abortion; identify possible barriers in implementing policy and programmatic options on access to safe abortion services and ways to address these; and discuss ways to engage with decision-makers through the identification of various mechanisms (e.g. policy dialogues).

***Technical support to countries on safe abortion policies***

HRP/RHR continues to provide financial and technical support to Moldova and Ukraine, for scaling up comprehensive abortion care. A proposal was submitted to the James Tudor Foundation (JTF) to support an evaluation of the six sites strengthened with JTF funding over the past 5 years, and to evaluate the nationwide provision of abortion care according to Moldova standards and guidelines. An interactive map will be developed, based on the evaluations, which will highlight the location of services provided according to national standards, as well as gaps to be addressed in future health-system strengthening.

***Workshop on effective communications and advocacy on reproductive health and rights in the framework of the project "Comprehensive care for unwanted pregnancy": Ukraine***

This was carried out for the Ukraine Ministry of Health, as part of its ongoing support for scaling up the programme, "Comprehensive care for unwanted pregnancy".



### *Support for updating post-abortion care guidelines: Myanmar*

Support was provided to the Ministry of Health in Myanmar to update their guidelines for post-abortion care, in keeping with the clinical care recommendations of the WHO *Safe abortion: technical and policy guidance for health systems (4)*. Pilot training sessions in the management of incomplete abortion with misoprostol were also held for doctors, as well as midwives.

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# Adolescents and at-risk Populations

## Summary

As recommended by the Scientific and Technical Advisory Group (STAG) in 2013, the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) has increased its focus on adolescent sexual and reproductive health. In 2013, work on adolescent sexual and reproductive health, especially in the area of research, continued to be a focus, and the work on this area will expand in 2014. Similarly, the Department continues to give emphasis to the other key areas, including violence against women, female genital mutilation, and humanitarian settings.

Since the activities of the Adolescents and At-risk Populations (AGH) team have a focus on populations that are most disadvantaged, and on addressing inequalities, tools to expand access to and coverage of health services for such populations are of key interest. Substantial work is being carried out on innovations, especially mobile technology solutions, to support improving access to and use of health care. Additionally, the thrust of the team on improving the sexual and reproductive health of adolescents and at-risk and vulnerable populations entails a strong focus on rights. In this context, among others, a key achievement in 2013 included the development of a guideline on ensuring human rights in family planning programmes.

The team also coordinated the Department's and WHO's work on supporting the review of progress and identification of remaining gaps in implementation of the International Conference on Population and Development (ICPD) Programme of Action, for its 20th anniversary in 2014. While significant progress has been made in many of the diverse goals of the Programme of Action, preliminary results from the review demonstrate that profound disparities persist. The Department led an intra-organizational task team to identify priority topics to address. A package of eight evidence briefs focusing on the core neglected topics of the Programme of Action has been developed for use by advocates and policy-makers at the forthcoming events for identification of priorities in further implementation of ICPD, including at the Commission of Population and Development.

### Key objectives

The Adolescents and at-risk Populations team is responsible for research and normative work on the sexual and reproductive health of adolescents and at-risk populations/situations, including violence against women, humanitarian settings, and harmful practices. The team aims to generate knowledge and develop evidence-based recommendations to improve the sexual and reproductive health and rights of adolescents and at-risk populations, especially through expanding access to, and quality of, information and services. Special attention is placed on equity and rights and accessing disadvantaged populations. Systematic implementation of evidence-based recommendations and WHO guidelines is also a key aspect of the work of the team, which involves key partnerships with academic institutions, the United Nations and other partners, especially nongovernmental organizations.

## Major achievements

- A research protocol was developed for a multicountry study to determine the effectiveness of a three-pronged intervention strategy in reducing unplanned pregnancy among postpartum and post-abortion adolescents. The components of intervention include: a communication strategy, structured postpartum contraceptive counselling, and provider training in postpartum intrauterine device and implant insertion.
- Global and regional estimates on the prevalence and health burden of violence against women (2013) were launched and disseminated widely through media, journal publications and meetings with WHO regional offices. Papers were published on "The global prevalence of intimate partner violence against women" in *Science* and on "The global prevalence of intimate partner homicide" in *The Lancet*.
- The THRIVE (Technologies for Health Registries, Information, and Vital Events) consortium was established in 2013, and is focused on scaled deployment and impact assessment of a smart registry platform (known as the Dristhi project in its initial deployment in India) in multiple countries.

## 1. Introduction

One of the key pillars of the work of the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) focuses on improving the sexual and reproductive health of adolescents and at-risk populations. The work of the Adolescents and At-risk Populations (AGH) team in the areas of research and research synthesis, developing norms and guidelines, supporting monitoring and evaluation, and promoting implementation of evidence-based interventions, including through advocacy and partnerships, aims to improve the sexual and reproductive health and rights of adolescents and most disadvantaged and vulnerable populations.

In addition to work on adolescents, significant work is conducted in the areas of violence against women, female genital mutilation, humanitarian settings, and innovative approaches such as mobile health (mHealth), to enhance access to and coverage of health services for populations of key interest.

The following sections summarize key activities and products carried out/delivered during 2013 and plans from 2014 to achieve the above goals and related mission of the Department.

## 2. Research and development

### 2.1 Interventions research to prevent adolescent pregnancy

#### *Progress*

A key research priority area for adolescent sexual and reproductive health that was agreed following a search of the literature and discussion at the 2013 Scientific and Technical Advisory Group (STAG) meeting, was determining the effectiveness of interventions to prevent adolescent pregnancy. During 2013, a draft research protocol was written, based on a review of existing evidence on this topic. A small advisory group of experts in adolescent and contraceptive research was convened to review the feedback on the draft. Existing evidence, albeit limited, points to the need for a package of interventions to reduce unintended pregnancy

in adolescents. These interventions must address barriers at the community and provider levels, as well as increasing access to and availability of contraception for adolescents. This will be a multicountry study to determine the effectiveness of three interventions in reducing repeat pregnancy among postpartum and post-abortion adolescents: a communication strategy, structured postpartum contraceptive counselling, and provider training in postpartum intrauterine device (IUD) and implant insertion.

#### ***Planned activities***

- In 2014, the multicountry study to determine the effectiveness of interventions to prevent adolescent pregnancy will be implemented (*Improving contraceptive choice and acceptability for adolescents during the postpartum and post-abortion periods: a stepped wedge design*). Specifically, the core protocol will be finalized and submitted for technical and ethical review at WHO headquarters. Collaborating partners and study sites will be identified, and site visits conducted.

## **2.2 Early adolescence study**

### ***Progress***

Over the past decade, there has been growing awareness of the importance of addressing younger adolescents (10–14 years), because this is a time when (i) enormous physical, psychological and social changes are beginning or are well under way; (ii) important public health problems, such as early child bearing, early initiation of sexual activity and interpersonal violence, are being experienced; and (iii) attitudes and values that have enormous implications for individuals' lives in the years ahead, are formed

Reviews of research evidence and programmatic experiences, as well as a stakeholder consultation that the Department convened, reiterated the dearth of research in this area. Working with the Johns Hopkins Bloomberg School of Public Health, the Department developed a protocol for a multicountry study to explore the evolving nature of gender and social relations in adolescents. Seed funds have been secured for the study and partnerships established with research organizations in China, Egypt, India, Kenya and Nigeria, and ground work has been done in each site.

The objectives of the study are to find out how sexual development occurs in young adolescents (10–14 years) in different social and cultural settings, how the context shapes sexual development, and how sexual development – including gender socialization – in early adolescence influences sexual behaviours in middle and later adolescence. The tangible outputs of the study would include findings from each of the study sites, as well as a description of the study methods and a set of tools that could be used by researchers in other sites. The ultimate aim of the study is to provide decision-makers at global and national levels with evidence from high-quality research, in order to improve their understanding of, and raise their commitment to, investing in the current and future health of very young adolescents.

### ***Planned activities***

- In 2014, phase 1 of the study will be initiated, while efforts are made to identify study sites and partner organizations in Europe and Latin America.

## 2.3 Systematic review of comprehensive adolescent health programmes

### *Progress*

Over the past few years, there has been a growing interest in comprehensive adolescent health programmes. It is recognized that, by providing a broad set of services to children and youth, one can improve the outcomes for young people and especially those experiencing greatest disadvantage.

Comprehensive programmes differ from discrete interventions, in that they represent a package of services or activities. Comprehensive adolescent and youth programmes usually have the following major elements in common:

- *health services*: this should include sexual and reproductive health and some of the following services – mental health, abuse, counselling, medical care;
- *education*: support for matriculation, retention and completion, after-school programmes, out-of-school youth;
- *social supports*: job training and employment, youth recreation (e.g. arts and music) adult–youth interaction, etc.;
- *family and parents*: including special sessions offered to parents, such as parenting skills workshops;
- *life skills*: social and emotional learning, self-efficacy, self-esteem, diet/nutrition, etc.

This systematic review, which is being carried out in collaboration with the Department of Population, Family and Reproductive Health at Johns Hopkins Bloomberg School of Public Health, aims to explore what is known about such comprehensive approaches in adolescent health programmes, including the evidence base and effectiveness of programmes.

All studies (peer-reviewed literature) and/or programme reports (grey literature) published or written between January 1998 and April 2013 were assessed. Studies had to include adolescent or youth participants and, if the target population was broader, the majority of participants had to be in the age range 10–24 years. There were no language restrictions.

A total of 36 119 records were screened by title and abstract. Of those, 542 full-text records were assessed for eligibility and 181 records were included for data extraction. At the end, 10 programmes were retained for inclusion and qualitative synthesis, six from the United States of America (USA) and four from outside of the USA (Egypt, Ethiopia [two studies] and Mexico).

### *Planned activities*

- The findings of the review are being synthesized, and a draft manuscript is being prepared for submission to a peer-reviewed journal by early 2014.

## 2.4 Addressing violence against women in antenatal care

### *Progress*

The study continues to progress, with the formative research in South Africa completed. Formative research findings indicate that:

- antenatal care clinic staff recognize that violence affects the health of the patient population, and they are receptive to training;

- women attending antenatal care would welcome support and services around violence against women;
- policy-makers similarly seek tools and guidance on how to address violence against women in the health-care setting.

Revisions to the protocol for phase II, on the basis of the results from the formative phase, have been approved by the Ethical Review Committee. Training manuals were developed and nurse researchers have been recruited and trained. Data systems for electronic data collection and data management are being finalized, along with the study instruments. A methodology for process evaluation has been developed to complement the clinical trial and to assess issues related to feasibility, safety, data quality and implementation.

#### ***Planned activities***

- The randomized controlled trial (RCT) phase of the study to address violence against women among antenatal clinic patients in South Africa will be initiated in January 2014.
- Additionally, a handbook on interventions research for addressing violence against women, and ethical and safety recommendations on interventions research on intimate partner violence against women, will be finalized, in collaboration with RTI International.

## **2.5 Systematic reviews on violence against women**

### ***Progress***

Two systematic reviews on the prevalence and correlates of violence against sex workers, and the links between violence against sex workers and HIV outcomes are finalized and have been submitted for publication.

### ***Planned activities***

- Based on above systematic reviews, a WHO publication *Addressing violence against sex workers in the context of HIV: what works?* is being developed. Operations research on integrating violence against women in programmes for prevention of mother-to-child transmission of HIV will be supported.
- Additionally, a Cochrane/Campbell systematic review on effective interventions to address gender norms will be conducted.

## **2.6 Female genital mutilation**

### ***Progress***

In 2013, two studies were supported: (i) on the psychological consequences of female genital mutilation in Nigeria, in collaboration with College of Medicine, University of Ibadan, and (ii) on the relationship between fistula and female genital mutilation in Sierra Leone, in collaboration with College of Medicine and Allied Health Sciences, University of Sierra Leone and Karolinska Institute (Sweden).

Additionally, the Secretariat is providing technical support to Sudan for the implementation of a multi-year initiative to tackle female genital mutilation, in cooperation with the Government of the United Kingdom of Great Britain and Northern Ireland.



### ***Planned activities***

- The studies in Nigeria and Sierra Leone will be finalized and country teams will be supported in writing up and publishing the findings of the research. Based on the identified research priorities, research proposals will be prepared for potential funding opportunities.

## **2.7 Child marriage**

### ***Progress***

The Department, in collaboration with the Inter-Parliamentary Union, carried out a study of child marriage, to determine the levels and trends of child marriage in African countries, and its determinants and consequences. The methods included a desk review of relevant literature, and reports and key informant interviews showed that there has been little decline in the levels of child marriage in Africa over the last two decades, even where laws that prohibit the harmful practice are in place. The findings highlight the need to develop and apply sound laws and provide a model for that. Other recommendations include the need to build social norms that do not support child marriage. These findings and recommendations were presented at the Pan-African Parliamentary conference in November 2013, in South Africa.

### ***Planned activities***

- The Department will continue to engage with the Inter-Parliamentary Union to prepare evidence-based reports on child marriage and to support the Union in engaging parliamentarians around the world for its prevention.

## **2.8 Innovations to improve access to and coverage of sexual and reproductive health, especially for at-risk populations**

### ***Progress***

Implementation research was conducted across numerous mHealth projects as part of RHR's involvement as technical adviser to recipients of the United Nations Innovation Working Group mHealth catalytic grant mechanism for reproductive, maternal and child health (RMNCH) projects (see Fig. 1). Technical support has been provided through country workshops and targeted consultancies, to assist projects in achieving scale.

A commentary was published in *The Lancet* on modernizing vital registration systems (1).

Fig. 1. Implementation research sites for scaling up successful mHealth projects



#### *Planned activities*

- There is one research study planned to develop and test an mHealth intervention for one African and one Asian population, targeted at increasing young people's access to, and use of, adolescent sexual and reproductive health services, improving health workers' ability to reach young people, and decreasing risky sexual behaviour and early pregnancy; this will build on the existing "Dristhi" smart registry mHealth platform already developed and deployed in India.
- Stakeholder review and evidence synthesis are planned, on approaches for strengthening adolescent sexual and reproductive health through mHealth.

### 3. Norms, standards and tools

#### 3.1 Guidance on ethical issues for research on adolescents

##### *Progress*

The Department developed guidance for researchers and members of ethical review boards/committees on addressing commonly occurring ethical challenges in developing/reviewing protocols for research on adolescent sexual and reproductive health. The development process included a mapping of the literature and extensive consultations with key informants. The guidance contains four parts:

- part one highlights the significance of accurately and uniformly describing a proposed study population;
- part two explores the notions of autonomy, informed consent and assent, and how to determine an adolescent's competence, capacity and maturity in the research context;
- part three explores the nature and implications of the principle "the best interests of the child", and how this notion should be applied when researchers encounter a conflict between their ethical and legal obligations in relation to adolescent research participants;
- part four explores information sharing in relation to adolescents in the research context.

##### *Planned activities*

The guidance will be published during the first half of 2014 and will be actively disseminated to researchers, using a variety of means, including peer-reviewed publications and presentations at conferences.

#### 3.2 Violence against women

##### *Progress*

- WHO clinical and policy guidelines for *Responding to intimate partner violence and sexual violence against women* were published (2).
- Essential health-care services for survivors of violence against women: as part of a United Nations initiative on essential services for violence against women, the United Nations Population Fund (UNFPA), UN Women and WHO co-hosted an expert consultation to identify core or essential services and health systems elements for delivering services to survivors of intimate partner and sexual violence, drawing upon the WHO guidelines (2).
- *16 ideas for programming to address violence against women in the context of the HIV epidemic* (3) was launched on 25th November 2013, ahead of the 16 Days of Activism Against Gender Violence campaign. The tool provides evidence-based summaries on interventions to address violence against women in the context of HIV responses. The tool was disseminated on November 25th to the Global Fund's portfolio managers, as part of the Global Fund's ongoing efforts to expand programming for gender-based violence in its HIV grants.
- A chapter on addressing violence against sex workers was included in the WHO, UNFPA, Joint United Nations programme on HIV/AIDS (UNAIDS), Global Network of Sex Work Projects (NSWP) operational guidance on *Prevention and treatment of HIV and other sexually transmitted infections for sex workers in low- and middle-income countries*, published in October 2013 (4).

**Planned activities**

- A clinical handbook and health-systems job aids for delivering services to survivors of intimate partner violence and sexual violence will be finalized, field-tested and published.
- A training curriculum and tool for health-care providers to deliver services to survivors of intimate partner violence and sexual violence will be developed.
- A manual for simplified psychological interventions for survivors of conflict-related sexual violence will be developed and field-tested jointly with the Department of Mental Health.
- In collaboration with UN Women and UNFPA, a package of essential health-care services for survivors of violence against women will be developed. The tool will be field-tested and published to assess the forensic systems for strengthening generation of medico-legal evidence.

**3.3 Innovations to improve access to and coverage of sexual and reproductive health, especially for at-risk populations****Progress**

A guide for engaging with mobile network operators to achieve scale of mHealth projects was finalized, providing mHealth implementers with a resource to plan interactions with these service providers and develop partnerships that promote project sustainability.

Additionally, an “mHealth and ICTs” (information and communications technology) for RMNCH framework was published in *Global Health: Science and Practice* (5) The article and accompanying user guide are being adopted across a variety of United Nations agencies.

A smart registry platform (known as Dristhi in its initial deployment in India) was developed by the Department, in collaboration with the Columbia University and the Foundation for Research in Health Systems, with support from the Wellcome Trust, the Bill and Melinda Gates Foundation, the United Nations Development Programme (UNDP)/UNFPA/United Nations Children’s Fund (UNICEF)/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and Norad, in Karnataka State, India, in partnership with the Ministry of Health and Family Welfare of India, ThoughtWorks and Ona Systems. The platform focuses on strengthening the ability of skilled health workers to more effectively deliver, and account for, their current package of RMNCH services to their beneficiary populations, and aspires to meet the health information needs of health-care providers, decision-makers and their populations. The platform provides access to tools to deploy common and emerging best practice mHealth strategies (registry approach, reminders, multimedia content, decision support, reporting, and integration into information systems). The construction of the technology platform allows for adaptation to other settings, to other health domains and cadres of health workers.

**Planned activities**

- WHO mHealth Technical and Evidence Review Group (mTERG) review of approaches for strengthening adolescent sexual and reproductive health through direct-to-client mHealth interventions and/or interventions that facilitate health-worker management of clients and provision of adolescent sexual and reproductive health services.

### 3.4 International Classification of Diseases revisions

#### *Progress*

The ICD (8) is a key instrument of WHO. It was initially developed for coding causes of death, with continuous evolution to coding morbidity, as well as recording specific diseases, injuries, signs, symptoms, complaints, social circumstances, reasons for presentation to medical examination, and external causes of both injury and disease.

The Department serves as the Secretariat to coordinate the efforts to revise Chapters 14 (Diseases of the genitourinary system), 15 (Pregnancy, childbirth and the puerperium) and 16 (Certain conditions originating in the perinatal period) of the ICD for the 11th version; it also coordinates a Topic Advisory Group (TAG) to support the revision, and has a seat on the Small Executive (oversight) Group of the ICD-11 revision process.

In 2013, the Genitourinary and Reproductive Medicine TAG advanced the development of its proposal for revisions and considered the recommendations of a sub-working group on conditions to include a new “sexual health” chapter, comprising conditions previously classified within mental health (such as gender identity disorders) and other conditions that may affect sexual health or well-being (e.g. sexual pain disorders). This chapter remains in development.

#### *Planned activities*

- Revision towards ICD-11, as related to the chapters and topics related to sexual and reproductive health, will continue. In order to develop a coordinated response and workplan on the development of a new “sexual health” chapter, RHR will continue to lead discussions with the Mental Health Department, ICD, and external stakeholders.

## 4. Monitoring and evaluation

### 4.1 Trends in adolescent sexual and reproductive health and health-care outcomes

#### *Progress*

#### *Secondary data analyses on the sexual and reproductive health of adolescents and young adults in low- and middle-income countries*

In line with STAG recommendation to carry out systematic reviews and secondary analyses to address information gaps in the burden of sexual and reproductive health issues in adolescents, this activity aims to answer a set of research questions regarding the reproductive health of adolescents and young adults in low- and middle-income countries. Specifically, the project aims to assess the levels and trends in:

- pregnancy before the age of 18 years;
- use of family planning among sexually experienced adolescents and young adults;

- use of maternal health services among adolescents and young adult mothers;
- gender-based violence, including female genital mutilation, among adolescents and young adults;
- sexual risk behaviour and HIV infection, among adolescents and young adults across a set of low- and middle-income countries, with documentation of differentials and trends by urbanicity, age and wealth.

To date, the database has been developed to include the latest Demographic and Health Surveys (DHS) datasets that recently became available. Analysis plans have been prepared for the first two research questions. Analysis of early birth will include countries for which there are three time points, with one in the past 5 years, for a total of 34 countries. The trends will be presented by Human Development Index (HDI) levels. Within HDI levels, correlation between age at first sexual intercourse and early birth will be evaluated using multivariate logistic regression models, adjusting for family planning use, urbanicity, wealth and literacy. Subanalysis on child marriage is also being considered. Family-planning analysis will also include 34 country datasets and will focus on trends by method mix and disaggregation by HDI levels. It will also include a subanalysis on reasons for discontinuation.

#### *Trends in first births in adolescents*

An analysis of trends in first births in adolescents in three East African countries – Kenya, Uganda and the United Republic of Tanzania – was carried out using the data from the DHS. The analysis examined trends in first births by age (younger and older adolescents), according to educational level, economic status, marital status and religion. The findings demonstrate the lack of decline in early childbearing in young adolescents in rural areas.

#### *Lessons learnt in programming for adolescent sexual and reproductive health*

In 2014, the world will commemorate the 20th anniversary of the ICPD and, in 2015, the target date of the Millennium Declaration. To enhance the information available on adolescent sexual and reproductive health issues for supporting the discussions in reviewing progress at these key dates, a set of reviews were carried out and discussed at a consultation of partners and experts. The reviews included the following topics:

- providing adolescents with age-appropriate and culturally sensitive sexuality education;
- providing adolescents with sexual and reproductive health services, and increasing community support and adolescent demand for them;
- empowering adolescents – especially girls – to protect themselves and to take charge of their lives;
- exploring effective ways of fostering participation and leadership by adolescents;
- exploring effective ways of preventing violence against adolescent girls and fostering gender norms that support equality between women and men, boys and girls.



***Planned activities***

- The findings of the reviews will be reported in peer-reviewed journal articles. The reviews on adolescent sexual and reproductive health programming will be published as a series in the *Journal of Adolescent Health*.

## **4.2 Documenting the process of implementation of programmes providing sexual and reproductive health education and services to adolescents**

***Progress***

The Department documented case-studies in four very different countries, Colombia, Estonia, Nigeria and Pakistan, which have scaled up comprehensive adolescent sexual and reproductive health education programmes, unlike other small-scale and time-limited initiatives. Case-studies used a modified version of the WHO-ExpandNet framework to allow potential application of successes elsewhere. Additionally, programmatic evaluations were initiated and carried out, to understand barriers to scaling up the provision of sexual and reproductive health service to adolescents and how they are being overcome in India, Moldova and Viet Nam. The evaluations were completed in Estonia and Moldova, and are in the process of planning/being undertaken in India and Viet Nam.

***Planned activities***

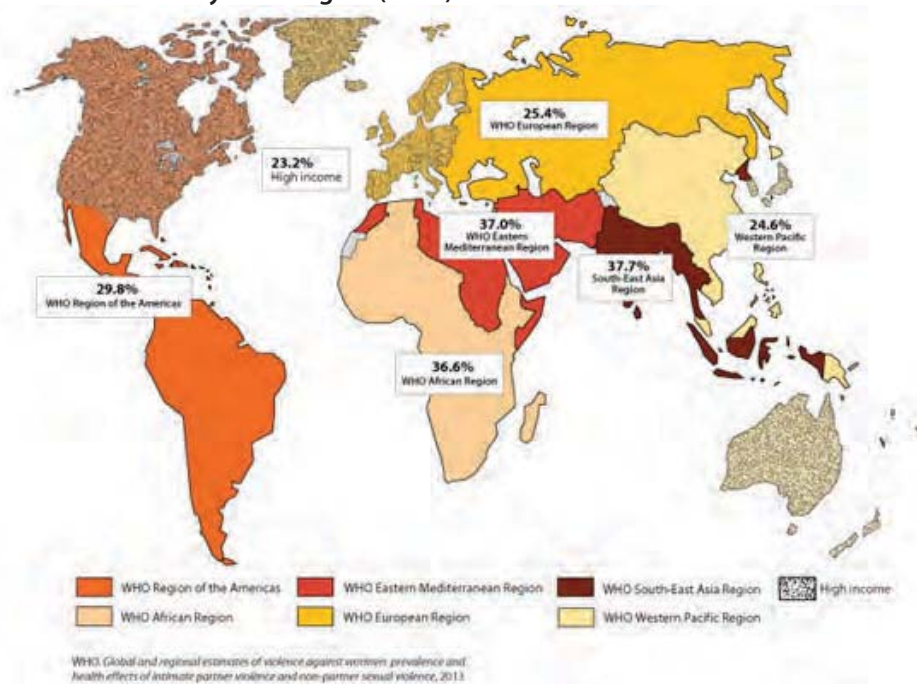
- The Department will publish the results of the case-studies to help drive policies and programmes.

## **4.3 Global estimates on the prevalence of violence against women**

***Progress***

The Department co-led the expert group on interpersonal violence for the Global Burden of Disease Study, with colleagues at London School of Hygiene and Tropical Medicine. A report, *Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence (9)*, was published in June 2013 and disseminated widely. Papers on the prevalence of intimate partner violence, non-partner sexual violence and intimate partner homicide were published in *Science (10)* and *The Lancet (11)*. The study showed that, overall, 35% of women worldwide have experienced physical and/or sexual intimate partner violence or non-partner sexual violence, and that most of this violence is intimate partner violence. Worldwide, almost one third (30%) of all women who have been in a relationship have experienced physical and/or sexual violence by their intimate partner. Globally, 7% of women have been sexually assaulted by someone other than a partner. Fig. 2 shows the prevalence rates of physical and/or sexual intimate partner violence in WHO regions.

**Fig. 2. Regional prevalence rates of physical and/or sexual intimate partner violence by WHO region (2010)**



### **Planned activities**

- Evaluations from ongoing analysis of existing databases and studies on violence against women will be conducted and used to contribute to regular updating of the estimates of the global burden of disease related to intimate partner violence, sexual violence and child sexual abuse.
- Estimates of the incidence of intimate partner violence and non-partner sexual violence, as well as their health outcomes, to be available on the Global Health Observatory.
- A survey on the magnitude, risk factors and consequences of conflict-related sexual violence is planned to be implemented in one country.

## **4.4 Innovations to improve access to and coverage of sexual and reproductive health, especially for at-risk populations**

### **Progress**

In 2013, a research study on the Mother/Baby 7-day mCheck programme developed by WHO Patients for Patient Safety Champions was completed. The programme's aim was to help mothers and their family members recognize postpartum danger signs, and to encourage the mother and her family to seek appropriate care. The study assessed the feasibility, and measured the impact, of this programme on mothers' knowledge of danger signs and their treatment-seeking behaviour. Based on the findings, a larger scale-up of the Mother/Baby mCheck programme is being planned for additional sites.

***Planned activities***

Approval was gained for the RCT research protocol testing the Dristhi mHealth tool in rural India. Data collection will begin in early 2014 and will survey 9500 mothers and children from the service areas of 100 auxiliary nurse midwives, to evaluate the impact of the Dristhi mHealth package on RMNCH outcomes and service delivery in the rural district of Koppal in northern Karnataka, India.

## 5. Dissemination, advocacy and partnerships

### 5.1 Shaping the research agenda

***Progress******Definition of research priorities in child marriage***

In collaboration with Girls Not Brides, the Department organized a consultation to define research priorities on child marriage – preventing child marriage and responding to the needs of child brides. The outcomes of the consultation were an overview of existing research on child marriage, key gaps in knowledge and understanding, a mapping of ongoing and planned research to address these gaps, and an agreement on research priorities.

***Definition of research priorities in female genital mutilation***

In 2013, a renewed international interest was seen on ending female genital mutilation. In response, the Department convened an expert consultation in September 2013, to explore and determine research priorities. The consultation recommended HRP to focus its research on health aspects of female genital mutilation, to better inform interventions and guidance as part of a continuum of care, and on developing better instruments for supporting monitoring and evaluation, especially of interventions and programmes at national level.

***Planned activities***

- The research priorities on female genital mutilation and child marriage will be disseminated, using a variety of means, including peer-reviewed publications and presentations at conferences.

### 5.2 Dissemination of WHO guidelines/tools/research findings and derivative products

***Progress******Adolescent sexual and reproductive health***

A variety of means were used to disseminate the outputs of the research and guidelines and to support partners within and outside the United Nations to take research into action. In addition to peer-reviewed journal articles (see publication list), the following are some examples of research dissemination:

- presenting at high-profile international conferences, such as Women Deliver (Malaysia, March 2013) and the ICPD (November 2013, Ethiopia);
- participating in/contributing to high-profile events to mark International Women's Day and the International Day of the Girl Child;
- contributing to high-profile publications such as the Second report of the independent Expert Review Group on Information and Accountability for Women's and Children's Health (12), established to review progress in the *Global Strategy for Women and Children's Health (13)* and UNFPA's in its State of

the World's Population report, *Motherhood in childhood: facing the challenge of adolescent pregnancy* (14);

- integrating the outputs in country workplans, receiving support from Canada, France and Sweden as part of the H4+ initiative (WHO, UNFPA, UNICEF, The World Bank, UNAIDS, UN Women joint country support for MDGs 4 and 5).

#### *Violence against women*

- The WHO clinical and policy guidelines on violence against women were widely disseminated, including through two workshops – one with 12 countries in the Western Pacific and South-East Asia Regions and another with Francophone countries in the African Region. National adaptation and dissemination workshops were held in China and India, in December 2013.
- The Department co-sponsored the Sexual Violence Research Initiative Forum 2013, “From Evidence to Action”, which took place in Bangkok 14–17 October, and chaired the meeting. The conference brought together approximately 200 researchers, policy-makers and programmers from over 50 countries, to discuss the latest research on sexual violence, intimate partner violence, child abuse and neglect, trafficking for sexual exploitation, and sexual and other forms of gender-based violence in conflict and other humanitarian crises, through plenary, panel and workshop sessions. WHO’s report on the prevalence and health effects of intimate partner violence and non-partner sexual violence (9), as well as the clinical and policy guidelines for the health sector (15), were presented at the conference.
- The 57th Commission on the Status of Women focused on the prevention and elimination of violence against women and girls. WHO convened a high-level panel with the First Lady of Zambia as a panellist, on the health-sector response to violence against women. The WHO Director-General, along with 10 other heads of agencies, signed a statement making a commitment to address violence against women.
- A panel side event at the World Health Assembly 2013, on violence against women, was facilitated by RHR and the Department of Violence and Injury Prevention. It involved participation of ministers of health from Belgium, India, the Netherlands, Norway Mexico, USA and Zambia. The conclusions from the panel led to a proposal being considered for an agenda item on violence against women at the next World Health Assembly.
- Technical assistance was provided to Cambodia, El Salvador and Lao People’s Democratic Republic in implementing prevalence studies using the tools and methodology of the *WHO multi-country study on women’s health and domestic violence against women* (16). Ongoing support is being provided to the WHO Country Office and Ministry of Health, Department of Reproductive Health, Uganda to strengthen the policy environment and capacity for addressing violence against women. A readiness assessment was conducted to identify strengths and gaps in the national response and develop a strategy based on this assessment.
- A tool was developed to assess national forensic systems, in order to strengthen generation of medico-legal evidence, especially in conflict-related sexual violence. In April 2013, a technical consultation was held, in collaboration with the United Nations Office on Drugs and Crime, to identify how best to strengthen forensic systems. Outcomes of this workshop included a policy brief

and job aids to help countries convene stakeholders to assess the strengths and weaknesses of their forensic systems for generating medico-legal evidence for sexual violence. In addition, two survey tools have been developed for measuring experience and perpetration of conflict-related sexual violence.

- A meeting was held in October 2013 with researchers conducting interventions research in health settings, with the aim of consolidating evidence and knowledge in this field, discussing methodological issues, and providing concrete recommendations for health-based interventions research among women experiencing intimate partner violence. This network of researchers aims to strengthen the evidence base for effective interventions, by learning from and sharing experiences with researchers conducting interventions research on health-sector interventions for responding to violence against women, in order to establish a more robust evidence base for what works.

*Innovations to improve access to and coverage of sexual and reproductive health, especially for at-risk populations:*

An online mechanism to register and catalogue mHealth projects along the RMNCH continuum of care was launched at mRegistry.org. The mRegistry.org is a collaboration between WHO mTERG, UNICEF, Johns Hopkins University, frog design, Ona Systems and WHO HRP, and is intended to provide decision-makers, mHealth implementers and technologists with a central repository of information on mHealth projects, providing more information on the various implementation strategies and evidence that exist for projects worldwide.

A taxonomy for cataloguing evidence on mHealth, which was developed by the WHO mTERG, was adopted for use by USAID, K4Health, and mHealthEvidence.org.

***Planned activities***

In the area of violence against women, the following dissemination and advocacy activities will be carried out:

- support the development of an organization-wide plan on violence against women as part of the preparations for the agenda item on violence against women at the next World Health Assembly;
- continue to collaborate with UN Women and UNFPA on the development of a package of essential health-care services for survivors of violence against women;
- advocacy on violence against women as a health issue in the ICPD Beyond 2014 and post-2015 development agenda processes;
- continued support to Uganda to implement activities on strengthening the policy environment and capacity for addressing violence against women in the health sector;
- a series in *The Lancet* on violence against women will be coordinated, together with the London School of Hygiene and Tropical Medicine.

### **5.3 Strengthening and formation of partnerships**

***Progress***

The THRIVE (Technologies for Health Registries, Information, and Vital Events) consortium was established in 2013, and is focused on scaled deployment and impact assessment of a smart registry platform (known as the Dristhi project in its initial deployment in India) in multiple countries. The THRIVE consortium consists

of leading academic, technology, implementation, and donor agencies committed to user-focused design, research-informed adaptation, scaled deployment, and impact assessment of the smart registry tools.

#### ***Planned activities***

- The THRIVE consortium will conclude the development of a multi-site research protocol for the smart registry next year. Government, research and technology partners have raised enough support and funding to deploy the smart registry platform in three to five countries in the coming year. Additional partnerships will increase support for expanded functionality of the smart registry to include deployments for (i) RMNCH and adolescents; and (ii) RMNCH and noncommunicable diseases. The smart registry will also link with the DHIS 2 health management system next year, increasing opportunities for deployment in the 30 countries across four continents that are currently using the system. Finally, an RCT for the smart registry, which received approval at the end of 2013, will be initiated in one state in India in the coming year.

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# Research capacity-strengthening

## Summary

### Key objectives

The work of the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) in the area of research capacity-strengthening aims to strengthen research capacity in countries, to enhance sexual and reproductive health research relevant to national and regional needs, facilitate participation of local institutions in global research, and support development and implementation of evidence-based policies and programmes.

### Major achievements

- In 2012, 15 institutions were awarded Long-term Institutional Development grants. Individuals receiving training grants have published papers in international peer-reviewed journals.
- Centres supported by the Department carried out further capacity-strengthening efforts in regions for strengthening research capacity and advocating evidence-based reproductive health practices, such as:
  - the biannual meeting of the Latin American Association of Reproductive Health Researchers – over 200 researchers in sexual and reproductive health participated;
  - capacity-building in operational research in reproductive health in countries of eastern and central Europe. Representatives from 17 countries of the WHO European Region presented/discussed operational research projects implemented as part of national programmes and developed with support from the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children’s Fund (UNICEF)/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP);
  - at the International Federation of Gynecology and Obstetrics (FIGO) 2012 congress, ReproNet-Africa hosted a session entitled “Controversies in reproductive health policies in Africa”, attracting approximately 80 attendees.
- Building on past and existing work, a renewed approach was used as the means to deliver the research capacity-strengthening efforts of HRP: the concept of the HRP Academic Alliance, and an outline of its operational mechanisms were developed.

## 1. Introduction

The long-standing work of the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) in research capacity-strengthening has contributed to enhancing research by institutions in low- and middle-income countries, through:

- developing appropriate infrastructures (research institutions);
- developing appropriate skills, and confidence, through training and creating opportunities to apply such skills;

- supporting researchers to conduct studies based on national priorities in reproductive health, and facilitating their participation in regional and global research;
- fostering linkages, partnerships and collaborations with partners in the United Nations and other international organizations.

Over the years, institutions and individual researchers in low- and middle-income countries have been identified and supported to enable them to conduct high-quality research in sexual and reproductive health relevant to the needs and priorities of their countries and regions.

In implementing this work, various structured capacity-strengthening grant schemes are used. These include the Long-term Institutional Development grant (LID); Small Grants Scheme; Service Guidance Centre grant; Resource Maintenance Grant; Programme Capacity-Strengthening grant; Competitive Intra-Regional grant; and Research Mentoring Grant. Individual capacity-strengthening activities support workshops, seminars and fellowships in key aspects of sexual and reproductive health.

In 2013, while continuing the implementation of ongoing activities, a renewed approach that aims to further consolidate the research capacity-strengthening efforts and the collaborating institutions with the global research it carries out, the Department developed the concept and operational mechanisms of a United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children's Fund (UNICEF)/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) Academic Alliance.

## 2. Research capacity-strengthening

### 2.1 WHO African Region

#### *Progress*

#### *Institutional capacity-strengthening*

During 2013, LID grant activities continued in the eight institutions in eight countries that had also received grants in 2012: Burkina Faso (Institut de Recherche en Sciences de la Santé, Ouagadougou), Democratic Republic of the Congo (Université de Kinshasa, Faculté de Médecine Département de Gynéco-Obstétrique, Kinshasa), Cote d'Ivoire (Cellule de Recherche en Santé de la Reproduction, Abidjan), Ethiopia (University of Addis Ababa, School of Medicine, Addis Ababa), Guinea (Cellule de Recherche en Santé de la Reproduction, Conakry), Malawi (University of Malawi, Blantyre), South Africa (Effective Care Research Unit, East London) and the United Republic of Tanzania (Kilimanjaro Christian Medical Centre, Moshi). Supported centres published numerous articles in national and international peer-reviewed journals. For example, an article was published on policy gaps for subsidizing delivery care (Burkina Faso) (1), as well as articles on maternal and perinatal outcomes of labour (Democratic Republic of the Congo) (2, 3).

### *Research training grants*

A Courses Workshops Seminar grant was awarded to the Witwatersrand Reproductive Health and HIV Research Unit Johannesburg, in South Africa. This was used to fund two participants from Nigeria to attend a research methodology course in sexual and reproductive health and gender-based violence, presented in Johannesburg, 12–28 August 2013, and attended by 13 participants from Nigeria, South Africa, Swaziland, Uganda, United Republic of Tanzania and Zambia.

### *Regional network of research institutions*

The Department continued to support ReproNet-Africa for Region-specific networking, partnership, and advocacy for reproductive health issues. These included publication of a newsletter and management of a website for information dissemination. The website, which was launched in November 2009, receives an average of 100 visits a week and by August 2013 the newsletter had 300 confirmed readers. At the Federation of Gynecology and Obstetrics (FIGO) 2012 Congress, held from 7–12 October 2012 in Rome, Italy, ReproNet-Africa hosted a 90-minute session entitled “Controversies in reproductive health policies in Africa”, which attracted approximately 80 attendees.

## **2.2 WHO Region of the Americas**

### *Progress*

#### *Institutional capacity-strengthening*

LID support continued to two institutions: in Paraguay (the Centre for Population Studies [CEPEP], Asunción) and in Bolivia (Centre for Research in Development Sciences [CIDES] of San Andrés University, La Paz). The two centres have completed their 5-year cycle of the LID grant, and are working on implementing research projects.

#### *Research project support*

The above two institutions receiving LID grants also received support to work on their research projects: CEPEP – “Intimate partner violence and reproductive coercion against women”; and CIDES “Quality of care in pregnant adolescent women”. It is expected that the research projects will be completed in 2014 and the results will be published.

#### *Research training grants*

Research training grants were awarded through the Latin-American Program for Research in Sexual and Reproductive Health, administered by the Biomedical Institute of Experimental Medicine in Argentina. This institute coordinates individual research training activities in the Region of the Americas. A total of 16 fellows were awarded courses or practical training of 6 months or less. Of these, six grants were awarded for students to take an online course by the Geneva Foundation of Medical Education and Research, on Research Methods in Sexual and Reproductive Health (4).

#### *Dissemination of research findings*

The XXIII Biannual Meeting of the Latin American Association of Reproductive Health Researchers (ALIRH) took place in Cancun, Mexico, from 12 to 14 November 2013. ALIRH is an international nongovernmental organization that aims to promote development of original scientific research applicable to human

reproduction and sexual and reproductive health in Latin America; disseminate the results of these scientific investigations; and facilitate the exchange of scientific information among its members. ALIRH members come from various specialties relevant to reproductive health, including obstetrics and gynaecology, human reproduction, endocrinology, basic sciences, demography, epidemiology and social sciences. The meeting, with participation of more than 200 scientists, aimed to share research results and their application to sexual and reproductive health in the Region. A special lecture was delivered by an ALIRH member, where the contribution of HRP to research and research training, including institutional strengthening to the Region of the Americas, was highlighted.

As in previous years, the Department continued supporting 10 institutions in the Region of the Americas for the HINARI (Access to Research in Health) Programme, in order to gain access to more than 15 000 information resources (5).

## 2.3 WHO Eastern Mediterranean and European Regions

### *Progress*

#### *Institutional capacity-strengthening*

During 2013, LID grant support continued in one institution in Afghanistan for the third year. The centre continued to conduct research methodology training courses, with an aim to enlarge the pool of researchers in reproductive health. The centre has submitted details of a research project for funding by the HRP research capacity-strengthening programme, along with an application for the fourth year of support from the LID grant; this is under scientific review.

In the European Region (including central Asian countries), a LID grant was awarded for the first time to Tajik Scientific Research Institute of Obstetrics, Gynaecology and Perinatology of the Ministry of Health of the Republic Tajikistan, and technical support was provided to the institute for developing a research protocol as part of the grant.

#### *Research project support*

The two above institutions receiving LID grants also received support in preparing research proposals. These two research proposals have been submitted and are currently under scientific review. It is expected that they will be approved and funded in early 2014.

#### *Research training grants*

No individual training grants were awarded in 2013. Instead, support was provided to the following group-training activities:

- research methodology workshop in Afghanistan: the workshop involved 40 participants from tertiary hospitals, the majority of whom were from the maternity and obstetrics and gynaecology department of Kabul Medical University, and the Ministry of Public Health. Five research proposals were developed. One of the research proposals is approved by the institutional review board for ethics review, while the others are pending approval;
- two research centres were established in Afghanistan, in Malali and Rabia Balkhi hospitals, with the aim to facilitate research activities in reproductive health in these hospitals. These centres have prepared two research protocols focusing on maternal health;

- a consultation was organized in Kaunas, by the University of Kaunas, Health Sciences: “Capacity-building in operational research in reproductive health in countries of eastern and central Europe”. Representatives from 17 countries of the WHO European Region discussed their experiences in using knowledge and skills in operational research as part of country programmes for improvement of reproductive health, and made recommendations for further improvement of the process of national capacity-strengthening in operational research, and for publishing results in peer-reviewed journals.

## 2.4 WHO South-East Asia and Western Pacific Regions

### *Progress*

#### *Institutional capacity-strengthening*

LID grants were awarded to three institutions: the Health Research Epidemiology Unit, Ministry of Health, Bhutan; National Institute of Public Health, Cambodia; and Department of Medical Research, Upper Myanmar.

#### *Research project support*

Support was given to the LID grant recipient institutes to develop research proposals based on national priorities. The institute in Cambodia has submitted a research project: “Empowering adolescents towards better reproductive health”, while Myanmar submitted a research project “Sexual behaviour and contraceptive practices among adolescent university students in Mandalay District”. These research projects will be implemented in 2014 following scientific and ethical review.

#### *Research training grants*

No individual research training grants were awarded in 2013; instead, support was provided to the following group-training activities.

- Bhutan organized a qualitative workshop on research methodology, which was attended by 38 participants who were trained in research methodology and preparing research proposals. The Department supported a second workshop in Bhutan for development of a national research strategy. The National Strategy for Health Research for Bhutan 2013 has been finalized and published ;
- Myanmar conducted two workshops in 2013: (i) “Responsible conduct of research and preparing a scientifically strong research proposal”; and (ii) “Evidence-informed policy-making in the health sector”. Two research proposals were finalized and have been submitted for scientific review. One of the past research training grant recipients from Myanmar published a journal article, “Gender differences in exposure to SRH [sexual and reproductive health] information and risky sexual debut among poor Myanmar youths” (6).

## 2.5 Inter-regional: WHO Geneva Foundation for Medical Education and Research training course on sexual and reproductive health research

Since 2003, the Department has participated in the Geneva Foundation for Medical Education and Research (GFMER) training course on SRH research methodology and attracts participation of health professionals mostly from low- and middle-income countries. Since 2010, the course has been conducted online



and runs from May to November. The course modules developed by RHR include the core module on research methodology, and thematic modules on key sexual and reproductive health issues.

### ***Progress***

Every year, 13 to 15 participants with the best performance and highest quality of work during the online course are selected to attend a workshop at WHO headquarters in Geneva. The objectives of this intensive training course are to further refine participants' skills in research protocol development and improve their research skills. The Geneva workshop provides participants with additional opportunities to interact with each other and with WHO staff and share their experiences while improving their professional skills.

In 2012, 147 participants completed the course, with 102 completing their research projects. In 2013, 236 participants completed the course by December, with 96% coming from low- or middle-income countries. Most of the research projects focused on family planning, adolescent health, STIs, and maternal and perinatal health.

### ***Planned activities***

- To continue supporting the GFMER training platform by developing and updating the course modules.
- To assist the extension of the training platform to other countries, by facilitating new partnerships and implementation of some modules on STI/HIV, in other United Nations languages, including Russian.

## 3. HRP Academic Alliance

Building on past and existing work of the Department on research capacity-strengthening, a comprehensive review of various research capacity-strengthening schemes, discussions within the regional advisory panels and the Scientific and Technical Advisory Group in 2013, the concept of the HRP Academic Alliance as the means to deliver the research capacity-strengthening efforts of HRP was further developed, together with an outline of operational mechanisms.

### ***Planned activities***

The HRP Academic Alliance will promote increased collaboration and communication between the national regional research capacity-strengthening efforts and the research HRP conducts/supports. The overall aim is to deliver high-quality, high-impact research in sexual and reproductive health, through strengthened linkages between global collaborative research and mature and emerging research centres in low- and middle-income countries, including those HRP has supported over the years. Activities planned for 2014–2015 are within the main lines of work and principles presented next.

### **3.1 Operationalization of the HRP Academic Alliance, including finalization of the working mechanisms**

Research and research capacity-strengthening activities will be linked, encouraging participation of emerging countries in HRP's collaborative, multicountry studies. Regional hubs will be identified to lead regional research capacity-strengthening activities. A first meeting of the HRP Academic Alliance

steering committee, including representation from regional advisory panels, is planned for February 2014.

### **3.2 Strengthening the research capacity of emerging institutions**

The following strategies will be used to continue supporting research capacity and skills in low- and middle-income countries, bearing in mind that different models of development in capacity-building will be used for different institutions, depending on their existing capacity and their needs. These will include:

- LID grants;
- Research Mentoring Grants;
- Group Training Programme grants for selected training programmes, focusing on (i) young champions, and (ii) emerging concepts.

### **3.3 Capacity-building in all aspects of research**

Efforts will focus on capacity-building in all aspects of research, from research question identification, to implementation, dissemination of result findings, and transferring research into policy and practice, and on promoting high technical and ethical standards and practices.

### **3.4 Linking research capacity-strengthening with multicountry studies**

In 2014, research projects initiated in the Department will be conceptualized from their inception, with integrated capacity-building and institutional support for institutions receiving research capacity-strengthening grants. Opportunities will be presented for centres to take part in multisite research and get so-called hands-on experience of international research, and for individual scientists to contribute to HRP-supported research.

### **3.5 Attracting young researchers to the field of sexual and reproductive health**

To ensure a generation of solid scientists in the field of sexual and reproductive health for the years to come, the HRP Academic Alliance will use a number of specific mechanisms to engage postgraduate students. Specifically, there will be opportunities for MSc and PhD students to collaborate with HRP's research in a way that helps them fulfil their theses' requirements, as well as opportunities for postdoctoral fellows to contribute directly to HRP-supported research. This effort will further strengthen HRP's collaboration with academic institutions worldwide.

#### **4.6 Facilitating communication and resource-sharing between centres**

An e-platform will be developed to enable organizations engaged in research on sexual and reproductive health to share information on their current work and their future plans; engage researchers and facilitate discussions among stakeholders for better understanding and trust; share resources such as online courses; and share information on research tools that is available from other web sources.

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# Biostatistics and Data Management

## Summary

### Key objectives

The biostatistics and data management team provides support for statistical and data management for research projects of the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children's Fund (UNICEF)/World Health Organization (WHO)/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), and supports research capacity-strengthening in biostatistics and data management.

### Major achievements

- Support in statistics, data management, research coordination and monitoring was provided for more than 15 clinical trials and epidemiological studies during 2013.
- The team conducted on-site research training of staff in eight collaborating centres participating in HRP projects, in Argentina, Brazil, Ethiopia, Hungary, India, Mozambique, Thailand and South Africa.
- The team has participated in research capacity-strengthening activities for researchers from low- and middle-income countries:
  - organized by the Geneva Foundation for Medical Education and Research;
  - in the context of the project "Medical Abortion Assessment Tools for Community Workers", the team gave a lecture to investigators from RHR collaborating institutions on how to apply and interpret statistical indicators that are commonly used in studies of diagnostic research.

## 1. Introduction

The services of the biostatistics and data management team contribute to the quality of the research projects of the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children's Fund (UNICEF)/World Health Organization (WHO)/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP). The work is carried out in two streams: technical support for research projects, and capacity-building for collaborating institutions in low- and middle-income countries. In addition, the team provided information technology (IT) support to the whole Department, which included software support (implementation/ installation, and licences for software used by staff) and hardware support (including updating of desktops following the WHO migration to Global Synergy).

## 2. Support for research activities

The biostatistics and data management team provides technical support in biostatistics and data management for protocol development and review, including advice on study design (including case-report forms [CRFs]); development of data-management systems; implementation of data quality-control procedures; computation of sample-size estimates; writing of interim and

final statistical analysis plans; data analysis and preparation of data-management and statistical reports; and participation in writing scientific papers resulting from the projects. For all projects, the team also develops and deploys a comprehensive monitoring and data quality-assurance programme, and trains research teams in these areas in the context of research projects.

## 2.1 Progress and planned activities

### *Technical support for clinical trials and epidemiological studies*

During 2013, support was provided to 15 projects of the Department; in most of the cases, these were related to data-management and statistics support of trials and surveys, and in some cases they were related to statistical modelling for global monitoring of key reproductive health indicators (see Annex 1 for a comprehensive list of projects receiving statistical and data-management support).

The following provides a list of some research studies to which statistics and data-management support is provided.

- **A15229. Multicentre randomized clinical trial of two implantable contraceptives for women, Jadelle and Implanon:** the database was successfully closed after an intensive process of interaction with sites and corresponding corrections and validations. The final analysis of the primary outcomes from the study reporting the 3-year follow-up data is being conducted and it is planned that this will be complete by the end of 2013.
- **Study A65719. Pericoital oral contraception with levonorgestrel: a prospective, open-label, single arm, multicentre study to evaluate efficacy, safety and acceptability:** data collection has been completed for two sites. Monitoring visits and refresher training in data management have been conducted for three sites (Brazil, Hungary and Thailand) during the year. Data cleaning is ongoing for two complete sites (Thailand and Singapore). The interim analysis of the study was conducted and results shared with the members of the Data Safety and Monitoring Board. Plans are being made to start conduction of the final analysis of the data in autumn 2014, following completion of data collection and cleaning by the end of summer 2014.
- **Study A65779. How well do community health workers assess eligibility and follow-up care for early medical abortion: a multicountry validation of assessment tools in Ethiopia, India and South Africa:** the biostatistics and data management team participated in the investigators' meeting in March 2013 in Geneva. It is planned that data collection will be completed by all sites by winter 2013, and that preliminary final analysis of the multicountry paper will start by the beginning of 2014.
- **Study A65709. A demonstration project for the implementation of the WHO antenatal care model in Mozambique: a cluster randomized controlled trial:** study staff have been trained in how to collect and record data on the antenatal care register book, as well as how to transfer the collected data to the data-management centre. On-site monitoring of the collaborating clinics were conducted after the training, and the study guidelines have been modified according to the real situation. The data-management system has been developed and runs smoothly. The pilot study is being conducted to test the data-collection and data-management processes.

- **Study A65783. Non-inferiority of short-term catheterization following fistula repair surgery:** data-collection and data-management activities concluded in August 2013. A final researchers' study meeting took place in September 2013 (Kampala, Uganda), where the final results were presented and discussed. Preparation of the manuscript is ongoing and it is expected that it will be sent to a journal by the end of 2013.
- **A65711. Feasibility and safety study of a new device (Odón device) for assisted vaginal delivery (phase I trial):** 30 cases have been recruited in Buenos Aires, Argentina, to test the safety and feasibility of the device. Data collection for 1-year follow-up and data cleaning are continuing. The preliminary report on the results of the first 30 cases has been created. New sites (Hong Kong, Monaco, South Africa and Switzerland) are preparing for the launch of the study.
- **Study A65742. A randomized, placebo-controlled study of prophylactic ibuprofen in addition to a pain-control regimen for early medical abortion with mifepristone and misoprostol:** data-collection forms (CRFs) have been designed. The protocol is being revised according to comments from the review panel.
- **Training midwives in Kyrgyzstan to provide safe abortion care with mifepristone and misoprostol:** the design of the CRFs to be used in this project has been completed, involving a meeting of the Forms Review Committee.
- **Addressing violence against women in antenatal care: testing an intervention in South Africa and Mozambique:** the design of the CRFs has finished. A site visit was conducted to plan and coordinate data collection using a mobile technology (Open Data Kit [ODK]) that is not GCP (Good Clinical Practice) compliant and will require development of an interface with OpenClinica for supervision purposes.

As part of statistics support to research conducted by the Department, the members of the biostatistics and data management team contributed to the writing of 10 papers published in 2013 (see Annex 2).

The team also continued the updating of the projects repository, contributing protocols, forms, databases and other relevant information.

#### ***Research capacity-strengthening in biostatistics and data management***

The biostatistics and data management team has a strong commitment to support research capacity-strengthening activities at country level. In 2013, onsite training was provided to staff participating in research projects in eight sites in collaborating centres, which helped these sites to improve compliance with GCP and to improve the quality of the data collected and of the corresponding statistical analyses. Other capacity-strengthening work included giving lectures within the context of specific research projects, and at the course "From Research to Practice, Training Course in Sexual and Reproductive Health Research", organized by the Geneva Foundation for Medical Education and Research (September 2013).



### 3. Planned activities for 2014

The biostatistics and data management team aims to consolidate the crucial support (in terms of data management and statistics) provided to the research projects of the Department and, at the same time, as recommended by previous Scientific and Technical Advisory Group (STAG) meetings, to have specific “products”, particularly methodological papers.

In 2014, the team will work in several important trials with decentralized data management. Several statistical and data-management activities will continue to be outsourced during 2014.



Annex 1: List of RHR biostatistics and data management team projects (continued)											
RHR team Code	Project name	STATUS			2013				2014		
		Ongoing	New		1st quarter	2nd quarter	3rd quarter	4th quarter	1st quarter	2nd quarter	3rd quarter
MPH A65711	Feasibility and safety study of a new device (Odón device) for assisted vaginal delivery (phase I trial)	X			Data collection, query management, and progress reporting contd. DM system setup and training for 4 new sites.	Data collection, query management, and progress reporting	Data collection, query management, and progress reporting	Data collection, query management, and progress reporting	Data collection, query management and progress reporting	Data collection, query management and progress reporting	Data collection, query management and progress reporting
PPF A15229	Multicentre randomized clinical trial of two implantable contraceptives for women, Jadelle and Implanon	X			Data collection and database cleaning; data entry, query resolution, ICD-10/ICPM coding of old forms, data cleaning	Database cleaning (and preliminary statistical analysis?)	Database cleaning and preliminary analysis	Database cleaning and preliminary analysis	Data closure and final analysis		
PPF A25165	Sperm suppression and contraceptive protection provided by NET-EN [norethisterone enantate] combined with testosterone undecanoate (TU) in healthy men	X			Preliminary statistical analyses			Final analysis			
PPF A65719	Pericoital oral contraception with levonorgestrel: a prospective, open-label, single-arm, multicentre study to evaluate efficacy, safety and acceptability	X			Data collection, query management and progress reporting	Data collection, query management and progress reporting	Data collection, query management and progress reporting	Data collection, query management and progress reporting	Data closure and final analysis		

Annex 1: List of RHR biostatistics and data management team projects (continued)

RHR team Code	Project name	STATUS			2013				2014		
		Ongoing	New		1st quarter	2nd quarter	3rd quarter	4th quarter	1st quarter	2nd quarter	3rd quarter
PUA A65742	A randomized, placebo-controlled study of prophylactic ibuprofen in addition to a pain-control regimen for early medical abortion with mifepristone and misoprostol	×			Data-management system set-up and training	Data collection, query management and progress reporting	Data collection, query management and progress reporting	Data collection, query management and progress reporting	Data closure and final analysis		
PUA A65779	How well do community health workers assess eligibility and follow-up care for early medical abortion: a multicountry validation of assessment tools in Ethiopia, India and South Africa	×			Data collection continued, data-management system set-up and training for two new sites	Data collection, query management, and progress reporting	Data collection, query management and progress reporting	Data collection, query management and progress reporting	Data closure and final analysis		
PUA A15066	Secondary analysis on acceptability of misoprostol	×			Final analysis						
PUA AXXXXX	Training midwives in Kyrgyzstan to provide safe abortion care with mifepristone and misoprostol	×			Final version of forms, forms committee, printing	Data collection and training	Final analysis				
STI STI	The introduction and impact of the <i>careHPV™</i> test into cervical cancer prevention and control programmes based on VIA [visual inspection and analysis] and cryotherapy		×		Data collection	Data collection	Data collection	Data collection	Data collection	Data collection	Final analysis

DM: data management; GRR: Gender and Reproductive Rights; ICD-10: *International statistical classification of diseases and related health problems*, 10th revision; ICPM: *International Classification of Procedures in Medicines*; MPH: *Maternal and Perinatal Health*; PFP: *Promoting Family Planning*; PUA *Preventing Unsafe Abortion*; SAP: *statistical analysis plan*; STI: *Sexually Transmitted Infection*.



# Research Project Review and Ethics

## Summary

### Key objectives

The Research Project Review Panel (RP2) has a mandate from the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children's Fund (UNICEF)/World Health Organization (WHO)/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), to cover the scientific, technical, financial and ethical review of all new proposals and annual review for all multi-year projects. The ethics focal point oversees, through RP2, the consistency of ethical recommendations applied to research projects; provides support for ethics capacity-strengthening associated with the Department's activities; provides presentations on ethics in the field of reproductive, maternal, newborn and child health at regional and international conferences; and addresses issues associated with ethical, legal and social implications (ELSI) debates.

### Major achievements

Successful, cost-effective and efficient review of the following new and ongoing HRP research projects was accomplished through RP2 in 2013:

- 32 projects were reviewed for either first submission, resubmission or continuing review, with five remaining in active electronic review;
- 12 RP2 members were involved in committee review meetings (face to face, video or teleconferencing), with half of these being able to provide continuous and repeated assessments of the same protocols in the context of subsequent committee reviews;
- 18 RP2 members were involved in reviews by electronic means, for projects continuing from previous years.

In 2013, the area of research review and ethics achieved:

- development of a database on research projects reviewed through independent HRP governance bodies, the Scientific and Ethics Review group (SERG) and RP2, since 1984–2012;
- Ethics: (i) an ELSI grant was submitted and approved through external leveraged funding on a sexual and reproductive health topic; and (ii) peer-reviewed ethics papers were published in basic science/animal-based sexual and reproductive health research, and also on the concept of vulnerability.



## 1. Introduction

The Research Project Review Panel (RP2) provides independent external review, in fostering recognition of universal ethical principles and scientific principles of good research practice, in the development and implementation of studies and in the implementation of guidelines. The purpose of this is to protect the health and rights of individuals in different social and cultural settings, as acknowledged and supported by the 41st World Health Assembly (1988) in resolution 41.9, specific to the field of reproductive health and research.

## 2. Research Project Review Panel

RP2 is an independent body whose members include multidisciplinary external experts in the field of sexual and reproductive health (SRH), with proven capacity to address research proposals and evaluate protocols with regard to scientific, technical, financial and ethical considerations. The experts on the review panel are not involved in the development of projects for the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children's Fund (UNICEF)/World Health Organization (WHO)/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), and if any other conflict of interest is declared, this will negate the ability of the expert to participate in any decision-making on the outcome of a project review.

RP2 was formed by HRP in 2010, through the consolidation of the five specialist panels and the former Scientific and Ethical Review Group (SERG), which performed reviews of research concept notes and projects. RP2 thus currently reviews research projects at various stages of development. All projects submitted electronically to the RP2 Secretariat were reviewed by members of RP2 – for new projects this was done through a face-to-face meeting, while for approved multi-year projects requesting annual assessment (continuing review), review was completed electronically (see Table 1).

Table 1. New and multi-year HRP proposals reviewed by RP2 in 2013, either in consensus or via interim review					
		Outcome of RP2 consensus meetings and interim/continuing review			
Type of review (meeting or interim)	Number of projects submitted	Full approval	Conditional approval with amendments and clarifications	Exempt or resubmission required	Disapproval/ stopped
RP2					
November	15	7	3	4	1
Interim/ continuing review	17	16	1	0	0
<b>Totals</b>	<b>32</b>	<b>23</b>	<b>4</b>	<b>4</b>	<b>1</b>

The average length of time for a new project to obtain an RP2 assessment following a review meeting was 2.5 days. The time it took for researchers to provide responses to a conditional approval (i.e. by resubmitting the revised project to RP2 for final approval) varied widely – from 2 days to 20 weeks. Collectively, from mid-2010 to 2013, for new projects, the average amount of time to complete the full process of HRP review through RP2 was approximately 7.6 weeks, with some projects completing within 2 days and a few requiring substantial revision, with the longest time to completion being 35 weeks.

The time for multi-year-approved projects to complete the continuing review process varied between 24 hours and 13 weeks. Information on the additional time for HRP projects to complete either a new project or continuing review through the ethics body at WHO headquarters (the WHO Ethics Review Committee), as well as any required local ethics review, is not available.

All current RP2 members (except three members who were individually invited in 2011 or 2012) will have completed their 3-year term by the end of either December 2013 or June 2014. RP2 was self-audited and evaluated for compliance to be accredited as an international ethics body. New terms of reference and standard operating procedures have been developed for a renewed RP2, and membership will require reassignments and newly appointed membership, as RP2 continues through 2014.

### 3. Ethics in sexual and reproductive health

Owing to funding constraints, RP2 members have not been able to conduct or support regional or national research ethics capacity-strengthening workshops in 2013. However, the HRP–RP2 research project review application form includes a section with detailed requests regarding research ethics considerations, which has stimulated discussions during workshops on development of research proposals.

RP2 members, together with the ethics focal point, were able to secure external funding in 2012 for research studies on ethics, to be conducted in 2014, (i) for an ethical, legal and social implications (ELSI) workshop on addressing issues associated with the implementation of specific SRH guidelines; and (ii) for an ELSI summer workshop on addressing new technologies in reproductive medicine. The ethics focal point, representing RHR and HRP: (i) was invited and externally supported to participate in SRH-related ethics activities, including two regional symposia on reproductive medicine, as well as four international workshops; and (ii) provided presentations to support RHR colleagues. Two peer-reviewed journal articles were written and published, together with the ethics focal point, on (i) ethics and basic/animal research (1); and (ii) the ethical topic of “vulnerability” (2). A set of ethics guidance for research with adolescents is in the process of development by the Adolescent and At-risk Populations (AGH) team within RHR. This will then be subjected to review and assessment by the RP2 ethicists.

Bioethics committees, opinion leaders, religious spokespersons, scientists, political parties and others provide teachings, recommendations and indications on choices and decision-making relating to human reproduction. These various teachings, recommendations and indications often reflect different points of view on the same subject; however, they are rarely presented at the same time

or in an unbiased manner. In addition, in the context of debates and discussions on issues related to human reproduction, points of view and positions might be inaccurately portrayed and/or inaccurately attributed to individuals, organizations, religions, political parties or others. An independent, multidisciplinary and fully comprehensive and representative ELSI body has been established by HRP, to begin to accurately describe, from relevant points of view, the multiple critical issues on the basis of which decisions involving human reproduction are made. Following a first meeting convened at the end of 2012, discussions were continued, with a teleconference meeting in May 2013. As a result, a specific document, currently in draft, has been developed to address the issue of contraception from a religious perspective.

## References

1. Dancet EA, Brännström M, Brasky K, Chai D, Chan AW, Conn PM et al. The role of scientists and clinicians in raising public support for animal research in reproductive biology and medicine. *Biol. Reprod.* 2013;88(2):33. doi: 10.1095/biolreprod.112.105908.
2. Luna F, Vanderpoel, S. Not the usual suspects: addressing layers of vulnerability. *Bioethics.* 2013;27(6):325–32. doi: 10.1111/bioe.12035.

# Advocacy and communications

## Summary

### Key objectives

Through its advocacy and communications work, the Department of Reproductive Health and Research (RHR) aims to promote uptake of its evidence-based outputs, to build awareness of key issues in sexual and reproductive health, and to raise funds and ensure the continued commitment and engagement of Member States, the World Health Organization (WHO) and other agencies. issues associated with ethical, legal and social implications (ELSI) debates.

### Major achievements

- 27 new technical publications in English were produced and distributed (please refer to list in Annex 1).
- 23 translations of RHR documents were published.
- Results were published in the scientific press, in 98 peer-reviewed articles (please refer to list in Annex 2). There was a sharp increase in the number of times these articles were cited by others – an indication of increased relevance and impact.
- Ten issues of the Department's electronic newsletter, *Reproductive Health Update*, were sent out during 2013.
- There were 22.3 million page views on the WHO reproductive health and Reproductive Health Library (RHL) websites and 570 000 video views on the HRP YouTube channel.
- RHR and HRP outputs were widely disseminated, and high-level advocacy for sexual and reproductive health was carried out, at 36 different conferences, symposia and international meetings (please refer to list in Annex 3).
- Web features were prepared for a number of international days relevant to the Department's work, such as International Day for the Elimination of Violence against Women and International Day of the Girl Child. These were well supported by the WHO central web services, which featured aspects of RHR's work at least once a month during 2013, on the WHO home page. A Facebook story on the Day of the Girl Child generated almost 1000 likes in one day.
- 2013 saw an increased and effective collaboration with the WHO central Department of Communications, which worked with RHR to support a number of events, such as Women Deliver and the International Conference on Family Planning. There were also several press releases produced and disseminated in support of key publications launched during the year.

## 1. Introduction

Advocacy efforts in the World Health Organization (WHO) Department of Reproductive Health and Research (RHR) are still led by teams, and advocacy budgets are managed by each team. In developing its work in the area of advocacy, the Department takes three strategic approaches:

- advocacy aimed at increasing the uptake of its evidence-based outputs (e.g. evidence-based approaches, strategies, research findings, clinical and scientific guides and norms, and other departmental outputs);
- contributions to high-level advocacy and awareness-building for key issues in sexual and reproductive health – this involves the initiation of, or contribution to, international or regional partnerships, and engagement with the international development community (e.g. International Health Partnership [IHP +], H4+ [United Nations Population Fund {UNFPA}, United Nations Children's Fund {UNICEF}, WHO, World Bank, UN Women]);
- promotion of the work of the Department and the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), in order to raise funds and ensure the continued commitment and engagement of Member States, WHO and other agencies.

Key aspects of advocacy and communications are supported centrally within the Department, including document editing and production, multimedia development, creation of display materials, graphic design, web development, dissemination of information products, and conference and workshop site support. The Department also convenes a Documents Committee, which meets several times a year to review all proposals for new publications from the Department and aims to rationalize the issuing of documents; improve planning for document production within RHR; ensure that the documents produced reflect the overall strategies of RHR; and enhance the impact of RHR's work at the country level.

## 2. Achievements in advocacy and communications

### 2.1 Advocating for uptake of evidence-based outputs

#### *Technical publications, documents and information materials*

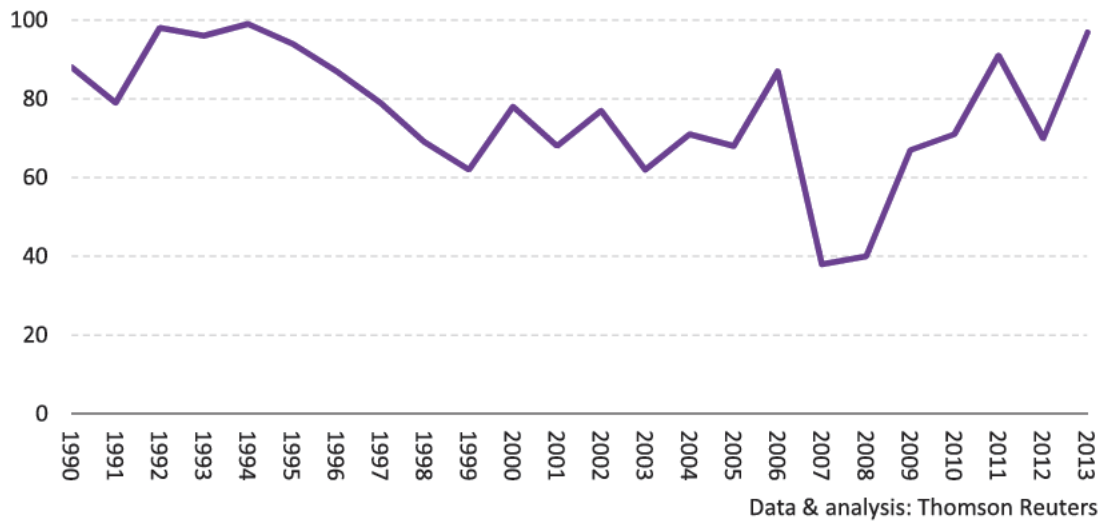
The Department produces and disseminates serial and non-serial documents and information materials for a variety of target audiences, including researchers, policy-makers, and health-care programme managers. In 2013, 27 new technical publications in English were produced and distributed. In addition, 23 versions of existing documents were published in languages other than English, and requests by external partners to translate RHR publications into non-official languages were managed. RHR guidelines and tools were introduced and demonstrated at 36 workshops, with participants including ministry of health staff, programme managers, and health-care providers.

#### *Peer-reviewed publications*

HRP results were published in the peer-reviewed scientific press in 98 articles in 2013 (please refer to list in Annex 2). These articles were analysed by Thomson Reuters Evidence, a firm that specializes in bibliometric analysis, following the

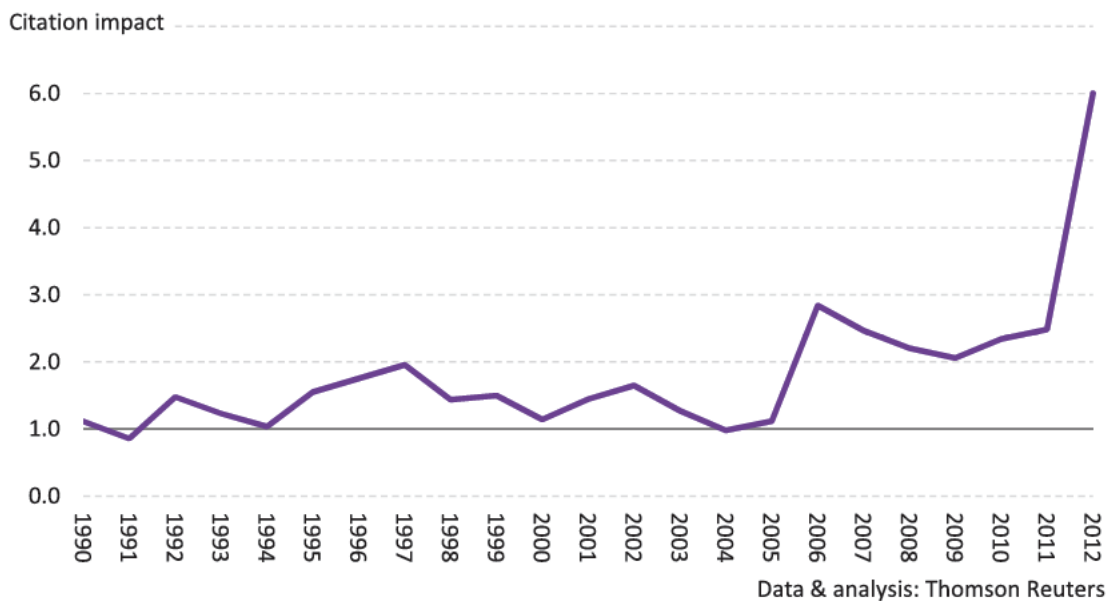
same methodology used for the *HRP External evaluation* in 2012.<sup>1</sup> This represents an increase over previous years, as shown in Fig. 1.

Fig. 1. Number of HRP papers by year, 1990–2013



The normalized citation impact of HRP papers averaged 1.42 during the period 1990–2007 and then rose to 2.14 by 2008–2011, already more than two times the global average. In 2012, the HRP citation impact reached 6.0, owing to the issue of a number of papers that were extremely highly cited. Trends in citation impact are shown in Fig. 2.

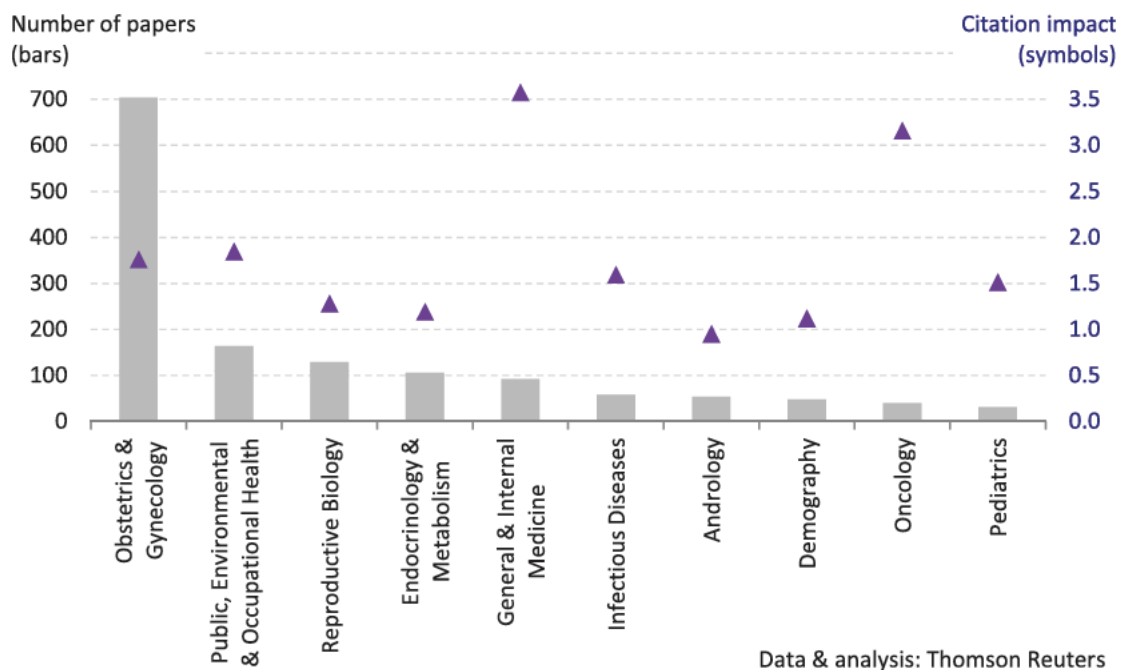
Fig. 2. Trends in citation impact of HRP papers, 1990–2013



1 Gurney K, Sheridan-Jones B, Thomson S. Bibliometric analysis. In: *HRP External evaluation 2008–2012*. Geneva: World Health Organization; 2013:245–80 ([http://www.who.int/entity/hrp/about\\_us/governance/analysis.pdf?ua=1](http://www.who.int/entity/hrp/about_us/governance/analysis.pdf?ua=1), accessed 23 January 2014).

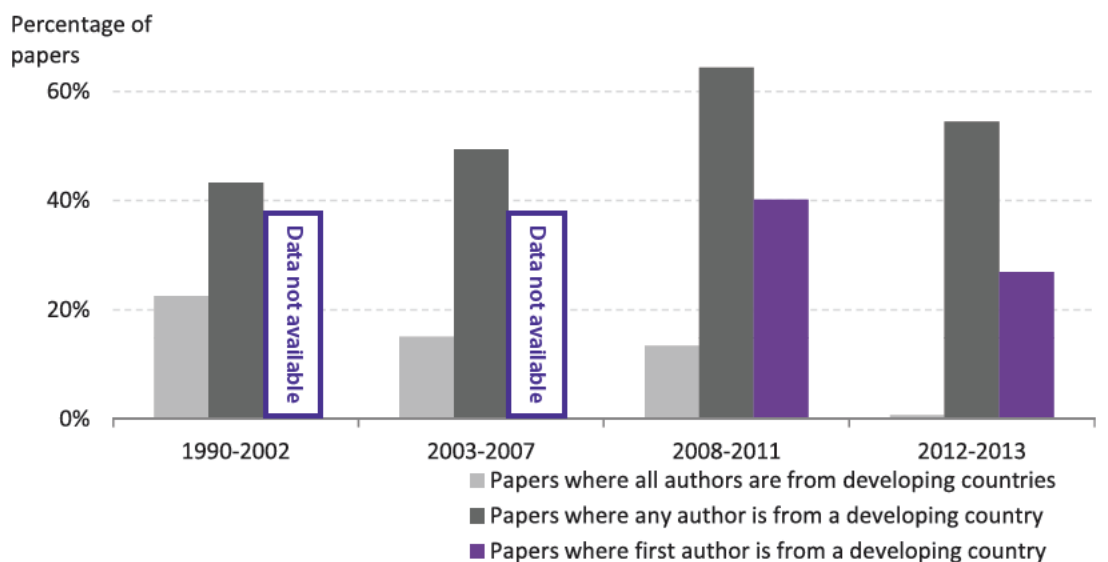
An analysis of the categories of journal in which HRP published revealed that obstetrics and gynaecology journals account for the highest share of HRP research publications, with more than one third (40.9%) of HRP papers falling into this category in 2012. This research is well cited within its category, with a citation impact approaching twice the world average, as shown in Fig. 3.

Fig. 3. Output and citation impact in the 10 most frequently used Web of Science journal categories, 1990–2012



The percentage of HRP research papers published where all the authors are from low- or middle-income countries has decreased since 1990, as shown in Fig. 4. HRP's collaborating centres have been instrumental partners in HRP's global research agenda, with a corresponding reduction in purely independent research. This trend is reflected in the reduction shown in Fig. 4.

Fig. 4. Percentage of papers with authors from low- or middle-income (developing) countries, 1990–2013, 1990–2012





Taken together, these indicators of research performance are significantly above the world average, and indicative of research that is of strong international standing. In 2014, the programme will aim to increase the participation of authors from low- and middle-income countries, in particular under the HRP Academic Alliance.

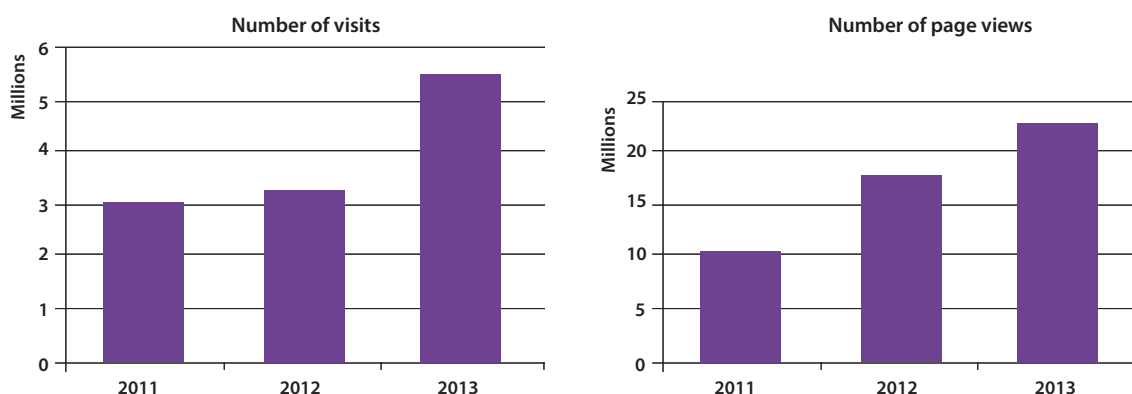
## Websites and electronic media

The Department's electronic newsletter – *Reproductive Health Update* was also produced regularly during the year (10 issues during 2013). *Reproductive Health Update* is a monthly email bulletin highlighting recently published research from the Department, notable events, and new RHR publications. The number of subscribers, who have all “opted in” to this newsletter, now stands at over 3000. Anyone with an interest in the work of the Department can subscribe. Link-monitoring software shows a high click-through rate from the e-bulletin to the RHR website and to downloading of electronic copies of publications (see Table 1), as well as high interest in externally published research articles from the Department.

The reproductive health and HRP websites continue to be updated daily. The “What’s new?” section, which includes the latest publications, research articles and events, is regularly promoted in the *Reproductive Health Update*. The Department continues to expand the sites and, during 2013, a new section on mHealth (mobile health) was added that showcases the Department's work on mobile technology. Also in 2013, the publications section was reorganized to help users find material more easily.

There was also continued growth in the number of both visits and page views in 2013. The number of visits rose from 3.3 million in 2012 to 5.5 million in 2013, as shown in Fig. 5. This, in turn, resulted in a higher number of page views, up from 17.4 million in 2012 to 22.3 million in 2013.

Fig. 5. Number of HRP website visits and page views, 2011–2013



The reproductive health website is one of the few WHO sites with material available in all six official languages and with some publications available in other languages as well, as shown in Fig. 6. Given that 40% of visitors seek sites in languages other than English, this is an area that will continue to be important for the Department in 2014.

Fig. 6. Visitors to the reproductive health website by language, 2013

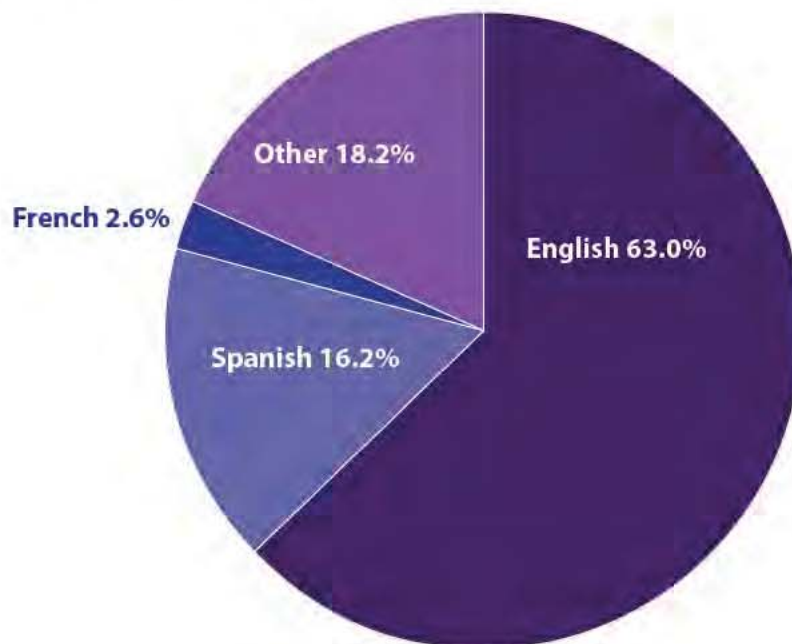


Table 1. Documents with the highest number of downloads from the website

Title	Number of downloads
<i>Medical eligibility criteria for contraceptive use</i> , 4th ed. Geneva: World Health Organization; 2010.	12 590
WHO RHR. <i>WHO laboratory manual for the examination and processing of human semen</i> , 5th ed. Geneva: World Health Organization; 2010.	11 712
WHO RHR, London School of Hygiene and Tropical Medicine, South African Medical Research Council. <i>Global and regional estimates of violence against women. Prevalence and health effects of intimate partner violence and non-partner sexual violence</i> . Geneva: World Health Organization; 2013. <sup>a</sup>	6 149
Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs and World Health Organization. <i>Family planning: a global handbook for providers, 2011 update</i> . Geneva: World Health Organization; 2011.	5 563
Violence against women. Health sector response. Infographic: <i>Addressing violence against women among patients seeking antenatal care</i> . Geneva: World Health Organization; 2013. <sup>a</sup>	3 806

<sup>a</sup> Published November 2013.

For people who may have difficulty in accessing material through the web, the Department continues to produce a CD-Rom of its materials, which is also regularly disseminated at conferences and workshops.

Additionally, HRP's You Tube video channel, launched in 2012, continues to enjoy a high level of success. The number of video viewings in 2013 reached 570 000, with a total of 2 million minutes watched. It currently has 1200 subscribers.

## 2.2 Fundraising

Fundraising and donor relations remain vital in the changing global fiscal climate and as RHR adapts under the umbrella of WHO organizational reforms. A list of donors can be found in Annex 4. RHR leadership transition was a core element of donor relations in 2013. Dr Temmerman, with support of HRP colleagues, reached out to donor partners seeking to reaffirm the partnerships. Donors expressed their vote of confidence in RHR, with 18 donor partners increasing their support during the 2012–2013 biennium, along with nine new donors joining the department during the same period and three former donors returning.

In 2013, donor relations and resource mobilization took shape in new forms. RHR leadership worked collaboratively with research partners and donors to establish and launch large-scale multi-year initiatives. Donor partners were involved more than ever in resource mobilization, providing guidance to RHR and raising funds on the behalf of the Department. Donor communications also continue to grow, but with an emphasis on e-communications for efficiency and scope.

## 3. Planned activities

In November 2013, the Department embarked on the development of a communications and advocacy strategy for 2014–2016, as well as an implementation plan for 2014. The work, which will likely result in major changes in RHR communications and advocacy work, will be completed in April 2014. As an interim measure, in early 2014 the team is pressing forward on planned and ongoing activities.

With regard to the uptake of evidence-based outputs, the Department will continue to produce and disseminate technical publications and guidelines in English and other languages, complementing articles published in peer-reviewed journals.

The reproductive health and HRP websites will continue to be updated on a daily basis and the language sites expanded.

Throughout 2014, an extensive programme of high-level, targeted events and activities is planned, including active participation at the Third Global Symposium on Health Systems Research in October, which will provide an opportunity to share cutting-edge research on sexual and reproductive health, addressing the development of people-centred health systems. In addition, the Department will participate in other similar events relating to sexual and reproductive health.

Resource mobilization in 2014 will continue to build upon the successes of the last year. Benefiting from the engagement of donor partners as key advisers and catalysts for growth is vital, if the Department is to maintain the momentum. As the Academic Alliance takes shape, it will provide a growing infrastructure for channelling funds to research centres in-country. And as the Department's communications strategy is implemented, the Department will reach and connect with donors in new ways, to provide timely and relevant information as the year unfolds.

## Annex 1. Technical publications issued in 2013

1. 16 ideas for addressing violence against women in the context of the HIV epidemic. A programming tool.
2. Annual technical report 2012.
3. Baseline report on globally sexually transmitted infection surveillance 2012.
4. Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Global guidance on criteria and processes for validation.
5. External evaluation. 2008–2012. UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction.
6. Guide to fostering change to scale up effective health services.
7. Highlights of 2012. Department of Reproductive Health and Research including UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP).
8. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence.
9. HRP programme budget 2014–2015.
10. Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus.
11. The H4+ partnership. Joint country support to improve women's and children's health. Progress Report.
12. 26th meeting of the Policy and Coordination Committee.
13. Programming strategies for postpartum family planning.
14. Monitoring national cervical cancer prevention and control programmes: quality control and quality assurance for visual inspection with acetic acid (VIA)-based programmes.
15. Responding to intimate partner violence and sexual violence against women. WHO clinical and policy guidelines.
16. Responding to intimate partner violence and sexual violence against women: clinical and policy recommendations. Summary.
17. Sexually transmitted infections. The importance of a renewed commitment to STI prevention and control in achieving global sexual and reproductive health.
18. WHO guidance for measuring maternal mortality from a census.
19. WHO guidance note. Comprehensive cervical cancer prevention and control: a healthier future for girls and women.
20. WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention.

## Evidence briefs/information sheets/statements/infographics

1. Statement for collective action for postpartum family planning.
2. Preventing gender-biased sex selection. An interagency statement (OHCHR, UNFPA, UNICEF, UN Women and WHO).
3. mHealth project briefs:
  - Preventing stock-outs of antimalarial drugs in sub-Saharan Africa. Novartis's SMS for Life.
  - SMS printers aid early infant diagnosis of HIV/AIDS in Nigeria. CHAI's SMART.
4. Assisting community health workers in India. Dimagi's CommCare.
5. Supporting treatment of childhood malnutrition in Zanzibar. D-tree International's eNUT.
6. Small incentives improve vaccine coverage in Pakistan. IRD's Interactive Alerts.
  - Supporting pregnant women and new mothers in South Africa. Cell-Life's MAMA SMS.
  - Improving maternal and newborn access to services in Ghana. Grameen Foundation's MOTTECH.
  - Assisting community health workers in Rwanda. Ministry of Health's RapidSMS and mUbuguzima.
7. Task shifting to improve access to family planning.
8. Using lay health workers to improve access to key maternal and newborn health interventions in sexual and reproductive health.
9. Violence against women. The health sector responds (infographic).
10. WHO's work on sexual and reproductive health for emergency risk management and humanitarian response.

## Language versions

1. Beginning with the end in mind. planning pilot projects and other programmatic research for successful scaling up. FRENCH
2. Highlights of 2012. Department of Reproductive Health and Research including UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP). FRENCH
3. UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. External evaluation. 2008–2012. Executive summary. FRENCH
4. From Kampala to Dakar and on to Addis. Publication for IBP Initiative. FRENCH
5. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. ARABIC/CHINESE/ENGLISH/FRENCH/RUSSIAN/SPANISH

6. Guide to fostering change to scale up effective health services. FRENCH
7. Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. FRENCH/SPANISH
8. Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. Executive summary. CHINESE
9. Monitoring national cervical cancer prevention and control programmes: quality control and quality assurance for visual inspection with acetic acid (VIA)-based programmes. SPANISH
10. Responding to intimate partner violence and sexual violence against women: clinical and policy recommendations. Summary. FRENCH/RUSSIAN
11. Safe abortion: technical and policy guidance for health systems FRENCH/RUSSIAN/PORTUGUESE
12. Strategies and laboratory methods for strengthening surveillance of sexually transmitted infections. 2012. FRENCH
13. Task shifting to improve access to family planning. FRENCH
14. Violence against women, information sheets on understanding and addressing violence against women. (Overview, Intimate partner violence, Sexual violence, Femicide, Female genital mutilation, Human trafficking, Health consequences) FRENCH

## Annex 2. Articles published in scientific journals in 2013

### HRP 2013 publications list

1. Abalos E, Cuesta C, Grosso AL, Chou D, Say L. Global and regional estimates of preeclampsia and eclampsia: a systematic review. *Eur. J. Obstet. Gynecol. Reprod. Biol.* 2013;170(1):1–7. doi:10.1016/j.ejogrb.2013.05.005.
2. Abdel-Aleem H, Alhusaini TK, Abdel-Aleem MA, Menoufy M, Gulmezoglu AM. Effectiveness of tranexamic acid on blood loss in patients undergoing elective cesarean section: randomized clinical trial. *J. Matern. Fetal Neonatal Med.* 2013;26(17):1705–9. doi:10.3109/14767058.2013.794210.
3. Abdel-Aleem H, d’Arcangues C, Vogelsong KM, Gaffield ML, Gulmezoglu AM. Treatment of vaginal bleeding irregularities induced by progestin only contraceptives. *Cochrane Database Syst. Rev.* 2013;10:CD003449. doi:10.1002/14651858.CD003449.pub5.
4. Ali M, Seuc A, Rahimi A, Festin M, Temmerman M. A global research agenda for family planning : results of an exercise for the setting of research priorities. *Bull. World Health Organ.* 2013 ([http://www.who.int/bulletin/online\\_first/13-122242.pdf](http://www.who.int/bulletin/online_first/13-122242.pdf), accessed 23 January 2014).
5. Bayer LL, Edelman AB, Caughey AB, Rodriguez MI. The price of emergency contraception in the United States: what is the cost-effectiveness of ulipristal acetate versus single-dose levonorgestrel? 2013;87(3):385–90. doi:10.1016/j.contraception.2012.08.034.



6. Belhadj H, Rasanathan JJK, Denny L, Broutet N. Sexual and reproductive health and HIV services: integrating HIV/AIDS and cervical cancer prevention and control. *Int. J. Gynecol. Obst.* 2013;121(Suppl. 1):S29–S34. doi:10.1016/j.ijgo.2013.02.002.
7. Blencowe H, Lee AC, Cousens S, Bahalim A, Narwal R, Zhing N et al. Preterm birth-associated neurodevelopmental impairment estimates at regional and global levels for 2010. *Pediatr. Res.* 2013;74(Suppl. 1):17–34. doi: 10.1038/pr.2013.204.
8. Broutet N, Lehnertz N, Mehl G, Camacho AV, Bloem P, Chandra-Mouli V et al. Effective health interventions for adolescents that could be integrated with human papillomavirus vaccination programs. *J. Adolesc. Health.* 2013;53(1):6–13. doi:10.1016/j.jadohealth.2013.02.022.
9. Bustreo P, Chestnov O, Knaul FM, de Carvalho IA, Meriardi M, Temmerman M et al. At the crossroads: transforming health systems to address women's health across the life course. *Bull. World Health Organ.* 2013;91(9):622. doi:10.2471/BLT.13.128439.
10. Camargo EB, Moraes LF, Souza CM, Akutsu R, Barreto J, da Silva EM et al. Survey of calcium supplementation to prevent preeclampsia: the gap between evidence and practice in Brazil. *BMC Pregnancy Childbirth.* 2013;13(1):206. doi:10.1186/1471-2393-13-206.
11. Chandra-Mouli V, Baltag V, Ogbaselassie L. Strategies to sustain and scale up youth friendly health services in the Republic of Moldova. *BMC Public Health.* 2013;13:284. doi:10.1186/1471-2458-13-284.
12. Chandra-Mouli V, Bloem P, Ferguson J. The World Health Organization's work on adolescent sexual and reproductive health. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz.* 2013;56(2):256–61. doi:10.1007/s00103-012-1606-0.
13. Chandra-Mouli V, Mapella E, John T, Gibbs S, Hanna C, Kampatibe N et al. Standardizing and scaling up quality adolescent friendly health services in Tanzania. *BMC Public Health.* 2013;13:579. doi:10.1186/1471-2458-13-579.
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### Annex 3. Conferences, symposia and international meetings supported in 2013

1. Family planning conference, 7–11 January, Dar es Salaam, United Republic of Tanzania
2. World Cancer Day, 4 February, Geneva, Switzerland
3. Regional abortion competencies workshop, 11–15 February, Nairobi, Kenya
4. International Day of Zero Tolerance to Female Genital Mutilation, 6 February, Geneva, Switzerland
5. Scientific and technical Advisory Group (STAG), 19–22 February, Geneva, Switzerland
6. Commission on the Status of Women 2013, 4–10 March, New York, United States of America
7. International Women's Day, 8 March, Geneva, Switzerland
8. WHO/EURO Multi-Country review meeting on maternal mortality and morbidity audit
9. "Beyond the Numbers" technical meeting, 25–27 March, Riga, Latvia
10. Follow-up activities meetings, 25 March to 6 April, Lusaka, Zambia
11. 66th World Health Assembly, 20–28 May, Geneva, Switzerland
12. 11th Congress of the European Society of Gynaecology (ESG), 22–25 May, Copenhagen, Denmark
13. Women Deliver 2013, 28–30 May, Kuala Lumpur, Malaysia
14. Regional Maternal and Reproductive Health Programme Managers Meeting, 10–12 June, Phuket, Thailand
15. Policy and Coordination Committee (PCC), 20–21 June, Geneva, Switzerland
16. International Union against Sexually Transmitted Infections (IUSTI), 14–17 July, Vienna, Austria
17. 7TH SCCA meeting (Forum of African First Ladies against breast and cervical cancer), 21–23 July, Maputo, Mozambique
18. East, Central and Southern African Health Community (ECSA-HC) Best Practices Forum, 9–14 August, Arusha, United Republic of Tanzania
19. Workshop to develop provider training, dissemination and implementation HIV/family planning MEC wheel, 31 August to 9 September, Gaborone, Botswana



20. Colloque sur l'accès aux droits, de la lutte contre les violences faites aux femmes et de la lutte contre les violences et les discriminations commises à raison de l'orientation sexuelle ou de l'identité de genre [Colloquium on rights, violence against women and violence and discrimination based on sexual orientation or gender identity], 2–3 September, Paris, France
21. International Alliance of Women (IAW) Triennial Congress, 9–13 September, London, United Kingdom of Great Britain and Northern Ireland
22. West African Health Organisation (WAHO) Best Practices Forum, 9–13 September, Bobo Dioulasso, Burkina Faso
23. Human Rights Council side event at the Palais des Nations, 17 September, Geneva, Switzerland
24. Atelier sur les violences faites aux femmes [Workshop on violence against women], 23–26 September, Dakar, Senegal
25. Training workshop on family planning sponsored by the Asian Pacific office of UNFPA, WHO Regional Offices for South-East Asia and for the Western Pacific, 23–27 September, Manila, Philippines
26. International Day of the Girl Child, 11 October, Geneva, Switzerland
27. Sexual Violence Research Initiative (SVRI) Forum 2013, 14–17 October, Bangkok, Thailand
28. West Africa francophone meeting to disseminate training resource package, HIV/family planning tools and task/sharing guidelines, 20–26 October, Dakar, Senegal
29. WHO Regional Office for Europe meeting on Improving Quality of Antenatal and Postpartum Care and Referral System, 24–25 October, Yerevan, Armenia
30. Central Africa francophone meeting to disseminate training resource package, HIV/family planning tools and task/sharing guidelines, 27 October to 1 November, Douala, Cameroon
31. Meeting and pre-meeting workshop on violence against women and children, 28–31 October, Manila, Philippines
32. Conference on Parliamentarians responding to violence against women and girls in Africa, 1–2 November, Johannesburg, South Africa
33. International Conference on Family Planning, 12–15 November, Addis Ababa, Ethiopia
34. African Organisation for Research and Training in Cancer (AORTIC) 2013 congress, 21–24 November, Durban, South Africa
35. International Day for the Elimination of Violence against Women, 25 November, Geneva, Switzerland
36. H4+ Canada grant Inter-Country Annual Planning Meeting, 18–21 November, Freetown, Sierra Leone
37. Violence against women meeting, 25–26 November, Vienna, Austria

## Annex 4. Donors 2012–2013

### HRP donors

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Annex 4 continued

### **Programme Development in Reproductive Health (PDRH) donors**

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