Annual technical report
2014

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

Annual Technical Report, 2014
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## Acronyms and abbreviations

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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>ACS</td>
<td>antenatal corticosteroids</td>
</tr>
<tr>
<td>AHI</td>
<td>adolescent health intervention</td>
</tr>
<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
</tr>
<tr>
<td>ANC</td>
<td>antenatal care</td>
</tr>
<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>ASRH</td>
<td>adolescent sexual and reproductive health</td>
</tr>
<tr>
<td>ASRM</td>
<td>American Society for Reproductive Medicine</td>
</tr>
<tr>
<td>AYSRH</td>
<td>adolescent and youth sexual and reproductive health</td>
</tr>
<tr>
<td>BASTA</td>
<td>Battling Against Syphilis – a Team Approach (listserve)</td>
</tr>
<tr>
<td>BOLD</td>
<td>Better Outcomes in Labour Difficulty (project)</td>
</tr>
<tr>
<td>BV</td>
<td>bacterial vaginosis</td>
</tr>
<tr>
<td>C4-GEP</td>
<td>Comprehensive cervical cancer control: a guide to essential practice</td>
</tr>
<tr>
<td>CAF</td>
<td>Country Accountability Framework</td>
</tr>
<tr>
<td>CAPRISA</td>
<td>Centre for AIDS Prevention and Research in Southern Africa</td>
</tr>
<tr>
<td>CCM</td>
<td>Country Coordination Mechanism</td>
</tr>
<tr>
<td>CDC</td>
<td>United States Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CEFM</td>
<td>child, early and forced marriage</td>
</tr>
<tr>
<td>CERQual</td>
<td>Confidence in the Evidence from Reviews of Qualitative research tool</td>
</tr>
<tr>
<td>CESCR</td>
<td>Committee on Economic, Social and Cultural Rights</td>
</tr>
<tr>
<td>CHAI</td>
<td>Clinton Health Access Initiative</td>
</tr>
<tr>
<td>CIRE</td>
<td>Continuous Identification of Research Evidence</td>
</tr>
<tr>
<td>CoIA</td>
<td>Commission on Information and Accountability for Women's and Children's Health</td>
</tr>
<tr>
<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
</tr>
<tr>
<td>CoP</td>
<td>Communities of Practice</td>
</tr>
<tr>
<td>COS</td>
<td>controlled ovarian stimulation</td>
</tr>
<tr>
<td>CRPD</td>
<td>Committee on the Rights of Persons with Disabilities</td>
</tr>
<tr>
<td>CRVS</td>
<td>civil registration and vital statistics</td>
</tr>
<tr>
<td>CSE</td>
<td>comprehensive sexuality education</td>
</tr>
<tr>
<td>DECIDE</td>
<td>Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence framework</td>
</tr>
<tr>
<td>DHS</td>
<td>Demographic and Health Survey</td>
</tr>
<tr>
<td>DMPA</td>
<td>depot medroxyprogesterone acetate</td>
</tr>
<tr>
<td>DP</td>
<td>Depo-Provera</td>
</tr>
<tr>
<td>DSMB</td>
<td>Data Safety and Monitoring Board</td>
</tr>
<tr>
<td>EC</td>
<td>emergency contraception</td>
</tr>
<tr>
<td>ECOWAS</td>
<td>Economic Community of West African States</td>
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<tr>
<td>ECSA-HC</td>
<td>East, Central and Southern African Health Community</td>
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</table>
EDC  Education Development Center
EMTCT  elimination of mother-to-child transmission
EOBC  emergency obstetric care
EPF  European Parliamentary Forum
EPMM  Ending Preventable Maternal Mortality
ERC  see WHO-ERC
ESSENCE  Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts
EU  European Union
EVD  Ebola virus disease
FANC  focused antenatal care
FGM  female genital mutilation
FGM/C  female genital mutilation/cutting
FIGO  International Federation of Gynecology and Obstetrics
FIGO-RMC  FIGO's Reproductive Medicine Committee
FP2020  Family Planning 2020 (an outcome of the 2012 London Summit on Family Planning)
GAC  Grants Approval Committee
GAP  Gender and Rights Advisory Panel
GARPR  Global AIDS Response Progress Reporting System
GASP  Gonococcal Antimicrobial Surveillance Programme
GAVI  GAVI Alliance
GDG  Guideline Development Group
GEAS  Global Early Adolescent Study
GFF  Global Financing Facility
GIS  geographic information systems
GLOSS  Global STI Surveillance System
GRADE  Grading Recommendations, Assessment, Development and Evaluation
GREAT  Guideline-driven, Research priorities, Evidence synthesis, Application of evidence, and Transfer of knowledge
GRC  Guidelines Review Committee
GURM  genito/urinary and reproductive medicine
H4+  UNFPA, UNICEF, WHO, World Bank, UNAIDS, UN Women
HCV  hepatitis C virus
HPV  human papillomavirus
HRRP  UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction; also: Human Reproduction Programme
HSV  herpes simplex virus
IARC  International Agency for Research on Cancer
IBP  Implementing Best Practices
ICD  International Statistical Classification of Diseases and Related Health Problems
ICD-MM  *WHO Application of ICD-10 to deaths during pregnancy, childbirth and the puerperium (ICD-Maternal Mortality)*
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<th>Acronym</th>
<th>Definition</th>
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<td>ICD-PM</td>
<td><em>WHO Application of ICD-10 to perinatal deaths</em> (ICD-Perinatal Mortality)</td>
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<tr>
<td>ICMART</td>
<td>International Committee Monitoring Assisted Reproductive Technologies</td>
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<tr>
<td>ICPD</td>
<td>International Conference on Population and Development</td>
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<tr>
<td>ICSI</td>
<td>intracytoplasmic sperm injection</td>
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<tr>
<td>ICT</td>
<td>information and communication technology</td>
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<tr>
<td>iEtD</td>
<td>interactive Evidence-to-Decision (tool)</td>
</tr>
<tr>
<td>IFFS</td>
<td>International Federation of Fertility Societies</td>
</tr>
<tr>
<td>IMPRINT</td>
<td>Improving the reporting of clinical trials of infertility treatments</td>
</tr>
<tr>
<td>IMPT</td>
<td>Initiative for Multipurpose Prevention Technologies</td>
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<td>IPPF</td>
<td>International Planned Parenthood Federation</td>
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<tr>
<td>IPU</td>
<td>Inter-Parliamentary Union</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<td>IRP</td>
<td>Implementation Research Platform</td>
</tr>
<tr>
<td>IUD</td>
<td>intrauterine device</td>
</tr>
<tr>
<td>IUl</td>
<td>intrauterine insemination</td>
</tr>
<tr>
<td>IVB</td>
<td>Immunization, Vaccines and Biologicals (WHO Department)</td>
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<td>IVF</td>
<td>in vitro fertilization</td>
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<tr>
<td>IWG</td>
<td>Innovations Working Group</td>
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<tr>
<td>KAP</td>
<td>knowledge, attitudes and practices</td>
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<tr>
<td>LID</td>
<td>Long-term Institutional Development (grant)</td>
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<tr>
<td>LMIC</td>
<td>low- and middle-income countries</td>
</tr>
<tr>
<td>LNG</td>
<td>levonorgestrel</td>
</tr>
<tr>
<td>LSHTM</td>
<td>London School of Hygiene and Tropical Medicine</td>
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<tr>
<td>M&amp;E</td>
<td>monitoring and evaluation</td>
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<td>MAPS</td>
<td>mHealth for Assessment and Planning for Scale (tool)</td>
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<td>MCA</td>
<td>Maternal, Newborn, Child and Adolescent Health (WHO Department)</td>
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<tr>
<td>MCHIP</td>
<td>Maternal and Child Health Integrated Program</td>
</tr>
<tr>
<td>MCS</td>
<td>Multicountry Survey</td>
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<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
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<tr>
<td>MEC</td>
<td>Medical eligibility criteria for contraceptive use</td>
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<tr>
<td>MHTF</td>
<td>Maternal Health Task Force</td>
</tr>
<tr>
<td>MISP</td>
<td>Minimum Initial Service Package</td>
</tr>
<tr>
<td>MMEIG</td>
<td>Maternal Mortality Estimation Interagency Group</td>
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<tr>
<td>MMWG</td>
<td>Maternal Morbidity Working Group</td>
</tr>
<tr>
<td>MOH</td>
<td>ministry of health</td>
</tr>
<tr>
<td>MPHO</td>
<td>medical products of human origin</td>
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<tr>
<td>MPT</td>
<td>multipurpose prevention technology</td>
</tr>
<tr>
<td>MSI</td>
<td>Marie Stopes International</td>
</tr>
<tr>
<td>MSI</td>
<td>Management Systems International</td>
</tr>
<tr>
<td>MSM</td>
<td>men who have sex with men</td>
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<tr>
<td>mTERG</td>
<td>Technical and Evidence Review Group on mHealth for RMNCH</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>NASG</td>
<td>non-pneumatic anti-shock garment</td>
</tr>
<tr>
<td>NCD</td>
<td>noncommunicable disease</td>
</tr>
<tr>
<td>NET-EN</td>
<td>norethisterone enanthate</td>
</tr>
<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
</tr>
<tr>
<td>NIH</td>
<td>United States National Institutes of Health</td>
</tr>
<tr>
<td>NVI</td>
<td>Noncommunicable Diseases, Disability, Violence and Injury Prevention (WHO Department)</td>
</tr>
<tr>
<td>OHCHR</td>
<td>Office of the UN High Commissioner for Human Rights</td>
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<tr>
<td>OHSS</td>
<td>ovarian hyper-stimulation syndrome</td>
</tr>
<tr>
<td>OpenSRP</td>
<td>Open Smart Register Platform</td>
</tr>
<tr>
<td>PAHO</td>
<td>Pan American Health Organization</td>
</tr>
<tr>
<td>PCC</td>
<td>Policy and Coordination Committee</td>
</tr>
<tr>
<td>PCOS</td>
<td>polycystic ovary syndrome</td>
</tr>
<tr>
<td>PICO</td>
<td>population, intervention, comparator and outcome</td>
</tr>
<tr>
<td>PID</td>
<td>pelvic inflammatory disease</td>
</tr>
<tr>
<td>PMNCH</td>
<td>Partnership for Maternal, Newborn and Child Health</td>
</tr>
<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
</tr>
<tr>
<td>POCT</td>
<td>point-of-care test</td>
</tr>
<tr>
<td>PPFP</td>
<td>postpartum family planning</td>
</tr>
<tr>
<td>PPH</td>
<td>postpartum haemorrhage</td>
</tr>
<tr>
<td>PREBIC</td>
<td>Preterm Birth International Collaborative</td>
</tr>
<tr>
<td>PRS</td>
<td>Programme Reporting Standards</td>
</tr>
<tr>
<td>PSI</td>
<td>Population Services International</td>
</tr>
<tr>
<td>RCS</td>
<td>research capacity strengthening</td>
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<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
</tr>
<tr>
<td>RDT</td>
<td>rapid diagnostic test</td>
</tr>
<tr>
<td>RHL</td>
<td>Reproductive Health Library</td>
</tr>
<tr>
<td>RHR</td>
<td>Reproductive Health and Research (WHO Department)</td>
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<tr>
<td>RMNCAH</td>
<td>Reproductive, Maternal, Newborn, Child and Adolescent Health</td>
</tr>
<tr>
<td>RMNCH</td>
<td>reproductive, maternal, newborn and child health</td>
</tr>
<tr>
<td>RMNH</td>
<td>Alliance for Reproductive, Maternal and Newborn Health</td>
</tr>
<tr>
<td>Alliance</td>
<td>Research Project Review Panel</td>
</tr>
<tr>
<td>PRRR</td>
<td>Pink Ribbon Red Ribbon (global health initiative)</td>
</tr>
<tr>
<td>RMG</td>
<td>Research Mentoring Grant</td>
</tr>
<tr>
<td>RTI</td>
<td>reproductive tract infection</td>
</tr>
<tr>
<td>RTS</td>
<td>room temperature stable</td>
</tr>
<tr>
<td>SAWG</td>
<td>Scientific Advisory Working Group</td>
</tr>
<tr>
<td>SBA</td>
<td>skilled birth attendance/attendant</td>
</tr>
<tr>
<td>SDG</td>
<td>Sustainable Development Goal</td>
</tr>
<tr>
<td>SELMA</td>
<td>Simplified, Effective, Labour Monitoring-to-Action tool</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
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<tr>
<td>SRH</td>
<td>sexual and reproductive health</td>
</tr>
<tr>
<td>SRHR</td>
<td>sexual and reproductive health and rights</td>
</tr>
<tr>
<td>SPR</td>
<td><em>Selected practice recommendations for contraceptive use</em></td>
</tr>
<tr>
<td>STAG</td>
<td>Scientific and Technical Advisory Group</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>SVRI</td>
<td>Sexual Violence Research Initiative</td>
</tr>
<tr>
<td>TAG</td>
<td>Technical Advisory Group</td>
</tr>
<tr>
<td>TDR</td>
<td>Special Programme for Research and Training in Tropical Diseases (hosted at WHO)</td>
</tr>
<tr>
<td>TMB</td>
<td>treaty monitoring body</td>
</tr>
<tr>
<td>TPP</td>
<td>Target Product Profiles</td>
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<td>TRP</td>
<td>Technical Review Panel</td>
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<tr>
<td>TRP</td>
<td>Training Resource Package for Family Planning</td>
</tr>
<tr>
<td>TRT</td>
<td>Technical Resource Team</td>
</tr>
<tr>
<td>TT</td>
<td>tetanus toxoid</td>
</tr>
<tr>
<td>TU</td>
<td>testosterone undecanoate</td>
</tr>
<tr>
<td>UHC</td>
<td>universal health coverage</td>
</tr>
<tr>
<td>UIICC</td>
<td>Union Internationale Contre le Cancer</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV and AIDS</td>
</tr>
<tr>
<td>UNESCO</td>
<td>United Nations Educational, Scientific and Cultural Organization</td>
</tr>
<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children's Programme</td>
</tr>
<tr>
<td>UNODC</td>
<td>United Nations Office on Drugs and Crime</td>
</tr>
<tr>
<td>UNPD</td>
<td>United Nations Population Division</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>VIA</td>
<td>visual inspection of the cervix with acetic acid</td>
</tr>
<tr>
<td>WAHO</td>
<td>West African Health Organisation</td>
</tr>
<tr>
<td>WHA</td>
<td>World Health Assembly</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WHOCC</td>
<td>WHO Collaborating Centre</td>
</tr>
<tr>
<td>WHO-ERC</td>
<td>WHO-Ethics Review Committee</td>
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</tbody>
</table>
1. Introduction

The UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, also known as the Human Reproduction Programme (HRP), is the main instrument and leading research agency within the United Nations system concerned with sexual and reproductive health and rights. The World Health Organization (WHO) serves as the executing agency for HRP, which is housed within, and forms part of, WHO’s Department of Reproductive Health and Research (RHR Department).

Universal access to sexual and reproductive health and rights is recognized worldwide as crucial for accelerating progress towards achieving global goals for sustainable development and poverty reduction – including the Millennium Development Goals (2000–2015), the aims of the Programme of Action of the International Conference on Population and Development (ICPD, 1994), and more recently the commitments of the global Every Woman Every Child movement.

The collective blueprint formed by these goals – agreed upon across regions and by the world’s leading institutions concerned with sustainable development – underscores the critical importance of the continuing work undertaken by the RHR Department, including HRP, to promote universal access to sexual and reproductive health.

Established in 1972, the Department supports and coordinates research on a global scale; synthesizes research through systematic reviews of literature; builds research capacity in low-income countries; and develops dissemination tools to make efficient use of an ever-increasing body of research and information. By virtue of its unique co-sponsorship arrangement, the work of HRP is coordinated with, and contributes to, the work of its co-sponsors and partners including UNDP, UNFPA, UNICEF, WHO, World Bank, UNAIDS and the International Planned Parenthood Federation (IPPF).

The year 2014 represented a critical juncture for the Department and for HRP. Following a successful functional review in 2013, its programme of work was focused on a number of priorities, including family planning, maternal health, and adolescent sexual and reproductive health. The Department’s support for rights-based approaches was strengthened and integrated within all of its work.

This report brings together the achievements across all the Department’s thematic areas. It also underlines the urgency of the work that collectively needs to be done to accelerate progress towards realizing sexual and reproductive health and rights.
2. High-level advocacy and input to global initiatives for sexual and reproductive health

2.1 Introduction

The RHR Department, including HRP, has engaged in a range of global advocacy activities to promote sexual and reproductive health in the context of regional and global initiatives. These include contributions in follow up to global agreements and commitments relevant to sexual and reproductive health, such as: the International Conference on Population and Development (ICPD), Cairo, 1994, in its 20th anniversary year (ICPD Beyond 2014); the World Conference on Women, Beijing, 1995, in preparation for its 20th anniversary (Beijing+20); and the Millennium Development Goals (MDGs) and preparations for the post-2015 sustainable development agenda.

Other contributions include providing support for the accountability work conducted under the umbrella of the United Nations (UN) Secretary-General’s Every Women Every Child initiative; input to the discussions around the development of new accountability frameworks and the renewed Global Strategy for Women’s, Children’s and Adolescents’ Health; work carried out in the context of the UN H4+ initiative; and co-leadership of the performance, monitoring and accountability work of the Family Planning 2020 (FP2020) initiative as well as participation in its governing body.

Engagement with political platforms, with a specific focus on Parliaments and Parliamentarians, has also been prominent in our activities, including providing advice to Parliaments and undertaking joint research with the Inter-Parliamentary Union (IPU).

Major achievements

• The second FP2020 progress report was finalized with the leadership of the FP2020 Performance, Monitoring and Evidence (PME) working group, co-chaired by the Director of the RHR Department.

• The WHO Technical Guidance Note: Strengthening the inclusion of reproductive, maternal, newborn and child (RMNCH) health in concept notes to the Global Fund was completed for the Global Fund to Fight AIDS, Tuberculosis and Malaria.

• In support of the 20th anniversary of the ICPD Programme of Action (ICPD Beyond 2014), the Department has produced seven fact sheets on key sexual and reproductive health and rights (SRHR) aspects of the ICPD Programme of Action and has disseminated these at many events, including at a high-level meeting co-organized at the time of the UN Commission on Population and Development in New York.

• The Pan-African resolution on gender-based violence was developed with technical support from the Department, and was approved by the Pan-African Parliament.

• Reports on child, early and forced marriage legislation in Africa and the Asia-Pacific region were developed in collaboration with the Inter-Parliamentary Union and the Pan-African Parliament.

• A paper on Women and health: 20 years of the Beijing Declaration and Platform for Action was prepared in collaboration with other WHO departments and has been submitted for discussion at the WHO Executive Board in 2015.
2.2 Contribution to global initiatives and follow up of the commitments

2.2.1 The Every Woman Every Child movement and the accountability framework

Progress

The UN Secretary-General’s Global Strategy for Women’s and Children’s Health and the related Every Woman Every Child movement were launched in September 2010 to accelerate progress towards MDGs 4 (reduce child mortality) and 5 (improve maternal health). The commitments to increase the needed resources and implement effective actions in the context of the Global Strategy have contributed to improving health outcomes for women and children. The approximately 50% reduction in both maternal and infant deaths since 1990 has largely happened during the recent years since the launch of the Global Strategy. A critical part of this Global Strategy was the creation of an accountability mechanism to ensure that commitments to women’s and children’s health were being delivered on time and making an impact. As part of the Global Strategy, the UN Secretary-General called for the establishment of a process to ensure global reporting, oversight and accountability. This led to the creation of the Commission on Information and Accountability for Women’s and Children’s Health (CoIA) in 2011, which put forward 10 recommendations to strengthen accountability. Countries translated these recommendations into Country Accountability Frameworks (CAFs), with prioritized work areas that follow the cycle of “monitoring, review and remedy or action”.

In 2014, the Department provided technical support in the development of the third progress report on implementation of the Commission’s recommendations, *Accountability for women’s and children’s health: report on progress to May 2014* (1). The 2014 progress report describes the evolution of the accountability work, and marks the end of the first phase of implementation. The report also summarizes progress made globally and by countries towards implementing the Commission’s 10 recommendations. It also presents lessons emerging from midterm reviews in selected countries.

In the context of review of the accountability framework established by the UN Secretary-General’s Global Strategy for Women’s and Children’s Health, and the Every Woman Every Child movement, the Department supported the organization of the Stakeholder Consultation, co-convened with the Governments of Canada and Norway, and with the UN Secretary-General’s Office early in November 2014. The Consultation brought together approximately 100 senior representatives from governments, civil society and international organizations to set the foundations for continued improvements in women’s and children’s health post-2015, including the accountability framework and financing.

One of the key elements of the Consultation was the discussion around a shared vision for women’s and children’s health beyond 2015, including the key pillars for a renewed Global Strategy for the post-MDG period (2016–2030). It was agreed that the revised Global Strategy should include adolescents and thus the proposal was made for a Global Strategy for Women’s, Children’s and Adolescents’ Health, representing one overarching framework and common vision up to 2030.

The second key element was the discussion around the investment and financing for the Global Strategy through the newly created Global Financing Facility (GFF) as well as existing mechanisms such as the GAVI Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). The aim of the GFF is to leverage additional
funding to fill gaps, create better harmonization of programmes, and ensure country leadership in which financing is aligned with country priorities and plans.

**Planned activities**

- In 2015, the Department will support the development of the technical content of the renewed Global Strategy in alignment with the post-2015 sustainable development agenda; the Global Strategy for Women’s, Children’s and Adolescents’ Health is to be launched at the UN General Assembly in September 2015.

### 2.2.2 ICPD Beyond 2014 and Beijing +20

**Progress**

In 2014, the Department continued its efforts to support the ICPD Beyond 2014 process, including (i) providing support to the UNFPA-led review of progress and gaps in implementation of the ICPD Programme of Action at the 20th anniversary and (ii) providing technical input to countries on key areas of sexual and reproductive health. Seven fact sheets were developed relating to key areas of sexual and reproductive health and rights (SRHR) and these have been disseminated at various forums. In this regard, a side event was organized at the time of the UN Commission on Population and Development in New York in September, on SRHR as a key pillar of development. Additionally, the fact sheets were disseminated at a large meeting convened in collaboration with the WHO Regional Office for Africa, with representatives of 29 countries and partner agencies.

The Department also developed a position paper based on information available on progress and gaps in implementation of the ICPD Programme of Action: *Sexual and reproductive health beyond 2014: equality, quality of care and accountability* (2). The position paper highlighted three cross-cutting themes emerging from ongoing evaluation of the ICPD Programme of Action: to address inequalities, to ensure quality of care, and to enhance accountability.

The Department has also been involved in the Geneva ICPD Network, providing technical support on several issues related to SRHR, including: violence against women; family planning; child, early and forced marriage; adolescent health; and development of the post-2015 sustainable development agenda.

In addition to activities focused on ICPD Beyond 2014, the RHR Department also led WHO’s efforts in examining women’s health issues in the context of the 20th anniversary of the Fourth World Conference on Women, which was held in Beijing in 1995. The Beijing Declaration and Platform for Action set out 12 critical areas of action for the global realization of gender equality and women’s empowerment, one of which was women’s health (3). In view of the upcoming 20th anniversary in 2015, the United Nations Commission on the Status of Women will carry out a review and appraisal of the implementation of the Beijing Declaration and Platform for Action.

The Department led WHO’s efforts in preparing a paper examining achievements, unfinished agenda items, and emerging priorities relating to women’s health 20 years after the 1995 Conference and Declaration, with participation of all relevant WHO Departments: *Women and health: 20 years of the Beijing Declaration and Platform for Action* (4). The paper was discussed at the WHO Executive Board in January 2015, where Member States affirmed commitment to women’s health and provided guidance on WHO’s roles and activities.

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1 The factsheets are available at: [http://www.who.int/reproductivehealth/icpd/en/](http://www.who.int/reproductivehealth/icpd/en/)
Planned activities

- In early 2015, the comments from the WHO Executive Board about the paper on Women and health will be incorporated to develop a new version that will be discussed at the World Health Assembly in May 2015. The Department will continue to support the follow-up actions on Beijing+20 by providing technical input on health aspects that form part of the discussion.
- Additionally, the ICPD fact sheets and related evidence will be disseminated through various channels. The Department will remain actively engaged in the Geneva ICPD Network.

2.3 United Nations H4+ mechanism

The UN H4+ mechanism, which combines the efforts of UNFPA, UNICEF, WHO, World Bank, UNAIDS and UN Women, works with countries to support the implementation of commitments to the UN Secretary-General’s Global Strategy and the Every Woman Every Child movement, to accelerate progress towards MDGs 4 and 5. H4+ efforts focus on provision of joint support to countries in planning and implementing effective RMNCH interventions, by strengthening the health systems and improving equity in accessing quality services.

Progress

The Department led WHO’s efforts in monitoring support of the more than 58 H4+ priority countries through the development and implementation of a results-based global survey of progress in these countries. The Department used the H4+ survey results to conduct an analysis of: reported coordination and organization; implementation of the H4+ scope of work; and the contributions of the H4+ in assisting counties to mobilize financial, technical and additional resources. The resulting report, measuring progress in 2013, was presented at a UN General Assembly side session hosted by the H4+ and attended by principles of all six member organizations. The survey found that the H4+ collaboration had led to more effective coordination, collaboration and teamwork among those involved at the country level in advancing RMNCH. Additionally, the mechanism supported country efforts to bring RMNCH issues to the forefront of national attention while also attracting new partners and resources to RMNCH programming. Technical support and expertise was also a reported beneficial effect of H4+ support. The Department was key in providing some of this concentrated technical support to countries, namely through the organization of WHO feedback on 10 country plans for 2015 activities.

Planned activities

- In 2015, the Department will develop the H4+ 2014 progress report, building upon previous reporting, and will develop qualitative case studies of the H4+ mechanism in action at the country level. The Department will also support implementation of the latest recommendations on effective childbirth care for improved RMNCH in H4+ priority countries, and will support H4+ involvement in planning for the Global Financing Facility in support of Every Woman Every Child.

2.4 Collaboration with the Inter-Parliamentary Union and other parliamentarian networks

Together with the Inter-Parliamentary Union (IPU), the Department has established a constructive collaboration with other parliamentarian platforms at the regional level,
such as the European and Pan African Parliaments, which play a crucial role in defining health-related recommendations within the respective regions. Additionally, the Department engages with thematic platforms, such as the Parliamentarian Fora on Population and Development, which has a focus on reproductive health and rights.

The goal of the collaboration between the Department and parliamentarians is to better understand the parliamentary processes that can move the global health agenda forward, and to raise the levels of parliamentary investment in health. Additionally, this cooperation serves the purpose of providing technical support to parliamentarians in the development and implementation of health-related multilateral agreements, resolutions, declarations and other legislative tools. The Department has also established collaborations with national parliaments in the area of sexual and reproductive health and rights.

**Progress**

The RHR Department has been instrumental in expanding the mandate of the IPU Advisory Group on HIV/AIDS to include RMNCH. The Advisory Group is supported technically by WHO (represented by the Director of the RHR Department), UNAIDS, the Global Fund, and the Partnership for Maternal, Newborn and Child Health (PMNCH).

In follow up to the 2012 IPU resolution on *Access to health as a basic right: the role of Parliaments in addressing key challenges to securing the health of women and children* (5), the IPU General Assembly decided to initiate a process to review the resolution with the support of the RHR Department and other partners; this review will be presented at the next IPU General Assembly in Hanoi, Viet Nam, in 2015.

With the support of the Department, the IPU has placed increasing emphasis on reproductive health. Two issues were identified as entry points for this focus: (i) early, child and forced marriage and (ii) access to information and services relating to family planning.

More recently the Department supported the IPU in the preparation and negotiation of the resolution *Towards risk-resilient development: taking into consideration demographic trends and natural constraints*, which was adopted unanimously by the 130th IPU Assembly (6). The discussion around the resolution highlighted the role of parliamentarians in reviewing legislation and policies to meet the unmet need for contraception as well as sexual and reproductive health services.

The Department also collaborated with the IPU and the Pan African Parliament in the area of child, early and forced marriage, conducting a study on 10 African countries. The final report was presented at the Pan African Parliament, and was instrumental in the finalization of a Pan African Parliament resolution on gender-based violence.

In collaboration with the IPU, the RHR Department also conducted a study on child, early and forced marriage legislation in 37 countries in Asia and the Pacific. The findings of the study were presented at a Regional Seminar for Asia-Pacific Parliaments, on the theme of “Ending the cycle of violence against girls in Asia-Pacific”, which was organized by the Parliament of Bangladesh in Dhaka (23–25 September 2014). The Department also provided technical support in the general discussion on violence against women and girls in the region.

The Department also collaborated with other regional and thematic platforms on sexual and reproductive health issues. For example, we provided technical support to the Parliamentarian meeting on the occasion of the Conference on Family Planning in Addis Ababa, and to the International Parliamentarians’ Conference on the Implementation of the Programme of Action of the ICPD in Stockholm, both of which were organized by the European Parliamentary Forum (EPF).
Other activities included collaboration with national Parliaments such as with the Parliament of Italy on violence against women, and with the Parliament of Bangladesh on adolescent health and child, early and forced marriage.

**Planned activities**

- In 2015, the Department will facilitate the participation of the WHO Director General at the next IPU General Assembly in March, and the engagement of parliamentarians in global health initiatives, such as the post-2015 development agenda, FP2020, the World Health Assembly, and the accountability mechanisms.

- The Department also plans to finalize peer-reviewed papers in collaboration with the IPU on (i) child, early and forced marriage legislation in Africa, Asia and the Pacific; and (ii) the role of parliamentarians in the accountability frameworks for women's and children's health.

- In addition, the Department will conduct the review of the 2012 IPU resolution on accountability for women's and children's health, and will expand policy research on the impact of legislation on sexual and reproductive health.

### 2.5 The Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) mobilizes, manages and disburses substantial resources for national HIV/AIDS, tuberculosis and malaria programmes. Although much progress has been made, the burden of these diseases is still substantial and disproportionately affects women, adolescent girls, newborns and children, especially in sub-Saharan Africa and South Asia. As the Global Fund does not have a permanent country presence, its success depends on the collaborative efforts of countries and technical and development partners, particularly WHO. WHO has signed an agreement with the Global Fund to provide country-specific technical support to increase the quality of RMNCH elements in the Concept Notes used to apply for Global Fund support. The RHR Department has contributed to providing technical support to countries in developing proposals that include sexual and reproductive health aspects.

**Progress**

Along with other key WHO departments and the Roll Back Malaria Partnership, WHO has convened and conducted four capacity-building workshops for RMNCH consultants, partners, ministry of health (MOH) focal persons and WHO staff, involving 23 countries in the African Region.

Further, the Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCAH) Team participated in consultations organized in Burkina Faso, India South Africa and Uganda, to review draft Concept Notes developed by various countries. The Department also completed the WHO Technical Guidance Note: Strengthening the inclusion of reproductive, maternal, newborn and child (RMNCH) health in concept notes to the Global Fund (7).

Several challenges have been identified during the provision of technical assistance, including: (i) lack of technical assistance requests for RMNCH strengthening from the Country Coordination Mechanism (CCM) or from MOHs; (ii) RMNCH is not included in the CCM; (iii) the predefined financial split among diseases does not incentivize the inclusion of RMNCH interventions in Concept Notes; and (iv) with insufficient resources to maintain the current disease funding status, it is difficult to expand activities to address RMNCH.
The Department has also facilitated workshops and mock Technical Review Panel (TRP) reviews, including a peer review workshop held by the Global Malaria Programme and the Roll Back Malaria Partnership, in Kampala, 19–21 November 2014, for the countries planning to submit malaria Concept Notes in January 2015. This work includes funding a consultant to follow up with specific countries. More mock TRPs will be held in 2015.

**Planned activities**

- The Department will provide in-country technical assistance, including proactive facilitation of country dialogue (including programme split discussion) for countries in all WHO regions that are planning to submit Concept Notes in the 2015 submission windows for RMNCH and health systems strengthening.
- Further, following discussions with the Global Fund Steering Committee on 10 December 2014, a decision was made to expand the scope of the agreement with WHO to cover grant making, in part to address the challenges identified above.
- This confirms WHO as a more active partner in translating the concept notes reviewed by the TRP and the Grants Approval Committee (GAC) into nationally aligned and harmonized, disbursement-ready grants for Global Fund Board approval and grant signature. This also strongly positions the Department to help ensure inclusion of RMNCAH and communities, rights and gender elements in Concept Note policy and programming for effective implementation and maximal impact.

### 2.6 References

3. Thematic areas

3.1 Family planning and contraception

3.1.1 Introduction

Unmet need for contraception remains high in many settings. It is highest among the most vulnerable in society including adolescents, the poor, those living in rural areas and urban slums, migrants, refugees, people living with HIV, and internally displaced people. In 2012, an estimated 222 million women had an unmet need for contraception; that is, they were at risk of becoming pregnant while they did not wish to conceive, yet were not using a modern method to prevent pregnancy. Additionally, many women using contraceptives are not satisfied with their method, potentially putting them at risk for discontinuation without replacement with a more acceptable method, leading to unintended pregnancy. The mission of the Human Reproduction team in the area of family planning is to reduce the unmet need for family planning and contraception and thus to prevent unintended pregnancy.

To achieve this objective, the RHR Department, including HRP, is implementing a collaborative, science-driven approach. This section reports on how, in 2014, this approach has translated into concrete and coordinated activities towards achieving the ultimate goal of reducing unmet need for contraception.

Major achievements

- Several research studies have been completed during 2014:
  - A multicentre randomized clinical trial of two hormonal implant contraceptives – Jadelle® (75 mg levonorgestrel) and Implanon® (68 mg etonogestrel) – in seven countries involving 2963 women showed similar efficacy and safety for both devices.
  - A feasibility study of a new indicator for assessment of unmet need for family planning was completed. The indicator was “percentage of women of reproductive age attending HIV care and treatment services with unmet need for family planning”. The study led to the development of a screening tool (by WHO in collaboration with partners) for measurement of the indicator. This tool can be used to collect routine data on family planning needs in a more sustainable way, and in a way that allows for these data to be aggregated in a health information system.
  - The sperm suppression study, using norethisterone enanthate (NET-EN) and testosterone undecanoate (TU), showed a low pregnancy rate (four pregnancies in 320 participant pairs). However, the high frequency of severe adverse events (such as mood changes and disturbances, emotional disorders, injection site reactions, muscle pain and weakness) needs to be re-examined before further research will be pursued.
  - A multicentre study on peri-coital use of levonorgestrel has shown a pregnancy rate of 13 among 330 participants, with minimal side effects. This implies the possibility of using a contraceptive product as needed, when one has coitus.
• The process of updating the Medical eligibility criteria for contraceptive use is in progress. The HIV-related recommendations were released earlier than planned, on 24 July 2014, to respond to urgent country needs (in English and Russian).

• During 2014, the Department launched guidelines on human rights and contraceptive services as well as information on and analysis of existing quantitative indicators in relation to contraceptive services based on human rights. The Department also developed a framework on ensuring human rights in contraceptive services and information.

• The Implementing Best Practices (IBP) initiative worked with WHO regional and country offices to document best practices and introduce tools for scaling them up, supporting activities in over 25 countries.

3.1.2 Implementation research and development

The key components of research and development work within this thematic area are: (i) research activities to strengthen the evidence-base on priority needs (i.e. operations/implementation and service delivery research, and clinical efficacy and safety research); (ii) identifying research gaps and elaborating funding strategies to meet these gaps; and (iii) research synthesis and updating of the guidance in a timely fashion.

3.1.2.1 UPTAKE Project – a health sector and community-based participatory approach in a human rights framework to increase met needs for contraception.

The UPTAKE Project aims to address the unmet need for family planning/contraception through a participatory approach involving the community and health-care providers within a human rights framework. The human rights framework used by this project takes into account barriers to accessing contraception at the level of policies and guidelines, but also addresses barriers at the health services and the community levels. According to the WHO’s guideline Ensuring human rights in the provision of contraceptive information and services (1), one of the key health and human rights standards that should be considered is participation. Meaningful participation includes the active involvement of individuals, communities or community-based organizations in the functioning of community health services or systems. Community participation is a key component in frameworks for improving the quality of services.

To achieve the goal of addressing the unmet need for family planning and contraceptive services, the project will first develop an approach for engaging with communities and health providers. An intervention package will be developed during the formative phase using the approach that also takes into account the existing health systems, structures, relevant policy and existing human rights framework in the specific contexts, and then this package will be implemented in the intervention phase.

Participation of individuals and communities in all stages of decision-making and implementation of policies, programmes and services is a precondition for sustainable development and for achieving the highest attainable standard of health. However, increasing community participation is not enough to ensure family planning and contraceptive programmes' efficacy, uptake, feasibility and scalability. Health providers and the health system should be engaged. They will
ensure that the intervention is feasible and that it can be an integral part of the existing health system. Health-care provider and community engagement will lead to collaboration, shared understanding of quality of care and service provision, shared responsibility and continued partnership.

The success of the project will be seen in a shared vision of and an improvement in quality of care in family planning and contraceptive services and information provision, which may lead to increased utilization of services, and higher satisfaction with services and method use.

**Progress**

- The UPTAKE Project is a multicountry research study that will be implemented in Kenya, South Africa and Zambia and is projected to take four and a half years. The project is currently under review by the Research Project Review Panel (RP2).
- Formative phase activities have been initiated, including scoping reviews on community and health-care provider participation within family planning and contraceptive programmes and quality of care as defined by both the community and the health-care providers.
- WHO convened the first Working Group meeting on 8–9 December 2014 where experts and partners reviewed the project protocol and planned activities.

**Planned activities**

- The formative phase will be completed in 2015.
- The intervention phase will take place in 2016–2018.

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

In recent years, various family planning financing schemes have been developed and implemented to assist the poor and vulnerable, including voucher programmes, community-based insurance, and others. The evidence base supporting the implementation of these mechanisms, relating specifically to family planning/contraception, is very limited, and where evidence exists it is often of low quality.

The present initiative led by the RHR Department aims to strengthen the evidence base on financing mechanisms for family planning/contraception, and thus to provide governments, funding agencies and other donors with evidence-based guidance upon which future programmes and projects can be based. The Department will undertake systematic reviews of the existing evidence with the specific objectives of (i) identifying those areas in which the evidence base for financing of contraception is strong, (ii) identifying the current gaps in knowledge and potential research topics in health care financing in contraception, and (iii) serving as a basis for initiating dialogue on joint investment in research to fill the gaps identified by the systematic review process.

**Progress**

In response to a call for proposals from the RHR Department, five research teams were selected to conduct systematic reviews of financing mechanisms for family planning, namely: (a) voucher schemes, (b) performance-based financing, (c) conditional cash transfers, (d) community financing and community-based health
insurance, (e) out-of-pocket payments and user fees. The first researcher meeting was held in October 2014, organized by the Department and the Alliance for Reproductive, Maternal and Newborn Health (RMNH Alliance). The key outputs of the meeting included agreement on the key outcomes, screening strategies, mechanism for grading the quality of evidence, and development of a common template for a data extraction form and reporting format.

**Planned activities**

- The reviews are currently under preparation. A second technical meeting of researchers is planned for early April 2015, to bring together the five teams to present and peer-review the draft findings, reflect upon and discuss their implications, identify evidence gaps and, most importantly, devise new and innovative research approaches to addressing the gaps in a coordinated manner.

- After this meeting, there will be a large meeting of bilateral, multilateral and nongovernmental donors in the family planning community, which is tentatively planned for May 2015. The aim of this meeting is to present the results, identify gaps in the research, propose a research agenda to funders and ultimately to begin implementation of the findings.

- The reviews and consolidated findings will also be published in a special issue of a leading peer-reviewed journal (under discussion), and disseminated through the websites and networks of the Department.

**3.1.2.3 Demand-side financing project (voucher programme) for increasing demand and utilization of contraception**

Lack of access to affordable contraceptive services and commodities is contributing to unmet needs for family planning in many developing countries. Evidence on the best mechanisms to provide these affordable services and commodities to the underserved and poor are limited. Demand-side financing approaches have been implemented to increase access to and uptake of quality family planning services, improve maternal and child health outcomes and achieve national development goals in low-income countries.

**Progress**

Presently two quasi-interventional studies testing two different demand-side financing approaches with voucher schemes (multipurpose versus single vouchers) are being conducted in the Punjab province, Pakistan, with Population Services International (PSI) and Marie Stopes International (MSI) as implementing partners. The projects aim at evaluating the effectiveness of the voucher scheme approach in improving the uptake and continued use of modern contraception among the poor in targeted communities. The evaluation of the projects will contribute to 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.

Two manuscripts describing the baseline data and the project’s research protocol have been published in peer-reviewed journals in 2014 (2, 3).

**Planned activities**

- Following the baseline survey in 2012, both implementing partners initiated the implementation phase of the project in January 2013, and this is expected to be completed by January 2015.
• Preparations are under way with implementing partners for the end line survey of the project sites. Ethical approval from WHO and local sites have already been obtained. The tentative plan is to start the end line evaluation in early 2015 and complete the data collection, cleaning and analysis and finalize the report by mid-2015.

3.1.2.4 Postpartum family planning operations research under Muskoka

Under the agreement with the French Ministry of Foreign Affairs, the RHR Department is initiating a two-year operations research project focusing on meeting unmet need for contraception among women during the postpartum period. This activity is part of the overall work referred to as “Muskoka”, which has been implemented since 2011 by the Department in collaboration with the WHO Maternal, Newborn, Child and Adolescent Health Department, UNFPA, UNICEF and UN Women.

The theme of postpartum family planning (PPFP) was chosen as a priority for operations research by the RHR Department’s family planning team with agreement by the French Government and partners due to the high rate of unmet need for contraception among postpartum women. Although many countries have developed health policies and norms that promote family planning as part of efforts to achieve Millennium Development Goals 4 and 5, often these policies are not explicit or enforced during the postpartum period. The core intervention of this study consists of implementing a package of family planning services beginning in the prenatal period and continuing through six months postpartum.

The objective of the study is to contribute to meeting the family planning needs of women and couples by implementing a package of PPFP interventions within the health sector through an operations research study.

Progress

• A series of meetings have been convened within the family planning team and with the French Government to identify and agree on the research topic.

• Two research centres that have already received Long-term Institutional Development (LID) grants from the Department were identified as potential collaborators for the study: Institut de Recherche en Sciences de la Santé (IRSS) in Burkina Faso, and the University Clinics in Kinshasa, Democratic Republic of the Congo. A first meeting of the Department’s team working with the research institutes took place on 4–5 November 2014 in Geneva, followed by site visits to both countries in December 2014.

• The concept note was shared with the Muskoka technical committee in November 2014 and feedback was incorporated into the protocol.

Planned activities

• The protocol will be submitted to RP2 in January 2015.

• A mapping exercise to identify study sites will take place in January 2015.

• The formative phase and all preparations for the intervention will be completed by November 2015.

3.1.2.5 Feasibility, utility and effects of family planning counselling tools at the community level

The positive role of counselling tools in communicating high-quality, useful and accurate information to family planning clients is well established. The
RHR Department, 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 with limited education and training – (i) A guide to family planning for community health workers and their clients by WHO (4), (ii) The balanced counseling strategy: a toolkit for family planning service providers by the Population Council (5), and (iii) a hybrid version with key common features of both tools – as compared with the usual information material provided to community health workers in India (i.e. the control group).

**Progress**

The evaluation, conducted with a sample of 142 community health workers in India from 2011 to 2012, has shown that in almost all cases there were no major variations between the groups using the various counselling tools and the control group, and that community health workers were able to perform their counselling tasks appropriately and effectively when using the hybrid simplified tool, including facilitating the choice of an appropriate method and providing it, if available.

**Planned activities**

- Findings suggest that the availability of a counselling tool improves the quality of interaction between the service provider and the client. Accurate, standardized, structured and customized information tools on family planning are important instruments in helping service providers, particularly community health workers like the accredited social health activists or ASHAs, to save their time and energy in counselling. In turn, women are more likely to believe the authenticity of the information provided through tools that facilitate their decision-making.

3.1.2.6 Factors affecting access to emergency contraception in Malawi

Emergency contraception (EC) has been useful in reducing unintended pregnancies due to contraceptive failure (e.g. missed pills, condom slippage or breakage). However, there is low utilization of EC drugs in many countries and by many sectors who need them such as those who have problems with contraceptive use and adolescents who may have infrequent sex. A prospective cross-sectional study was initiated in August 2014 to investigate factors affecting availability and utilization of EC (1.5 mg levonorgestrel [LNG]) among women aged 10–49 years in Malawi. Specific objectives of the study include: (i) to assess availability of LNG and determine the stock levels at pharmacies, central medical stores, clinics (public and private) and rape victim support units; (ii) to identify factors that affect availability of LNG; (iii) to identify levels and characteristics of training of pharmacists on the provision of EC; and (iv) to assess EC-related knowledge and experience of service providers in support units for victims of sexual assault. This project is supported by the UN Commission on Life-Saving Commodities for Women and Children on Contraception.

**Progress and planned activities**

- The study is being conducted in the main capital region of Malawi, and is expected to be completed in early 2015. The data will identify gaps in the process of making the drug available, which can be addressed by further research and policy change.
3.1.3 Clinical and biomedical research

3.1.3.1 ECHO (the Evidence for Contraceptive options and HIV Outcomes Trial) – a multicentre, open-label, randomized clinical trial comparing HIV incidence and contraceptive benefits in women using depot medroxyprogesterone acetate, levonorgestrel implants and copper intrauterine devices

For more than 25 years, some epidemiologic studies conducted in a variety of contexts have suggested that women using depot medroxyprogesterone acetate (DMPA) may be at increased risk of HIV acquisition. The results across multiple studies have been mixed, however. As shown in a recent systematic review, although initial studies on the topic often assessed all hormonal contraceptive methods together (i.e. combined hormonal contraceptives and progestin-only contraceptives, with varying formulations and delivery systems), more recent studies have examined specific types of hormonal contraceptives separately (6).

The majority of evidence on oral contraceptive pills suggests they do not increase the risk of HIV acquisition. Some studies suggest increased risk among users of injectable contraceptives, specifically DMPA. The limited amount of evidence that exists for NET-EN and the contraceptive implant suggests no harm.

Progress

The randomized clinical ECHO Trial will provide the most definitive information concerning the comparative risk of HIV acquisition and other risks and benefits resulting from use of DMPA or levonorgestrel (LNG) implants, with copper intrauterine devices (IUDs) as the control group. The ultimate goal of this study – which uses gold standard study design and methods – is to provide policy-makers, programme managers, family planning service providers, advocates, and women contraceptive users with conclusive information about the comparative risks associated with the use of a variety of effective contraceptive methods. This information, combined with contraceptive efficacy data for each method, will allow for better-informed family planning decision-making. This three-arm trial (DMPA, LNG implant, copper IUD) can provide the essential scientific evidence and will address the question of whether use of DMPA or the LNG implant increases the risk of HIV acquisition.

To realise this study a consortium comprising major organizations has been set up. The ECHO Consortium was convened by the RHR Department, and it will be jointly led by FHI 360 and WHO, to coordinate the trial. Roles have been collectively defined by the team's strengths, based on the matrix of organizations and individuals involved. Other roles for the Department in the Consortium were to convene and establish the first Data and Safety Monitoring Board meeting and participate in several committees, including the Protocol Design Team, the Site Selection Committee and the Contraceptive Training, Management and Safety Subcommittee. The Department is also convening an annual meeting for the ECHO trial, to discuss research updates relating to HIV/AIDS and family planning/contraceptives.

The ECHO Trial will be conducted in 12 clinics in southern and eastern Africa. A protocol has been approved by RP2 and submitted to the WHO Ethics Review Committee (WHO-ERC). The Department is closely involved in the East London site in South Africa.

Planned activities

• Implementation of the study will start in July 2015.
3.1.3.2 Multicentre randomized clinical trial of two implantable contraceptives for women: two-rod levonorgestrel implant (Jadelle®) and one-rod etonorgestrel implant (Implanon®)

Contraceptive implants are increasingly popular in the world. Implanon® is a single-rod, implantable contraceptive that contains the progestin etonogestrel, providing contraceptive protection for up to three years. Jadelle® has two levonorgestrel rods and provides protection for up to five years. The safety and efficacy of single-rod versus two-rod implantable contraceptives were investigated in a multicentre clinical trial.

**Progress**

During the first quarter of 2014, the Department completed a multicentre, randomized clinical trial to assess the three- and five-year safety, efficacy and acceptability of the Jadelle® and Implanon® hormonal contraceptive implants. The study was conducted in seven countries: Brazil, Chile, Dominican Republic, Hungary, Thailand, Turkey and Zimbabwe. In total, 2963 women have been randomized to one of the two implants, while 971 women using the copper IUD (TCu 380A) were enrolled as an age-matched cohort. An article presenting the baseline characteristics of the study groups was published in Contraception in 2013.

Results of the study indicating that both contraceptive implants are safe and highly effective for up to five years of use, and that their effects are rapidly reversible upon removal, were presented for the first time at an international conference on the occasion of the European Society of Contraception and Reproductive Health 13th Congress in Lisbon (May 2014).

**Planned activities**

- A manuscript reporting on the three-year follow-up of clients in the implant study will be submitted to a peer-reviewed journal in January 2015
- The main paper analysing of the results of the five-year follow-up period of the study will be submitted for publication by end of first quarter in 2015.

3.1.3.3 Sperm suppression using norethisterone enanthate and testosterone undecanoate

**Progress**

To expand contraceptive options for men, the Department initiated a phase II trial of a product that combines a progestin (norethisterone enanthate, known as NET-EN) and an androgen (testosterone undecanoate, or TU), as this product has been shown to induce sperm suppression. However, the high number of side-effects (such as mood changes, etc.) reported by participants in the trial led to recruitment being discontinued in 2012. An investigators meeting was convened in July 2014 to discuss the results of the study and the plans for their publication and dissemination. Analyses showed only four pregnancies among the 320 participating couples in the efficacy phase, and more adverse events were reported in some centres (e.g. Indonesia) compared to others (e.g. India).

**Planned activities**

- The study report of the efficacy and safety findings will be finalized by January 2015.
- Serum hormone analyses and correlations with clinical findings are being completed as additional analyses.
• Dissemination and publication of the results will occur in 2015.

3.1.3.4 Peri-coital oral contraceptive use of levonorgestrel 1.5 mg

A prospective, open-label, single-arm, multicentre “proof of concept” study has been conducted to evaluate if oral levonorgestrel (1.5 mg), taken around the time of intercourse, up to six times a month, can offer an acceptable level of safety and contraceptive efficacy. The study will provide preliminary data to justify a pivotal phase III study to establish efficacy and safety of possibly using other methods, such as ulipristal, and to inform policies and programmes worldwide

Progress

Recruitment and follow-up of 330 participants in four countries were completed in mid-2014, and all study sites were closed.

Planned activities

• An investigators meeting is scheduled in January 2015 to discuss the findings on the efficacy of the regimen and to look at the problems and difficulties in conducting the study

• The report of study findings is expected to be submitted for publication by mid-2015.

• Dissemination of study results is also planned at conferences in 2015.

3.1.4. Norms, standards and tools

3.1.4.1 Continuous Identification of Research Evidence (CIRE) 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 United States Centers for Disease Control and Prevention/WHO Collaborating Centre for Reproductive Health (CDC/WHOCC), the RHR Department 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.

Regularly, the Department searches the PubMed bibliographic for newly published evidence (in any language) relevant to the Medical eligibility criteria for contraceptive use (8) and the Selected practice recommendations for contraceptive use (9, 10). 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 recommendation remains 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 Guideline Development Group (GDG) convened twice during 2014 (9–12 March and 24–25 September) to review and, where appropriate, revise specific recommendations in the Medical eligibility criteria for contraceptive use (MEC) as well as in the Selected practice recommendations for contraceptive use (SPR). The GDG comprises an external, multi-disciplinary, gender- and regionally-balanced membership with a WHO Secretariat. Following requirements for guideline
development established by WHO’s Guidelines Review Committee, the GDG considered the evidence summarized within systematic reviews prepared for the consultations and applied the Grading Recommendations, Assessment, Development and Evaluation (GRADE) approach to evidence review to formulate recommendations. Owing to the public health importance of recommendations on the use of hormonal contraceptive methods by women at high risk of HIV and women living with HIV, including women taking antiretroviral therapy, WHO released a technical statement with these recommendations on 24 July 2014 at the 20th International AIDS Conference in Melbourne, Australia (11).

**Planned activities**

- The finalized MEC revision is targeted for release in March 2015, during a PAHO/WHO Regional Office for the Americas Regional Forum on Women’s Health. The publication of the revised SPR will follow in the summer of 2015. The revisions will be published on the Department’s website. Related counselling tools and job aids will be updated accordingly.

- To facilitate the interpretation and adaptation of the MEC and SPR within national policies, an adaptation guide will be developed to assist national authorities to prepare and/or update family planning/contraceptive policies in their settings. WHO has observed that governments and implementing partners, as well as providers, are either not always aware of existing tools and guidelines, or are not effectively undertaking this activity.

- In response to requests from Member States and professional organizations, a pocket guide containing essential service delivery recommendations in a user-friendly format for health-care providers, provisionally titled The contraceptive service delivery tool, will be prepared and field-tested for usability during 2015. This project has been underway since 2014 and will apply the updated SPR recommendations once they are issued. Tentatively, field-testing is planned in Bangladesh, the Democratic Republic of the Congo and Kenya.

3.1.4.2 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 (PPFP) can help improve maternal, newborn and child health. The 2013 WHO publication, *Programming strategies for postpartum family planning*, outlines the important elements of a PPFP intervention, to help programme planners and managers identify opportunities to offer contraception to postpartum women within existing health systems (12).

**Progress**

Following the launching of the *Programming strategies for postpartum family planning* publication at the 3rd International Conference on Family Planning in Addis Ababa, Ethiopia (November 2013), translations of the document into French and Spanish were undertaken and completed in 2014.²

The French translation was released during a regional meeting of programme officers representing 14 francophone countries in February 2014, and the Spanish

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² All three language versions are available at: http://www.who.int/reproductivehealth/publications/family_planning/ppfp_strategies/en/
translation was disseminated through colleagues at PAHO/WHO Regional Office for the Americas. In addition, the English version of the programming resource was presented and disseminated during the 30th Triennial Congress of the International Confederation of Midwives in Prague, Czech Republic (June 2014), and during the Scientific Conference of the East, Central and Southern Africa College of Nursing meeting in Harare, Zimbabwe (September 2014).

**Planned activities**

- To enhance the usability of the *Programming strategies for postpartum family planning* document, as well as capitalize on the availability of other guidelines, tools and resources that complement the document, a consolidated PPFP package will be developed.

- This resource will offer a compilation of WHO guidelines and programme resources addressing PPFP and, importantly, explain how programme managers and policy-makers can apply the materials to design and strengthen their programmes.

### 3.1.4.3 Human rights and contraception

Unmet need for contraception remains high in many settings, and is highest among the most vulnerable in society: adolescents, the poor, those living in rural areas and urban slums, people living with HIV, and internally displaced people. The latest estimates are that 222 million (13) women have an unmet need for modern contraception, and the need is greatest where the risks of maternal mortality are highest.

**Progress**

In order to accelerate progress towards attainment of international development goals and targets in sexual and reproductive health, and in particular to contribute to meeting unmet need for contraceptive information and services, the World Health Organization (WHO) has developed guidelines and recommendations on *Ensuring human rights in the provision of contraceptive information and services* (1). These guidelines were launched in 2014 at a high-level event at the UN Human Rights Council, and have been disseminated to partners during the course of the year. In addition, the Department developed a framework on ensuring human rights in contraceptive services and information. The framework was also released in 2014 (14).

**Planned activities**

- In 2015, the Department has plans to work on strengthening normative standards for monitoring, evaluation and accountability at country, regional and global levels. In this regard, the Department will be working to strengthen monitoring and evaluation of human rights dimensions in contraceptive service programmes through development of a new tool, and to strengthen quality of care in contraceptive programmes through development of human-rights-based quality assessment.

### 3.1.4.4 Contraceptive services delivery in the Optimize MNH guidance document on task shifting/sharing

**Progress**

The WHO 2012 *Optimize MNH* guidance contains evidence-based recommendations for the safe provision of key maternal and newborn health interventions by different cadres of health workers (15). This document also
summarizes the WHO recommendations on the cadres ranging from lay health workers to mid-level providers who may be trained and supported to conduct promotional activities and to provide the following contraceptive methods safely: tubal ligation, vasectomy, IUDs, implants and injectables.

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”. WHO participated in a technical meeting in July 2014 organized by the United States Agency for International Development (USAID) and Marie Stopes International to discuss the development of these guidelines and to plan for future research to strengthen the evidence on task sharing.

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”. WHO participated in a technical meeting in July 2014 organized by the United States Agency for International Development (USAID) and Marie Stopes International to discuss the development of these guidelines and to plan for future research to strengthen the evidence on task sharing.

**Planned activities**

- The outcome of the technical meeting was a recommendation for agencies supporting research on task sharing: to explore how present and future projects can contribute to addressing gaps in the guidelines agenda; to determine how to position studies to ensure policy change at the national level; to consider looking at other outcomes such as cost, impact on workforce, provider perspectives and effectiveness of interventions; and to consider other workforce sectors, such as pharmacists and suppliers of medicines to pharmacies.

3.1.5 Monitoring and evaluation

3.1.5.1 Human rights and family planning indicators

The Department undertook a review of existing quantitative indicators for rights-based monitoring of contraceptive services and information; a report has been published in 2014 (16). A joint implementation guide for the WHO guidelines (Ensuring human rights in the provision of contraceptive information and services; 1) has been developed with UNFPA and will be released in 2015. WHO is also working closely with partners on the initiative led by Denmark and Ethiopia on family planning and contraception at the Human Rights Council.

3.1.5.2 Measuring 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 women living with HIV. Therefore the Department conducted a study to compare how well the use of a simplified questionnaire (adapted from Demographic and Health Survey [DHS] questions) determined unmet needs when used by (i) health-care providers during their interactions with clients at the HIV clinic or (ii) external interviewers conducting exit interviews among women attending HIV care and treatment services.

**Progress**

Using a cross-sectional study design, 1186 women aged 15–49 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 needs in a more sustainable way that can be aggregated in health information systems in order to monitor the progress in reducing unmet need for contraception among women living with HIV. The manuscript of the study has been written and submitted in 2014 for journal publication and we are awaiting comments.

**Planned activities**

- The study results will be published in 2015.

### 3.1.6 Dissemination and partnerships

Work on dissemination and partnerships, is intended to support utilization of evidence in countries through systematic introduction of science-driven solutions to inform health policies.

#### 3.1.6.1 Family Planning 2020 (FP2020)

The Government of the United Kingdom and the Bill & Melinda Gates Foundation, in partnership with UNFPA, national governments, donors, civil society, the private sector, the research and development community, and others from across the world, called a global Family Planning Summit in London in 2012 to support the right of women and girls to decide, freely and for themselves, whether, when and how many children they have.

The Summit gave rise to the Family Planning 2020 (FP2020) partnership and called for unprecedented global political commitments and resources, with the ultimate goal of supporting the rights of an additional 120 million women and girls in the world’s poorest countries to use contraceptive information, services and supplies, without coercion or discrimination, by 2020. The RHR Department has played a crucial role.

**Progress**

In the two years since the London Summit, FP2020 has made remarkable progress, including additional commitments from countries, increased disbursements from donors, and progress across multiple sectors. According to the latest progress report launched on 3 November 2014, across the 69 FP2020 focus countries, in 2013 8.4 million more women and girls are using modern contraception, more than 30 of those countries have made commitments to the FP2020 initiatives, and a total of US$ 1.3 billion has been provided by donor governments.

The governing body of the FP2020 partnership is the Reference Group, which sets the overall strategic direction and drives coordination among the partnership’s stakeholders. The Reference Group has 18 members representing multilateral organizations, civil society, developing countries, donor governments and the private sector. It is accountable for ensuring the achievement of the FP2020 final goal. The current co-chairs of the Reference Group are Dr Chris Elias, President of Global Development at the Bill & Melinda Gates Foundation, and Dr Babatunde Osotimehin, Executive Director of the United Nations Population Fund (UNFPA).

WHO, and in particular the RHR Department, has been on board since the inception of the initiative and has contributed actively. Dr Flavia Bustreo, Assistant Director-
General of the Family, Women’s and Children's Health Cluster at WHO, is a member of the Reference Group of FP2020, whereas RHR Director, Dr Marleen Temmerman, is the co-chair of the Performance, Monitoring and Evidence (PME) Working Group, together with a representative from the Population Council. The PME Working Group has provided technical advice and support to FP2020 in monitoring and evaluation of progress towards reaching the FP2020 goal, including the development of the progress reports for the first two years of the initiative. This task is developed in concert with two initiatives at the country level: Track2020 (led by the Futures Institute) and PMA2020 (led by the the Bill & Melinda Gates Institute for Population and Reproductive Health at the Johns Hopkins Bloomberg School of Public Health). The PME Working Group also has the mandate of strengthening accountability for implementing financial, policy and programming commitments made by country governments, donors, the United Nations, civil society and others.

The Department has also provided technical support to the FP2020 Rights and Empowerment Working Group, to ensure that the FP2020 work on contraception and human rights are in line with the guidelines and framework recently developed by WHO (1, 14).

3.1.6.2 RHR Department Contributions to the UN Commission on Life-Saving Commodities for Women and Children

Under the auspices of the UN 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, the RHR Department is part of the Technical Resource Team (TRT) for Contraceptives, which represents a merging of the previous TRTs on Emergency contraception, Female condoms and Hormonal contraceptive implants. In phase I of the TRT workplan, the focus was on global tools, policies and programme guidance. In phase II, the focus is now on service delivery and country-level programmes.

Progress

A review of the literature on best practices for increasing access to emergency contraception (EC) identified mostly studies on the knowledge, attitudes and practices (KAP) of providers and users, and studies on service provision and policy governance. For female condoms, the Department conducted and completed a desk review of surveys on KAP of female condom users and non-users in various countries with different levels of female condom use. In addition, a module on EC for the WHO/USAID/UNFPA Training Resource Package for Family Planning (TRP), including a sub-module for pharmacists, was completed and posted on the TRP website.3

The consolidation of more of 20 TRTs into just 9 was carried out in early 2014. At a meeting convened at UNICEF, New York, workplans were consolidated and links between TRTs were established. The first phase of the TRT workplan was to be completed in 2013, but some activities were carried over into 2014, including the conduct of operations research, and the work on policy development activities. New activities in phase II which the Department will be leading include the dissemination of the training materials on EC and other contraceptives through

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3 Available at: www.fptraining.org
the TRP for Family Planning, and the development of policy recommendations on improving access to the main commodities, in collaboration with the other TRTs.

**Planned activities**

- The carry-over activities of the phase I workplan will be completed in early 2015.
- The implementation of phase II of the TRT workplan is expected to be completed by end of 2015.

### 3.1.6.3 Activities of the Implementing Best Practices initiative

In 1999, WHO’s RHR Department, USAID, UNFPA and nine other agencies created the Implementing Best Practices (IBP) initiative to work at the global, regional and country levels to foster collaboration, reduce duplication and harmonize approaches to support the identification, implementation and scaling up of effective technical and managerial practices to improve reproductive health. With the IBP Secretariat based in the RHR Department, the partnership has grown to 44 organizations, allowing for close collaboration between the Department and the IBP partners.

The IBP initiative is guided by its current five-year strategy and accompanying results framework. The objectives of the 2011–2016 strategy are to (a) actively engage in work of the IBP Consortium; (b) support sustained collaboration to scale up effective reproductive health/family planning practices at the country level; (c) scale up and document the learning in five priority countries; and (d) enhance knowledge sharing that improves access to, and application of, information and resources. Objectives are reached through a combination of activities, some of which are highlighted below.

(i) **Supporting countries and regional bodies to document, scale up and share effective reproductive health practices**

**Progress**

(a) **Documentation**

The IBP Consortium recognizes the need for countries and regions to capitalize on the experiences and lessons learnt within their own countries as well as within the region. It is now widely recognized that there is a need to document effective practices in countries in order to be able to build on these experiences by sharing at the country and regional level. This documentation requires an in-depth look at the implementation of the particular practice, with an eye to identifying the essential elements for successful implementation and approaches to overcoming barriers. After extensive consultation with the IBP Secretariat and partners, Zambia, IBP’s first focus country, completed documentation of “best practices” in family planning in October 2014. The purpose of the documentation was to identify practices which would be incorporated into the plan for the implementation of their eight-year family planning strategy (2013–2020).

Our regional partner, the East, Central and Southern African Health Community (ECSA-HC), has also conducted a documentation activity. The tools used to document family planning best practices in Mauritius, Tanzania and Zimbabwe were based on the tools developed for the Zambia programme. The West African Health Organisation (WAHO) is also working with IBP to begin documenting good practice in the 15-country Economic Community of West African States (ECOWAS) region as a preparatory process for planning their upcoming Good Practice Forum, to be held in 2015. Due to the Ebola crisis, the Forum was postponed, but planning is still going ahead.
(b) Scaling up

Scaling up effective practices is the ultimate goal of the IBP initiative. The IBP’s publication, *Guide to fostering change to scale up effective health services* (17), which incorporates the WHO/ExpandNet tools – *Beginning with the end in mind* (18) and *Nine steps for developing a scaling up strategy* (29) – continues to be the cornerstone of this work. In July 2014, the IBP Secretariat supported the Ministry of Health in Burkina Faso to plan for the scaling up of the WHO Individual, Family and Community Model, which is being tested and supported by Enfants du Monde, WHO in Burkina Faso and UNFPA. A plan was developed and is now being finalized and validated by stakeholders.

Additionally, IBP supported the WHO Regional Office for Africa to conduct a workshop for 10 countries in eastern and southern Africa in February 2014 to introduce new family planning tools and guidelines as well as to orient participants to IBP, the Training Resource Package for Family Planning, the *Guide to fostering change to scale-up effective health services*, and approaches to the documentation of best practices. During site visits connected to the workshop, the Zimbabwe nursing student project – which was the result of high-level Zimbabwean government participation in the 2009 “Fostering change” workshop with ECSA-HC – was highlighted. The programme has expanded from the initial site to five additional schools in Zimbabwe.

A satellite workshop was also held at the 3rd International Symposium for Health Systems Research (September/October 2014). This workshop introduced the *Guide to fostering change to scale up effective health services*, while also presenting different experiences of scaling up. The discussions emphasized the essential elements of the approaches to scaling up.

Planned activities

- As a result of this documentation process in Zambia, IBP partners at the global, regional and country level will work with Zambia’s Ministry of Community Development and Maternal and Child Health to plan for scale-up of selected practices.
- The Department will lead the IBP partners to work with ECSA-HC to review the results of their documentation exercise in Mauritius, Tanzania and Zimbabwe, and assist in dissemination and utilization of results in 2015.
- The Department will also work with partners to support the planning and implementation of the WAHO Good Practice Forum. The first major planning activity will be held at the end of January 2015 and will focus on consolidating tools for documentation across the subregion as well as a prioritizing a list of “good” practices in family planning and other areas of reproductive health.

(ii) Partnership and knowledge management

Progress

During 2014, Management Systems International (MSI), Education Development Center (EDC) and Ipas joined the IBP Consortium, bringing the total to 44 partner organizations.

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4 English, French and Spanish versions of this are available at: http://www.who.int/reproductivehealth/publications/strategic_approach/9789241500319/en/
A new IBP website was launched at the June 2014 partners meeting. This website was reconfigured with assistance from Pathfinder International and using new software that makes it easy to adapt and update the site as needed.

IBP Consortium semi-annual meetings were held in June and December. In June, the Consortium tried a new meeting format, with the theme of “Adolescents” for a full day of discussions. This meeting attracted the largest ever attendance, with 120 attendees. As a result, a new task team was formed to lead the partners in adolescent health issues. The Department’s Dr Chandra-Mouli, who was present at the IBP meeting, is the co-leader of this group along with Pathfinder. Their first task was to gather and make available tools and resources on scale-up of adolescent and youth sexual and reproductive health (AYSRH) practices, with a particular focus on reproductive health/contraception, by the end of 2014. The theme of the December 2014 meeting was “Implementation science”, with a focus on understanding what this means for IBP and its partners. This meeting was held directly following the 7th Annual Conference on the Science of Dissemination and Implementation: Transforming Health Systems to Optimize Individual and Population Health, organized by Academy Health and the United States National Institutes of Health (NIH).

The IBP Consortium created and uses a reliable, consistent knowledge management platform, the Knowledge Gateway. This tool is used by over 350,000 people worldwide, with approximately 55,000 focusing on reproductive health and family planning. Particularly active Communities of Practice (CoPs) include Post-Partum Family Planning (with over 1300 members from 87 countries), Family Planning Integration with Immunization, Systematic Approaches to Scale-up, and the Maternal, Infant and Young Child Nutrition and Family Planning. Each CoP organizes face-to-face and virtual meetings and posts relevant documents. This year, many of the CoPs decided to hold webinars with all preparation and follow-up discussions taking place on the Knowledge Gateway platform.

**Planned activities**

- The Department will organize partners to plan for activities and sessions at the 4th International Family Planning Conference in Indonesia (November 2015).
- The IBP Secretariat will continue to support partners to conduct discussion forums and initiate communities of practice on key reproductive health topics.

(iii) Linkages to related activities in the RHR Department

**Progress**

The IBP Secretariat is responsible for the Department’s work with Muskoka funding for family planning in francophone West Africa. This work is also linked with the Ouagadougou Partnership, which focuses on supporting countries in this region with family planning. Aside from supporting countries to conduct activities related to high-impact interventions (such as community-based programmes, postpartum family planning, introduction of long-acting methods), the IBP Secretariat along with Department staff also supported the WHO Regional Office for Africa and three West African countries to begin planning for the scale-up of post-abortion care services, particularly focusing on the family planning element.
**Planned activities**

- Countries that participated in the WHO Regional Office for Africa workshop in Lomé, Togo (i.e. Chad, the Democratic Republic of the Congo and Togo) will be supported to scale up post-abortion care/family planning.

- The IBP secretariat will support the launch of the updated Medical eligibility criteria for contraceptive use and conduct a meeting to discuss implications for implementation with IBP partners in March 2015.

### 3.1.7 References


11. Hormonal contraceptive methods for women at high risk of HIV and living


3.2 Adolescent sexual and reproductive health

3.2.1 Introduction

One of the key priorities for the work of the RHR Department, including HRP, is adolescent sexual and reproductive health (ASRH). The range of related activities include research and research synthesis, developing norms and guidelines, supporting monitoring and evaluation, and promoting implementation of evidence-based interventions, including through advocacy and partnerships with the aim of improving ASRH and contributing to the reduction of unintended pregnancies and unsafe sexual behaviours.
The following sections summarize the key activities that have been carried out and the products that have been delivered during 2014, as well as the plans for 2015 to achieve the above goals and related objectives of the Department.

**Major achievements**

- Two research protocols for testing the effectiveness of interventions to reduce unintended pregnancy in adolescents were developed and fieldwork was initiated.

- The Global Early Adolescent Study (GEAS), exploring gender norms and healthy sexuality among early adolescents, was extended to 10 countries where data collection efforts were initiated in 2014.

- Six papers reporting evidence on key ASRH issues were published in peer-reviewed journals, and a special supplement of the *Journal of Adolescent Health*, reviewing the progress made in various aspects of ASRH and rights in the 20 years since the International Conference on Population and Development (ICPD) was published and launched at multiple high-level meetings.

**3.2.2 Research and development**

*3.2.2.1 Intervention research to reduce adolescent risk behaviour and prevent pregnancy*

**(i) Adolescent Health Experience After Delivery – the AHEAD trial**

Unintended pregnancy among adolescents (aged 10–19 years) is a common public health problem globally, and is associated with significant health risks and social costs. In low- and middle-income countries, complications from pregnancy and childbirth are among the leading causes of death for adolescents. Adolescents who have had one unintended pregnancy are at high risk for a rapid, repeat pregnancy (defined as a subsequent pregnancy within two years). Reported rates of rapid, repeat pregnancies among adolescents range from 20% to 50%.

**Progress**

The Department initiated a research study seeking to identify effective interventions to prevent rapid, repeat pregnancies in adolescents. Following input from a technical advisory group, a phase 1 protocol to investigate a complex intervention to prevent rapid, repeat pregnancy was developed. The core protocol has been approved by the HRP Research Project Review Panel (RP2) and the WHO Ethics Review Committee (WHO-ERC). A country-specific protocol has been developed for Ghana, and protocols are being developed for Malawi and Mexico, with a target deadline of 31 December 2014. A site visit to Ghana and submission to the country Institutional Review Board (IRB) occurred in November 2014 and the protocol was approved.

**Planned activities**

- Site visits to Malawi and Mexico are planned for January 2015.

- Data collection will begin in February 2015.

- We anticipate results from phase 1 for these two countries in the early autumn of 2015, and will work to develop the protocol for phase 2 throughout 2015.
(ii) Prevention of first pregnancy – systematic review and conceptualization

A recent systematic review showed that most interventions designed to increase contraceptive use among young people were not successful (1). There are three key problems with designing interventions to reduce pregnancies among adolescents. First, unlike for other populations at risk for unwanted pregnancy, most adolescents do not visit health-care facilities. Second, in many settings, sexual activity before marriage is not socially acceptable, and therefore the numbers of adolescents at risk for unwanted pregnancy are significantly underreported. Third, evidence suggests that even if adolescents seek services at health-care facilities, providers are often inadequately trained to assist them or are biased against providing appropriate counselling and a wide range of contraceptives.

Progress

Given these three key barriers and evidence from previous research, the Department plans to initiate a multi-country school-based intervention study. In the study locations, comprehensive sexuality education (CSE) would be provided in all schools in selected locations, while selected intervention schools would also provide contraceptive counselling and provision of contraceptive methods (or referral to a nearby facility with health-care providers who are well trained to provide unbiased contraceptive services to adolescents). School-based interventions will reach the majority of adolescents, since the majority of adolescents are in school in most low- and middle-income countries.

Planned activities

• We plan to hold a meeting for donors and stakeholders about the proposed intervention study in the first half of 2015.

(iii) Adolescent/Youth Reproductive Mobile Access and Delivery Initiative for Love and Life Outcomes – the ARMADILLO study

The Scientific and Technical Advisory Group (STAG) has recommended that the Department explore and capitalize on the diverse ways in which young people use mHealth interventions to access sexual and reproductive health (SRH) information and services. Therefore, the Department has developed a concept for a study assessing the coverage, impact and cost-effectiveness of a text-message-based platform delivering SRH information on demand to youth.

Progress

The phase 1 formative protocol to develop message content and to pilot-test the platform has been approved by RP2 and submitted to WHO-ERC. A country-specific protocol for this initial formative phase has been developed for Kenya, and has also been approved by a local IRB. A second study site is currently being identified. A meeting of country principal investigators and study partners took place in Geneva in November 2014. At this meeting, plans for phase 1 implementation were finalized and study designs for phase 2 assessments of coverage, impact, and cost-effectiveness were discussed in detail. Phase 2 protocol development is underway.

Planned activities

• Implementation of phase 1 in Kenya is expected to begin in the first quarter of 2015.
(iv) Formative research to shape an intervention study on delivering adolescent health interventions alongside HPV vaccination in Tanzania

Working in conjunction with the Department of Immunization, Vaccines and Biologicals, the RHR Department supported the Faculty of Infectious and Tropical Diseases, at the London School of Hygiene and Tropical Medicine, London, United Kingdom, and the Mwanza Intervention Trials Unit, at the National Institute for Medical Research, Mwanza, Tanzania, to carry out formative research for a proposed intervention trial to test the feasibility and acceptability of delivering adolescent health interventions (AHIs) alongside vaccinations for human papillomavirus (HPV) in Tanzania.

The project explored the feasibility of integrating an adolescent health package with HPV vaccination through a three-step process: (a) a desk review of 39 policy documents; (b) a national stakeholder meeting with 37 policy-makers and partners; and (c) 18 key informant interviews with health and education policy-makers and district officials to explore perceptions of current programmes and AHIs that might be suitable for integration with HPV vaccination.

**Progress**

The formative research found that 13 school health interventions (SHIs) or AHIs are currently being implemented by the Government of Tanzania, mostly as vertical programmes. Coverage of current programmes is not universal, and is limited by financial, human resource and logistic constraints. Limited community engagement due to negative rumours and lack of strategic advocacy has affected uptake of some interventions, such as tetanus toxoid (TT) immunization. Overall, stakeholders and key informants considered deworming, vitamin A supplementation, TT vaccination and reproductive health education as the most suitable interventions for integrated delivery with HPV vaccination. However, other key stakeholders questioned whether linking deworming, which can be associated with side-effects, with HPV vaccination would be a good idea, and pointed out that vitamin A supplementation is not currently recommended by the Ministry of Health for children of primary school age. The research team therefore recommended exploring the possibility of screening short health promotion films followed by having a health worker available to answer questions, and TT vaccination being offered to girls in Standard VI (ages 13–14 years) and HPV vaccination being offered to girls in Standard IV (ages 9–10 years).

The research team concluded that given programme constraints, limited experience with integrated delivery and concern about real or perceived side-effects being attributed to the HPV vaccine, it would be very important to pilot-test the integration of AHIs/SHIs with HPV vaccination. Selected interventions would need to be simple and quick to deliver since health workers are likely to face significant logistical and time constraints during vaccination visits.

**Planned activities**

- In 2015, based on the findings of the formative research, the Department will continue to support the development of a protocol for the pilot-test phase of this project.

For further information on HPV and cervical cancer, please refer to section 3.6: Cervical cancer.
3.2.2.2 Descriptive research on adolescent development

(i) Global Early Adolescent Study

The RHR Department has collaborated with the Johns Hopkins Bloomberg School of Public Health in developing this large international study exploring gender norms and healthy sexuality among early adolescents, aged 11–13 years. The study seeks to (a) describe gender socialization as an evolving process in different cultural settings from early to late adolescence; (b) investigate parental/caregiver and peer influences on gender socialization of young adolescents; (c) understand how the different contexts (schools, neighbourhoods, media, culturally diverse settings) within which a young adolescent develops moderate parental/caregiver influences on gender socialization; and (d) understand how gender socialization in early adolescence influences sexual behaviours and gender-based violence in middle and late adolescence.

The GEAS is divided into two phases. As part of phase 1, a set of cross-culturally appropriate and valid instruments applicable to early adolescents in urban poor settings are being developed. Phase 2 of the study will be a longitudinal study of early adolescents using the tools developed in phase 1.

The study is being carried out in urban poor areas of 10 cities: Assuit (Egypt); Baltimore (USA); Blantyre (Malawi); Cape town (South Africa); Edinburgh (Scotland); Gent (Belgium); Ile Ife (Nigeria); Nairobi (Kenya); New Delhi (India); and Shanghai (China).

These sites have been selected because they each have large populations of urban poor youth. They also represent a diverse range of cultural, geographic, ethnic and racial settings. Finally, there is a long history of research collaboration with organizations in each site. Other sites are likely to be added in Bolivia, Ecuador and Viet Nam.

Progress

In 2014, ethical clearances were secured by WHO and the Johns Hopkins Bloomberg School of Public Health Ethics Committees, and by the country sites, and steady progress was made in preparing for phase 2 of the project and in the development of the following tools:

- a semi-structured qualitative in-depth interview protocol to explore transitions into early adolescence, gendered messages, changing relationships and intergenerational similarities and differences experienced between parents and their adolescent children;
- a vignette-based instrument to measure gender norms contextualized by specific relationship portrayals;
- a multidimensional scale to measure overall gender norms contextualized by relationship portrayals;
- a survey instrument to assess early adolescent health behaviours and influencing factors.

Planned activities

- In 2015, the study tools will be finalized and data collection will be initiated.
3.2.2.3 Secondary data analyses on access, quality and use of ASRH services

(i) Analyses of access, quality and use of ASRH services in Mexico

Progress

Three separate analyses have been conducted using a large national population-based survey in collaboration with the National Institute of Public Health in Cuernavaca, Mexico. The topics are:

- contraceptive knowledge and utilization among adolescents in Mexico;
- perceived quality of sexual and reproductive health services by age in Mexico;
- postpartum contraceptive use among adolescents compared with young women in public hospitals in Mexico.

The analyses of the first two topics are still ongoing and will be completed in 2015. The results of the third analysis show that overall 43% of women who delivered in health-care facilities left the place of delivery without a contraceptive method. The proportion was highest among the adolescents aged 12–19 years (48%) compared with women aged 20–29 years (43%) and women aged 30–49 years (41%), but the difference was not statistically significant (P = 0.05). Place of delivery (public versus private hospitals) was significantly associated with postpartum contraceptive use by adolescents, with this being less common for those who delivered at public hospitals. A manuscript reporting the findings has been prepared and submitted for publication in a peer-reviewed journal (2).

Planned activities

- In 2015, after completion of the analysis, manuscripts on the other two topics will also be submitted for publication. The findings from all of these analyses will be used to inform the protocol development of phase 2 of the AHEAD trial, which is planned for 2015.

(ii) Systematic review on menstruation and health in adolescent girls in low- and middle-income countries

Progress

As part of its work to strengthen the evidence base on very young adolescents, the Department carried out a systematic review to understand the knowledge, sources of information, health and social effects, and adults’ response to menarche, menstrual hygiene and menstrual health in adolescent girls.

The review – which included 80 papers from 25 low- and middle-income countries – showed that many adolescent girls start their periods uninformed and unprepared. Mothers are the primary source of information for these girls but the information they provide is too little and too late, and often mothers pass on their own misconceptions. Because menstruation is widely seen as polluting and shameful, menstruating girls are often excluded and shamed in their homes and in their communities. Many do not have the means for self-care and do not get the support they need when they face problems. This hinders their ability to carry on with their everyday activities and may establish the foundation for life-long disempowerment. The findings were shared widely with partners, including UNICEF and UNESCO, to inform their related work.
(iii) Literature review on contraceptive use among adolescents in low- and middle-income countries

Progress

The Department carried out a review on contraceptive use in adolescents to determine the contraceptive needs of adolescents in developing countries, to identify barriers that adolescents encounter in accessing and using contraception, and to identify effective interventions to increase access and use of contraception among adolescents.

The main findings included:

• A significant number of adolescents are sexually active, and this increases steadily from mid- to late adolescence.

• All adolescents in low- and middle-income countries – especially unmarried adolescents – face a number of barriers in obtaining contraceptive methods and in using them correctly and consistently. Adolescents experience many of the same barriers that adults do in accessing contraception, but some of the barriers are specific to adolescents. And even when adolescents do obtain contraception, social pressure may prevent them from using it.

• Contraceptive use in adolescents could be increased by implementation of: favourable laws and policies; multifaceted communication programmes directed at community leaders and members, and at adolescents (i.e. programmes that inform, educate and create supportive norms for the provision and use of contraception); accurate and age-appropriate curriculum-based sexuality education; and the provision of a wide range of contraceptive methods through different adolescent-friendly outlets.

The review was published in Reproductive Health and has been accessed nearly 11 500 times since it was published in January 2014 (3).

3.2.3 Norms, standards and tools

3.2.3.1 Ethical guidance for research on adolescents

Progress

The draft document on this topic produced at the end of 2013 was reviewed internally and externally during 2014. The feedback was collated and carefully considered.

Planned activities

• A revised draft was prepared, which will be published and disseminated in 2015.

3.2.3.2 Digitization of the quality assessment guide

Progress

As part of an effort to improve the quality of adolescent-friendly health services, the Department commissioned the digitization of an existing quality assessment guidebook. The digitized guidebook provides instant scoring, with data tracking available from the most local level up to municipal, state and national levels. Health managers are provided with instant feedback and the ability to chart progress over time.
The Department has partnered with the Brazilian Ministry of Health (MOH) to translate the guide into Portuguese and build a website for roll-out in Brazil. In 2014, a meeting in Goiania, Brazil, with representatives from the MOH and adolescent health-care providers from each state, resulted in a draft version of the website being field-tested with feedback collated and passed to the web development team. The translation of the forms into Portuguese took place in September, and weekly meetings resulted in the linking of facility identity numbers to the website. The full tool was pilot-tested in six clinics in December 2014 and January 2015.

**Planned activities**

- Finalization of the tool is expected following a February 2015 meeting in Geneva.

### 3.2.4 Monitoring and evaluation

#### 3.2.4.1 Documenting the scale-up of programmes providing ASRH services

In most low- and middle-income countries, initiatives to provide adolescents with sexual and reproductive health education and services have been in the form of pilot projects – they are small, piecemeal and short-term. In a slowly growing number of countries, these initiatives have evolved from pilot projects to become large, comprehensive and sustained programmes. It is important to document how these countries have managed to scale up their programmes when so many others were unable to do so. These initiatives are often briefly described at seminars and workshops but there is generally little about them in the published literature. Unlike formal intervention studies, the evolution of these programmes is often slow and "messy"; it is a challenge to prepare succinct case studies that truly reflect their complex journeys. As a result, valuable lessons that could be learnt are not distilled and shared.

### Progress

The Department has identified a number of countries that have implemented large and sustained sexual and reproductive health service and education programmes for adolescents and has synthesized the information about their efforts, especially efforts to overcome barriers to successful scale-up, using a modified version of the WHO-ExpandNet framework on scaling up health innovations. The following regions and countries were included in this work:

- **Americas**: Argentina, Brazil, Colombia*, Ecuador
- **Africa**: Mozambique*, Nigeria*, Rwanda, Senegal
- **Europe**: Estonia*, Moldova*
- **South-East Asia**: India (selected states)
- **Eastern Mediterranean**: Pakistan* (selected provinces)
- **Western Pacific**: Mongolia.

As a result of this work, two articles have been published in peer-reviewed journals covering findings from Estonia and Nigeria (4, 5), and a number of others are due to be published shortly. The summary of the study on Colombia is presented in Box 1 (6).

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* indicates completed/nearly completed
Planned activities

In 2015, the Department is planning a consultation to bring together representatives from these countries to share the lessons learnt from their experiences.

Box 1: Scaling up youth-friendly sexual and reproductive health services in Colombia – a case study

Young people make up a quarter (24.5%) of Latin America’s population. Inadequate supply of specific and timely sexual and reproductive health (SRH) services and sexual-ity education for young people increases their risk of sexual and reproductive ill health. Colombia is one of the few countries in Latin America that has implemented and scaled up specific and differentiated health and SRH services: the Youth Friendly Health Services (YFHS) Model.

Research was conducted to provide a systematic description of the crucial factors that facilitated and hindered the scale-up process of the YFHS Model in Colombia. This included a systematic and comprehensive literature search on SRH services for young people and national efforts to improve the quality of care in Colombia and neighbouring countries, as well as interviews with a selection of key stakeholders. The information gathered was analysed using the WHO-ExpandNet framework.

In seven years of implementation of the YFHS Model in Colombia (2007–2013), more than 800 clinics have been made youth-friendly. By 2013, 30 departments and 536 municipalities had YFHS, thereby achieving 46.9% geographic coverage of the municipalities.

The analysis identified five elements that enabled the scale-up process: clear policies and implementation guidelines on YFHS; clear attributes of the user organization and resource team; establishment and implementation of an intersectoral and interagency strategy; identification of and support to stakeholders and advocates of YFHS; and solid monitoring and evaluation.

The elements that limited or slowed down the scale-up effort were: insufficient numbers of health personnel trained in youth health and SRH; high turnover of health personnel; a decentralized health security system; inadequate supply of financial and human resources; and negative perceptions among community members about providing SRH information and services to young people.

In conclusion, Colombia’s experience shows that successful large-scale implementation of youth health programmes depends on clear policies and implementation guidelines, championship by institutional leaders and authorities in YFHS, continuous training of health personnel, and inclusion of users in the design and monitoring of these services.

Source: Huaynoca et al., 2015 (6)

3.2.4.2 Evaluating ASRH and sexuality education programmes to understand the challenges to implementation and scale-up

Progress

The Department has supported programmatic evaluations to understand the challenges to implementation and scale-up of ASRH and sexuality education programmes, and how these challenges are being overcome.

(i) External review of the Healthy Generation project: youth-friendly health services in Moldova

The review of this project, which is supported by the Swiss Development Cooperation, identified three key findings that led to immediate action to improve services.

Firstly, youth-friendly health centres were not mandated to deliver the full package of services and therefore services were often limited to the provision of information and counselling. While a specific package of services to be provided by the youth-friendly health centres had been defined by the MOH, the centres...
were not authorized to provide the required clinical services to adolescents and had to refer their clients to specialized centres for diagnostic and treatment services, thus undermining the central idea that the youth-friendly health centres are supposed to provide a full package of services in one place, while guaranteeing confidentiality and privacy.

Secondly, among the assessed centres, the ones that were initially founded as nongovernmental organizations (and subsequently designated as youth-friendly health centres by the MOH) outperformed the newer public sector centres in relation to the six national quality standards and particularly in relation to friendliness and acceptability, raising questions on how to best increase motivation and improve health worker performance in the public sector.

Thirdly, while the explicitly stated objective of the project was to "improve the sexual and reproductive health of young men and women in Moldova, particularly those who are vulnerable and most at risk", no specific activities were planned or carried out to reach vulnerable and most-at-risk adolescents and no data were available on how many adolescents reached by the project belonged to this group.

(ii) Evaluation of the Tarunya project in Jharkhand State, India: supporting the implementation of the ASRH project

The Department was commissioned to conduct an evaluation of the ASRH project in Jharkhand State, north-west India, which is supported by the Tarunya project, funded by the Packard Foundation. The specific objectives of the evaluation were to study the project’s design, implementation, monitoring and outputs. The outputs of interest included improvements in the provision of quality health services, community support, adolescent awareness and adolescent demand for services, behavioural outcomes and health impacts, as well as strengthening of the relevant policies, planning, management and institutionalization. Field activities were completed in 2014. The results indicate that the Tarunya project improved the quality of health service provision in the following ways: it improved adolescent awareness on some aspects of ASRH; to a lesser extent, it improved adolescent demand for ASRH services; it strengthened policies, planning and management at state, district and local levels; and it brought the institutionalization of some of these changes. However, the state ASRH programme, implemented with support from the Tarunya project, had limited effects on the health behaviours of adolescents, including their health-seeking behaviours.

3.2.5 Dissemination and partnerships

3.2.5.1 Twenty years after International Conference on Population and Development – the status of adolescent sexual and reproductive health and rights

Progress

In 2014, the world commemorated the 20th anniversary of the ICPD, which took place in Cairo in 1994. In response to recommendations from the STAG and the Gender and Rights Advisory Panel (GAP), the Department reviewed the progress made in adolescent sexual and reproductive health and rights in the 20 years since the ICPD. In collaboration with UNFPA and the International Women’s Health Coalition, the Department reviewed the progress and evidence in the following ASRH-related areas:
• creating an enabling environment for ASRH: a framework and promising approaches;
• sexuality education: emerging trends in evidence and practice;
• effective strategies to provide ASRH services and to increase demand and support;
• ensuring youth rights to participation, and promotion of youth leadership in the development of sexual and reproductive health policies and programmes;
• addressing intimate partner violence and sexual violence among adolescents: emerging evidence of effectiveness.

The findings of the reviews were reported within a special supplement of the Journal of Adolescent Health, pre-published online in December 2014 (7). Launch events were organized in collaboration with partners in a number of North American and European cities. Key messages from the special supplement issue were also presented at a number of international meetings.

**Planned activities**

• In 2015, data and evidence from the work on ASRH will be disseminated through key international activities and large conferences, including the XXI Congress of the International Federation of Gynecology and Obstetrics (FIGO), and other large scientific and policy events.

### 3.2.6 References

3.3 Maternal and perinatal health

3.3.1 Introduction

In 2014, WHO’s work on maternal and perinatal health gained significant impetus with the launch of two key global initiatives. The consensus statement on Ending Preventable Maternal Mortality (EPMM) set a vision for maintaining the momentum and achieving further reductions in maternal deaths, and the Every Newborn action plan set the focus on a key component of infant mortality namely, newborn deaths (1, 2). Both initiatives focus on improving quality of care as well as reducing inequities in accessing care. The RHR Department’s, including HRP’s, research and normative work reflects the new agenda. Care during childbirth is the most critical period in this context. Key areas of work include promoting respectful care and reducing unjustified medicalization for mothers, and reducing stillbirth and intrapartum-related morbidity and mortality for babies.

As presented to and endorsed by the Scientific and Technical Advisory Group (STAG) in 2014, research priorities are to improve the quality of care during childbirth and provide guidance on caesarean section. The research and guidance activities are carefully integrated in this context. For example, the findings of the intrapartum care research project will be complemented with evidence-based guidance during childbirth. Similarly, the work on caesarean section will be complemented by WHO guidance on strategies to reduce unnecessary caesarean sections and a monitoring and evaluation tool on the implementation of the Robson classification of caesarean sections.

The antenatal care (ANC) guidance is a complex multidimensional project that will continue in 2015 with some specific outputs.

It is anticipated that the quality of care work will be expanded to include work on preterm birth following the publication of the WHO guideline in 2015.

Major achievements

- Secondary analyses of data from the WHO Multicountry Survey on Maternal and Newborn Health were published as a special supplement of the BJOG: An International Journal of Obstetrics and Gynaecology, and in articles published in other journals. An important finding was the significant under-utilization of antenatal corticosteroids in women delivering preterm babies.

- In fistula care, short-term catheter stay after surgery was found to be non-inferior to the more conventional two-week catheter stay in the largest fistula care trial to date (publication forthcoming).

- The WHO Fetal Growth Study recruitment was completed, with data gathered from 1440 women in 10 countries.

- Systematic analysis of causes of maternal deaths published in 2014 indicated that indirect causes and obstetric haemorrhage were the leading causes. WHO recommendations for augmentation of labour were published.

- The WHO statement on the prevention and elimination of disrespect and abuse during facility-based childbirth has been endorsed by more than 70 organizations.

- In May 2014, estimates of maternal mortality, including trends from 1990 to 2013, were published. Globally, there were an estimated 289 000 maternal deaths in 2013, a decline of 45% from 1990.
3.3.2.1 Improving quality of care for mothers and newborns

(i) Evidence-based antenatal care in Mozambique – a cluster randomized controlled trial

Antenatal care visits constitute one of the few times when women in many resource-poor settings seek care for their own health. Therefore they represent an important opportunity for reaching women with a number of interventions that may be vital for their health and the health of their unborn child.

The Department is conducting a facility-based cluster randomized controlled trial (RCT) with a “stepped wedge” design in Mozambique, by developing an intervention targeted at increasing the delivery of evidence-based practices included in the ANC package by midwives, and promoting the integration of key interventions into routine ANC (3).

The intervention includes: the provision of kits with all necessary medicines and laboratory supplies for ANC, a storage system, a tracking system, and training sessions for health-care providers.

**Progress**

On 2 June 2014, the Department, in collaboration with local partners and the Ministry of Health, successfully launched the intervention in the first facility. The ANC kits were well received by the health-care providers and pregnant women. Since then, the intervention has been rolled out in a new facility every two months as per the study design. As of December 2014, the intervention has been rolled out in four facilities, representing half of the selected facilities. The trial was featured in September on the homepage of the WHO website as an example of woman-centred health care and improved quality services.

**Planned activities**

- In 2015, the intervention will be rolled out at the remaining five selected facilities.
- The Department plans to implement a nested secondary study to survey postpartum contraceptive use.

(ii) Multicountry study to develop fetal growth standards

**Progress**

The Department 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 (4). The study had reached the expected sample size in the 10 participating countries by September 2014. Results of this study will have important clinical and research implications for the prenatal and postnatal periods, as well as for maternal health.

**Planned activities**

- The follow-up phase of the study will be finished by March 2015.
- The main analysis, including the development of customized fetal growth curve tools, and several secondary analyses will take place in the second half of 2015.
(iii) WHO Multicountry Survey on Maternal and Newborn Health

The WHO Multicountry Survey (MCS) on Maternal and Newborn Health 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 cases. It captured information on over 314,000 women in 359 facilities across 29 countries in five WHO regions.

The MCS has been a landmark study for several reasons. Firstly, it is the largest study of its kind to show that high coverage of effective evidence-based interventions in health-care facilities do not ensure good outcomes. This finding puts the emphasis on improving the quality of care by ensuring that care is not only effective but also delivered in a timely and efficient way, ensuring that it is safe, equitable and people-centred. The MCS firmly established a large research network that can conduct similar studies and also use the Department's research for research capacity strengthening.

Progress

Following the publication of the primary findings in The Lancet in May 2013, a series of 13 secondary analyses of the MCS dataset were published in a Special Issue on Maternal and Perinatal Morbidity and Mortality: Findings from the WHO Multicountry Survey in the BJOG: An International Journal of Obstetrics and Gynaecology in March 2014. These analyses explored a range of critical topics, including: postpartum haemorrhage, pre-eclampsia and eclampsia, abortion, indirect causes of maternal death, adolescent pregnancy, advanced maternal age, maternal education, infection and caesarean section, intrapartum-related perinatal mortality, twin pregnancy, preterm birth and neonatal near-miss cases.

A further three WHO MCS secondary analyses have been published in other journals, including an analysis of the use of antenatal corticosteroids and tocolytic drugs in preterm births in The Lancet, factors associated with corticosteroid use in China in the International Journal of Obstetrics and Gynaecology, and risk factors and adverse outcomes of small-for-gestational-age infants in PLOS ONE.

The study investigating the burden and causes of life-threatening maternal complications and the quality of emergency obstetric care in 42 tertiary public hospitals in Nigeria has been completed and the results have been analysed and accepted for publication in the BJOG: An International Journal of Obstetrics and Gynaecology. This is a related study using the near-miss approach, which assessed the timeliness of the interventions. The findings did not point to a clear link between time to intervene and adverse outcomes.

Planned activities

- Several more WHO MCS secondary analyses are currently under review by journals or are ongoing. It is planned that these will be published as a journal supplement.

(iv) Respect for women during pregnancy and facility-based childbirth: development and validation of measurement tools in three countries.

Every woman has the right to dignified, respectful care during pregnancy and childbirth. Recent evidence has demonstrated that globally many women experience disrespectful or abusive treatment during labour and delivery in health-care facilities, which can pose a significant barrier to women presenting...
to facilities for delivery (10). Disrespectful and abusive treatment during childbirth may also result in poorer health outcomes for women and newborns. Recent efforts to define and measure disrespect and abuse have resulted in highly variable estimates of prevalence.

Despite the growing recognition of this important public health problem (11), no effort has been made at the global level to define and measure its prevalence. To achieve this, there is a clear need for consensus on a universal definition of disrespectful and abusive treatment during childbirth in facilities, in order to develop and validate tools to measure disrespect and abuse globally.

The primary objectives of this study are:

• to develop an evidence-based definition and criteria for identification of disrespect and abuse during childbirth in facilities that can be used globally;
• to develop and validate tools for measuring disrespect and abuse during childbirth in facilities in three countries; and
• to explore individual, provider, institutional and health systems factors that either promote or prevent disrespectful and abusive practices during childbirth in facilities.

Progress

A two-phased, mixed methods study design is being used. Phase 1 is a formative phase that will use qualitative research methods (focus group discussions and in-depth interviews) and systematic reviews to develop an evidence-based definition, identification criteria and two tools for measuring disrespect and abuse in facilities: (a) an observation tool using direct observation during childbirth at facilities and (b) a community-based survey tool using women's self-reports 4–6 weeks postpartum. Phase 1 findings will also improve understanding of the individual-, provider- and facility-level factors that could contribute to disrespect and abuse.

In phase 2, these two new tools will be applied using quantitative and qualitative research methods in three countries. The two tools will be analysed and compared using quantitative research methods. The observational tool will be used as a reference standard against which the community survey tool will be validated. Three facilities per country will be used for the observational component, with community follow-up of enrolled women 4–6 weeks postpartum.

Planned activities

• Phase 1 will commence data collection in February 2015.
• Phase 2 will be implemented in 2016–2017.

(v) Facilitators and barriers to facility-based delivery in low- and middle-income countries

Progress

As part of the Maternal and Perinatal Health and Preventing Unsafe Abortion team's work on promoting quality of intrapartum care, a systematic review of qualitative evidence related to the facilitators and barriers to women delivering at health-care facilities in low- and middle-income countries was conducted and subsequently published. The review identified multiple barriers to women accessing facility-based delivery, including: traditional and familial influences;
distance to the facility; direct and indirect costs of childbirth; low perceived quality of care; and fear of discrimination and mistreatment by health-care providers (10).

Strategies and incentives to promote and sustain respectful, non-abusive, high quality care during facility-based childbirth are required to build trust between women and providers and promote institutional delivery. Between September and November this article was viewed online more than 4500 times.

**Planned activities**

- A systematic review of qualitative research on respectful maternal care (as an additional component of formative work on disrespect and abuse during facility-based delivery) is planned.

**(vi) Research and development of innovative tools for better outcomes in labour difficulty**

Complications arising during labour and childbirth account for a significant proportion of the global burden of maternal and newborn mortality and morbidity, particularly in low- and middle-income countries. Yet the quality of intrapartum care at many health-care facilities in low-resource settings remains suboptimal. The Department initiated the Better Outcomes in Labour Difficulty (BOLD) project to accelerate the reduction of intrapartum-related maternal, fetal and newborn mortality and morbidity by addressing the weaknesses in the process of labour care and bridging the disconnect between the health systems and the communities in low-resource settings. The project seeks to achieve this goal through a two-pronged approach: (a) develop a Simplified, Effective, Labour Monitoring-to-Action tool (SELMA) to assist health-care providers to monitor labour and take decisive actions more efficiently; and (b) develop innovative tools (termed “Passport to Safer Birth”) designed with community groups and health-care providers, to promote access to respectful, quality care for pregnant women at the time of delivery. It is envisioned that these tools will be integrated into a quality improvement approach, which will then be tested using intervention research.

**Progress**

The project kicked-off with a technical consultation (involving the Steering Committee and the Technical Advisory Group) in February 2014. Eight hospitals have been identified in Nigeria and Uganda for the initial data collection (cohort, qualitative and design research) that will inform the development of the tools. The final study protocols (with the conceptual framework) have been approved by the WHO Research Project Review Panel (RP2), the WHO Ethics Review Committee, and the Institutional Review Boards of all participating hospitals. Research training workshops have been conducted in both countries and data collection for the formative and clinical cohort started in both countries on 1 December 2014. The second technical consultation took place in November 2014.

**Planned activities**

- Data collection for both the cohort and qualitative/design research is expected to be completed by June 2015.
- Analysis of study results and development of prototypes of the tools are expected to be completed by the end of 2015.
(vii) The Gentle Assisted Pushing Study: a multicentre randomized controlled trial of gentle assisted pushing (GAP) in the upright posture to reduce prolonged second stage of labour

A prolonged second stage of labour is hazardous for the baby. To expedite delivery, fundal pressure is frequently applied, although there is very little objective evidence of the effectiveness or safety of this action. 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.

**Progress**

The objective of this RCT is to compare the use of (a) a gentle method of applying fundal pressure in an upright posture, (b) upright posture alone, and (c) routine practice to reducing the time of delivery and the associated maternal and neonatal complications in women who have not delivered within 15–30 minutes in the second stage of labour. A total of 1145 participants will be recruited in four sites in South Africa over an 18-month period. Healthy nulliparous women with uncomplicated, singleton, cephalic pregnancies, anticipating vaginal delivery, will be asked to participate. The primary outcome is mean time from randomization to delivery. Recruitment commenced in December 2014.

**Planned activities**

- Recruitment will continue throughout 2015 and be completed in mid-2016.

(viii) The Odón device

The objective of this study is to evaluate the safety and feasibility of using the Odón device to assist with vaginal delivery in singleton, term pregnancies during the second stage of labour under normal conditions (12). This study is a hospital-based, multicentre, prospective, phase I cohort study with no control group.

**Progress**

The phase I study continued recruitment in Argentina during 2014, with 45 women included by end of December. In 2014, a further development right for the Odón Device was obtained by Becton Dickinson; the company is in the process of developing a new prototype which will be used in the remainder of phase I participants.

**Planned activities**

- In 2015, phase I will be expanded to several other research sites.
- Recruitment of the planned sample size of 130 women will be completed in 2015.

3.3.2.2 Hypertensive disorders of pregnancy

(i) Screening for pre-eclampsia – evaluation of the predictive ability of angiogenic factors

Dysregulated angiogenesis during the preclinical phase of pre-eclampsia may provide an opportunity for early prediction through the measurement of serum and urinary predictive biomarkers in the first half of pregnancy. From 2006 to 2009,
5121 pregnant women with risk factors for pre-eclampsia (nulliparity, diabetes, previous pre-eclampsia, chronic hypertension) from Argentina, Colombia, India, Italy, Kenya, Peru, Switzerland and Thailand had their serum tested for sFlt-1, PlGF and sEng levels and their urine for PlGF levels at < 20 weeks’ gestation (index tests, results blinded from carers), and again at 23–27 weeks and at 32–35 weeks.

Progress

Data from the 5121 pregnant women have been analysed. Results show that measurement of these factors, early in pregnancy, is not predictive. The manuscript has been submitted for publication.

Planned activities

• The results of the study will be published in 2015 and secondary analyses are planned to look into the markers for stillbirth and preterm birth.

(ii) 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, and to reduce maternal morbidity and newborn mortality when supplementation starts at around mid-pregnancy, particularly in women with low calcium intake. A calcium dose of 500 mg (elemental) is included in the Essential Medicines List by the 19th Expert Committee on the Selection and Use of Essential Medicines (13), and current WHO guidelines issued in 2014 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, and it has been proposed that further improvements in outcomes may be achieved by earlier supplementation. Consequently, the Department engaged in 2011 in a multicountry, double blind, placebo-controlled RCT to assess if 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. If found effective, the groundwork will have been done for further research and then implementation of food fortification programmes.

Progress

The trial started in 2011 and, as of October 2014, 1798 women had been screened; 872 had been recruited and 284 pregnancies in sites in Argentina, South Africa and Zimbabwe were recorded. The sample size to be achieved is 1440 women.

Planned activities

• Recruitment will continue during 2015, and it is expected that it will be completed early in 2016.

(iii) Simplified Treatment for Eclampsia Prevention using Magnesium Sulfate (STEPMAG) trial

Magnesium sulfate (MgSO4) is the drug of choice for treatment of women with pre-eclampsia and eclampsia. There is clear evidence that it reduces the risk of eclampsia by close to 50% and probably reduces the risk of death in women with pre-eclampsia. Administration of the currently recommended dosage regimens requires resources that are often not universally available in low-income settings.
where severe morbidity and death relating to pre-eclampsia are most common. As part of WHO efforts to increase coverage of magnesium sulfate use as prophylaxis and treatment for eclampsia worldwide, a technical consultation was held in collaboration with Merck for Mothers in October 2013, to deliberate on how to generate an evidence base for an alternative, easier to use, but equally efficacious magnesium sulfate regimen. At this meeting, international research partners identified a clear need for a stepwise approach to establish the rationale and scientific basis for testing a simpler magnesium sulfate regimen.

**Progress and planned activities**

The Department has embarked on a number of converging activities to justify the need for and the choice of minimum dosage of magnesium sulfate in preparation for a large-scale non-inferiority trial.

(a) **STEPMAG preparatory systematic reviews**

As part of the STEPMAG trial preparatory activities, we have completed two systematic reviews: a systematic review of non-randomized studies on the use of alternative regimens of magnesium sulfate for treatment of pre-eclampsia and eclampsia; and a systematic review of clinical pharmacokinetic properties of magnesium sulfate in women with pre-eclampsia and eclampsia. An update of the Cochrane systematic review on alternative regimens of magnesium sulfate for prevention and treatment of pre-eclampsia and eclampsia is ongoing. All three systematic reviews will be published in 2015.

(b) **Magnesium sulfate dose finding study**

In order to improve the probability of success for the proposed WHO non-inferiority trial, a modelling and simulation approach is being explored to find a minimum effective and simplified dosage regimen. The goal of such a model-based approach is to systematically assess various dosing regimens to identify one that will achieve both equivalent (non-inferior) efficacy while being more practical to implement. Modelling and simulation provides a powerful tool to assess whether one or more selected dosing regimens will meet pre-specified non-inferiority margins for such a large-scale trial. The Department is exploring this methodology (through a pharmacokinetic–pharmacodynamic study) in collaboration with experts at Merck in the USA. The modelling team at Merck is currently exploring a stepwise use of three existing data sets of serum magnesium levels and health outcome data in women receiving magnesium sulfate for pre-eclampsia, eclampsia and fetal neuroprotection, to perform the modelling and simulation.

The protocol and modelling action plan was finalized in October 2014 and is undergoing review by the STEPMAG technical working group. Approvals and legal documents are currently being finalized with three institutions for Merck to be able to receive and use existing datasets for the modelling work. The study protocol will be published in the first quarter of 2015. Depending on the availability of the three data sets, it is expected that the modelling work will be concluded before the last quarter of 2015.

(c) **Global Clinical Practice Patterns in the Use of Magnesium Sulfate for the Prevention and Treatment of Eclampsia – a multicountry survey**

Although there are two recommended magnesium sulfate dosing regimens that are widely accepted, there has not been sufficient research to determine
the optimal magnesium sulfate regimen for women with severe pre-eclampsia or eclampsia. Additionally, there are significant barriers to accessing and using magnesium sulfate in health-care facilities. There is also some evidence of variability in the use of magnesium sulfate for the prevention and treatment of eclampsia in facilities around the world, and use of regimens other than those recommended by WHO have been described.

In the context of this uncertainty around the optimal magnesium sulfate regimen and the multiple barriers to its access and use, WHO will be conducting a survey to characterize current clinical practices in the prevention and management of severe pre-eclampsia and eclampsia in a global network of health-care facilities. This will be a two-part, cross-sectional, self-administered survey of facility administrators and individual health-care providers within institutions of the WHO Multi-Country Survey Network. The protocol has been finalized and is awaiting approval by the RP2. The survey will commence in early 2015.

3.3.2.3 Obstetric fistula

Progress

The report on the results of the RCT on short-term (seven-day) catheter stay following simple fistula repair was submitted to and accepted by The Lancet in 2014. The trial showed that seven-day bladder catheterization after repair of simple fistula was non-inferior to 14-day catheterization. It is safe and effective for managing women following repair of simple fistula with no evidence of a significant increased risk of repair breakdown, urinary retention or residual incontinence through three months after surgery. The trial dataset is currently being further examined using cluster analysis to develop a fistula classification system by patient and fistula characteristics within the collaboration with EngenderHealth on this project.

Under this collaboration, WHO has become part of the International Research Advisory Group for the Fistula Care Plus project (2013–2018).

The technical consultations resulted in priority research areas/questions, including measurement, and WHO will continue to collaborate with EngenderHealth under the Fistula Care Plus project. A manuscript on “Measuring the incidence and prevalence of obstetric fistula: approaches, needs and recommendations” has been published in the Bulletin of the World Health Organization in January 2015 (14).

Planned activities

• If the ongoing analysis on the classification system is successful, a technical consultation will be convened to reach consensus on fistula classification.

3.3.2.4 Postpartum haemorrhage

(i) Carbetocin room temperature stable (RTS) for preventing postpartum haemorrhage – a randomized, non-inferiority, active controlled trial

This is a hospital-based, multicentre, double-blind, randomized, non-inferiority, active controlled trial to evaluate if carbetocin RTS 100µg intramuscular (IM) is non-inferior to oxytocin 10 IU IM, as a uterotonic during the third stage of labour, for preventing postpartum haemorrhage in women delivering vaginally. Centres from 11 countries are expected to recruit 30 000 women over a period of 12 months. Should this trial demonstrate that carbetocin RTS is non-inferior to
oxytocin in preventing postpartum haemorrhage, in settings where the cold chain could not be guaranteed, oxytocin could be replaced by carbetocin RTS as the uterotonic used during the third stage of labour. The stability data from long-term studies performed at 30°C/75% relative humidity and accelerated at 40°C/75% relative humidity indicate that a shelf life of at least 24 months at 30°C is feasible for the new RTS formulation of carbetocin.

**Progress**

During 2014, the trial steering committee met, the protocol was finalized, an international contract research organization was engaged, and the selection of study sites was finalized.

**Planned activities**

The trial is scheduled to start in the first quarter of 2015. The initiation date at each participating centre will depend on when the protocol is approved at country level. Once the trial starts, monitoring visits will be organized to ensure compliance with the protocol and Good Clinical Practice.

**(ii) Non-pneumatic anti-shock garment**

The non-pneumatic anti-shock garment (NASG) is a simple device for improving survival in women experiencing obstetric haemorrhage-related hypovolemic shock.

**Progress**

In April 2014, a technical consultation was held in Geneva with research, donor and implementation partners to review the evidence on safety and effectiveness of the NASG and to identify research questions and next steps for the NASG research activities. Research priorities identified were:

- interrupted time series study of ongoing, large-scale NASG implementation in comprehensive emergency obstetric care facilities;
- pragmatic RCT of effectiveness of NASG in basic emergency obstetric care facilities (where NASG is primarily for first aid stabilization and referral), as well as economic analyses (cost-effectiveness, cost barriers) and qualitative research on barriers, enablers, feasibility, acceptability and other implementation considerations.

**Planned activities**

- Further implementation of the above-mentioned research will depend on the availability of dedicated funding.

**(iii) Stability of oxytocin along the supply chain**

The objective of this study is to evaluate how temperature variations during the supply chain and storage might affect the potency of the active ingredient of oxytocin products at health-care provider level. Several studies looked at the quality of oxytocin at the point of sale and found that in many places the active pharmaceutical ingredient was below the specifications. The possible causes identified were the poor quality of manufacturing and inappropriate conditions during transport or storage at the health-care facility, but no rigorous research has been done to confirm this.


**Progress**

This study will be implemented in Ghana and will be run in collaboration with the UN Commission for Life-Saving Commodities, Merck for Mothers, the WHO Essential Medicines and Health Products Department, and UNFPA. The protocol has been finished and partners have been contacted.

**Planned activities**

- With the completion of preparatory activities in 2014, the implementation in Ghana – and potentially one more African country – will take place in 2015.

(iv) Uterotonic agents for preventing postpartum haemorrhage: a network meta-analysis

Many different uterotonic drugs have been used for reducing the incidence of postpartum haemorrhage (PPH). These include oxytocin, misoprostol, ergometrine, carbetocin, and combinations of these drugs. Existing evidence presents conflicting results on relative effectiveness, making it difficult to draw firm inferences about all available drugs.

**Progress**

To close this gap, a systematic review and network meta-analysis of all uterotonic drugs for reducing the occurrence of PPH is currently being undertaken, with the aim of ranking their effectiveness and cost-effectiveness, and documenting their side-effect profiles. The protocol has been developed and registered as a Cochrane title, making this the first network analysis review by the Cochrane Pregnancy and Childbirth Review Group. The review is currently ongoing.

**Planned activities**

- The review will be completed by mid-2015.

3.3.2.5 Preterm birth

(i) PREBIC/WHO Preterm Birth Epidemiology Working Group

The Department has been collaborating with the Preterm Birth International Collaborative (PREBIC), which is a gathering of international researchers working in the area of preterm birth.

**Progress**

In 2014 two PREBIC meetings took place at WHO headquarters, one involving the whole PREBIC group, and another, later in the year, involving the epidemiology working group.

A technical consultation was held in September 2014 with the Preterm Birth Epidemiology Working Group (EWG) to review current work and knowledge gaps related to levels and trends in preterm birth rates, including the several lines of preterm birth analysis occurring within this collaboration on the WHO Multicountry Survey of Maternal and Newborn Health, Euro-Peristat datasets, and several national datasets from high-income countries, including Canada, Denmark, Finland, Japan, Norway, Sweden and the United States.

With the publication of the Antenatal Corticosteroid Trial (ACT) suggesting potential harm with expanding antenatal corticosteroid treatment to lower-level
health-care facilities (15), new research questions have also been identified for further discussion.

In addition, while many trials have been conducted on tocolytic drugs, no trial has established whether tocolysis using nifedipine (the currently recommended first-line tocolytic drug) actually improves substantive perinatal outcomes. In 2014, the Department drafted a trial protocol to address the question of whether nifedipine plus antenatal corticosteroids (ACS) are better than ACS alone for preventing perinatal mortality and severe morbidity in women with threatened preterm labour at gestational age less than or equal to 34 weeks.

**Planned activities**

- In 2015, the Department will collaborate with groups active in preterm birth research such as March of Dimes, PREBIC and the University of California San Francisco, who have initiated a large preterm birth research programme.
- The proposed trial comparing nifedipine plus ACS to ACS alone will be operationalized if specified funding is available.

**3.3.2.6 Implementation research**

The Department’s Maternal and Perinatal Health team follows and monitors the implementation of several implementation research projects supported by the Implementation Research Platform (IRP).

(i) **Effectiveness and acceptability of using skilled birth attendance (SBA) services through community reproductive health nurses (CORNs) in rural communities of Ethiopia – a randomized controlled trial**

This project was one of the successful applicants to the WHO IRP competitive funding. This three-arm cluster RCT will evaluate the effectiveness and acceptability of using skilled birth attendance (SBA) services through CORN in rural communities in the Gedeo Zone, Ethiopia. Study participants will be all pregnant women in the selected communities who will give birth at home and at community health posts during the study period. In intervention clusters, CORNs will be trained and deployed to provide basic reproductive health care, particularly SBA, for births at home (Arm 1) and births at community health posts (Arm 2), with a control arm of randomly selected clusters (Arm 3).

(ii) **The effect of training community health providers and provision of mother-baby packs on early ANC attendance and health facility deliveries in rural Zambia**

This project was another successful applicant to the WHO IRP competitive funding. The objective of this study is to increase hospital deliveries and first trimester ANC attendance by pregnant women in Samfya district, Luapula province, Zambia. This is a quasi-experimental intervention and control study. The target population will be pregnant women and community health providers at the intervention sites. The intervention will involve: (a) training community health providers on issues related to ANC and the importance of facility-based deliveries; (b) providing mother-baby packs at the community level prior to delivery; and (c) orienting facility-based health-care providers on good ANC practices. The control site will have pregnant women receiving routine ANC as per national protocols.
(iii) Assessing the impact of an intervention to improve the quality of emergency obstetric care (EOBC) on maternal and perinatal outcomes in Nigeria

As part of the IRP, supported under the IRP initiative for leveraging funding, the team of researchers from the Women’s Health and Action Research Centre (WHARC) in collaboration with the Immpact Program at the University of Aberdeen and the RHR Department will implement a project entitled “Assessing the impact of an intervention to improve the quality of emergency obstetric care (EOBC) on maternal and perinatal outcomes in Nigeria”. This project is a multicentre, quasi-experimental study that aims to assess the impact of a package of interventions when used in secondary and tertiary level health-care facilities in Nigeria. It will be conducted in three phases over a three-year period in four intervention hospitals, with four hospitals of similar status acting as control sites. The results will enable the identification of a system-wide quality-of-care framework for improving the delivery of EOBC for the prevention of maternal and perinatal morbidity and mortality in Nigeria.

(iv) 2011 Implementation Research Platform call for proposals

As a partner in the IRP call for proposals, the Department is managing the following three studies from IRP’s first call for proposals.

• “Assessing the acceptability, feasibility and effectiveness of a strategy for improving the quality and safety of maternal/neonatal health care in the health service contexts of four Middle Eastern countries.” This study will be completed in 2015.

• “Innovations for increasing access to integrated safe delivery, prevention of mother-to-child transmission (PMTCT) and newborn care in rural Uganda.” This study will be completed in 2015.

• “A matched pair cluster-randomized implementation study to measure the effectiveness of an intervention package aiming to decrease perinatal mortality and increase institution-based obstetric care among indigenous populations in Guatemala.” This study obtained a further Grand Challenges scale-up grant in 2014.

(v) A comprehensive strategy for building capacity for implementation research in low- and middle-income countries

A number of knowledge gaps have been identified by the IRP partners (the RHR Department/HRP, the Special Programme for Research and Training in Tropical Diseases, and the Alliance for Health Policy and Systems Research) over the past several years, including a need for effective strategies to build capacity for implementation research. With the calls for implementation research launched by IRP and by individual IRP partners, it is clear that while there is a growing interest in the field of implementation research, the capacity to propose and undertake well-designed implementation research studies is still very limited, especially in low- and middle-income countries (LMICs), by LMIC researchers and implementers. Currently, a proposal is being developed to promote implementation research in LMICs, to ensure a high level of competency on implementation research at the regional and country levels, and to create synergies and collaborations between programme implementers, individual researchers, and research/public health institutions.

Planned activities

• After selection of the institutions, capacity strengthening workshops and training programmes will be implemented in 2015.
3.3.3 Norms, standards and tools

3.3.3.1 Improving quality of care for mothers and newborns

(i) Antenatal care guidelines

ANC is an important part of the continuum of care for improving outcomes for mothers and their babies by providing a platform for health promotion, disease prevention, early detection and treatment of complications, birth preparedness and complication readiness. Most recent WHO guidance (2002) was based on the results of a trial that evaluated the effectiveness of a package of reduced visits with evidence-based interventions through goal-oriented clinic visits, known as focused antenatal care (FANC) approach (16).

Progress

As part of the Department’s efforts to consolidate evidence-based guidance on the provision of quality care during this period, recommendations for the interventions needed during the ANC period, as well as how these interventions should be delivered, are currently being developed (2014–2016).

The first working group and technical consultation took place on 22–25 April 2014. Priority questions and outcomes for the recommendations were finalized in October 2014. The Department is collaborating with other WHO Departments including the Department of Maternal, Newborn, Child and Adolescent Health, the Department of Nutrition for Health and Development, and the Department of Immunization, Vaccines and Biologicals, as well as other UN partners, and initiatives like Roll Back Malaria.

The focus of the guideline is the essential core package of ANC that all women should receive. The DECIDE (Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence) framework will be used to assess the evidence and the work is being developed under the following work streams: individual interventions, antenatal testing, barriers and facilitators to access to and provision of care, large-scale programme evaluation, health system and community level interventions, and modelling.

In preparation for this guideline, 56 Cochrane systematic reviews have been identified for updating. The updates of these reviews are in progress; four have been completed. The grading of evidence from all systematic reviews and preparation of draft narrative summaries are ongoing. Two papers that synthesise the qualitative evidence on barriers and facilitators are also being prepared.
Planned activities

- The recommendations will be finalized and published by the beginning of 2016 together with the publication of the Cochrane systematic review updates and other related systematic reviews.
- The Guideline Development Group will explore the use of online tools for communications, including for targeting different guideline components for different audiences. Modelling will be explored as an interactive decision-making tool for policy-makers.

(ii) Intrapartum care and obstructed labour

(a) WHO recommendations for augmentation of labour

Prolonged labour is an important cause of perinatal and maternal morbidity and mortality. Labour augmentation with oxytocin has commonly been used to treat slow labour resulting from weak or inefficient uterine contractions. Despite the benefits, the inappropriate use of labour augmentation can cause harm to the mother and her baby.

Progress

The primary objective of the WHO recommendations for augmentation of labour is to consolidate the guidance for effective interventions that are needed to reduce the global burden of prolonged labour and its consequences. In May 2014, the
new WHO guideline containing a total of 20 recommendations relating to the practice of labour augmentation was published on the Department’s website and disseminated through the Department’s network of partners, including hard copies (17).

**Planned activities**

- Evidence briefs are currently being developed and will be available by the first quarter of 2015.

**(b) Optimal caesarean section rate**

The proportion of deliveries by caesarean section at the population level is a measure of access to and use of an obstetric intervention for averting maternal and neonatal mortality and morbidity. It is useful as a reference for policy-makers and governments when assessing national and regional health indicators on maternal and infant health and use of resources. Monitoring global, regional and country estimates of caesarean section is important to assist countries to track levels of this life-saving health intervention to identify gaps, support decisions and inform ongoing efforts towards improving maternal and newborn health.

Despite WHO’s recommendation in 1985 stating that “there is no justification for any region to have a caesarean section rate higher than 10–15%”, rates worldwide have increased steadily in an unprecedented manner in both developed and developing countries. There is international concern about the validity of this benchmark in light of three more decades of accumulated evidence and improvements in both clinical obstetric care and methodologies to assess evidence and issue recommendations.

**Progress**

In 2014, the Department convened a technical consultation to review and update the 1985 statement. In preparation, the following reviews were undertaken:

- update of the 2007 caesarean section global estimates;
- trend analysis of the changes between countries and regions over the last few decades;
- systematic review of ecologic studies;
- worldwide analysis of the association between caesarean section and maternal and neonatal mortality.

The technical consultation was held in Geneva, on 18–19 October 2014. On the basis of the discussions and evidence presented, the group concluded that caesarean section rates higher than 10% do not necessarily contribute to reducing maternal and newborn mortality rates. In countries with low caesarean section rates, socioeconomic development rather than caesarean section rates is probably a more important factor in influencing mortality outcomes.

**Planned activities**

- Acknowledging that mortality outcomes are not the only important indicators, the Department will work with countries with reliable health information systems to conduct analyses at national or subnational levels to appropriately assess the association between caesarean section rates and morbidity indicators. The Department will explore research on assessing the psychosocial implications...
of caesarean section regarding the maternal–infant relationship, women's psychological health, and women's ability to successfully initiate breastfeeding.

(c) Monitoring of caesarean section practices

The lack of a standardized, internationally accepted classification system to monitor and compare caesarean section rates in a consistent and action-oriented manner is one of the factors preventing a better understanding of changes in caesarean section rates and the underlying causes. The Department published a systematic review in 2011 which concluded that the Robson 10-group classification would be in the best position to fulfil current international and local needs (18). In 2013 a systematic review to assess the experiences, opinions and challenges encountered by users of this classification, the pros and cons of the adoption, implementation and interpretation of the Robson classification, as well as the adaptation, modifications and recommendations proposed for its use was conducted and published (19).

Progress

These two reviews were the basis for the second discussion at the technical consultation in Geneva in October 2014, with the objective of endorsing a classification system that can be universally adopted and can overcome many of the barriers and limitations that have plagued the clinical and scientific community for the last three decades. The Group agreed to adopt the Robson Classification for this purpose. It is expected that the use of this classification would assist health-care facilities to optimize the use of caesarean section, assess the quality of care and clinical management practices and outcomes by group, and potentially also to assess the effectiveness of implemented strategies or interventions targeted at optimizing the use of caesarean section.

Another important aspect of caesarean section monitoring is to assess whether a particular health-care facility’s caesarean section rate is optimal or there are unnecessary caesarean sections according to its case mix. In a large international collaborative effort, the Department and its partners developed the C-Model, a global generic reference to determine the optimal caesarean section rate at the facility level according to specific characteristics of women attending the facility. The C-Model is designed to guide obstetric teams, health managers and other stakeholders in the complex task of optimizing caesarean section rates by providing a locally relevant reference. In order to facilitate use, an electronic calculator is available online to generate these estimates. 6

Planned activities

• In 2015, guidelines for the implementation, interpretation and reporting of the Robson Classification will be developed.

• The above-mentioned systematic reviews identified some issues that need to be addressed in order to standardize the classification:
  – establishing unambiguous definitions for spontaneous onset of labour, induction and augmentation; and
  – minimal gestational age to apply the classification.

6 Available at: http://200.144.255.68:8098/cmodel/
• Other critical issues to be examined during the development of the guidelines include: how to use indications within each group of the classification; and definition of optimal caesarean section rates for each group using an outcome-based approach.

• The C-Model will be pilot-tested and its robustness tested with interested partners and facilities.

(d) Social determinants of caesarean section

The contributing factors and determinants of the use or overuse of caesarean section are multiple and in many cases they are country- or context-specific. Social determinants are very important because women are more involved than in the past in the decision-making process for delivery. In addition, women are exposed and have access to a wide range of information on pregnancy and childbirth. Women's magazines and the internet are two of the most ubiquitous sources of information that can play a critical role in shaping women's opinions and influencing their decisions. However, the quality – including accuracy and completeness – of information available on the web is widely variable due to lack of governance or editorial control.

Progress

In 2014, the Department published the results of two reviews. The first assessed the quality and completeness of the information on caesarean section published in Spanish women's magazines (20) while the second review assessed information on the internet used by lay persons in Brazil, a country with the highest rate of caesarean section (21). The authors of both reviews concluded that the quality and completeness of the information is not sufficient to help the reader understand the real benefits and risks of each mode of delivery.

(e) Interventions to reduce unnecessary caesarean sections

Progress

In view of the increasing priority being given to this issue in the clinical and research contexts in the last few years, in 2014 the Department engaged in updating the Cochrane systematic review published in 2011 which evaluated the effectiveness and safety of non-clinical interventions for reducing unnecessary caesarean sections. The Cochrane review update was limited to RCTs, quasi-experimental studies, controlled clinical trials, controlled “before and after” studies with at least two intervention and control sites, and interrupted time series analyses. Observational studies, case reports or documentation of individual successful experiences are, for methodological reasons, not included. In order to complement the core findings of the Cochrane review, the Department is conducting a systematic review of these other methodological approaches plus innovative ideas on how to reduce unnecessary caesarean section. Even if these ideas provide no proof of effectiveness because they have not yet been tested according to current internationally accepted methodological standards, it is important to broaden the scope of the Cochrane review to get a more comprehensive understanding of all interventions proposed and implemented to optimize the rational use of caesarean section. This expanded review will help to pinpoint major determinants of unnecessary caesarean section as well as possible solutions for addressing escalating rates in many settings.
Planned activities

- The results of this updated review will be published in 2015.
- A call for ideas for strategies aimed at reducing unnecessary caesarean section, to stimulate new thinking and to engage researchers from low-resource settings is also planned.
- It is expected that this updated systematic review and the call for ideas will result in the identification of potential interventions that can be developed, shaped and tested in future research.

3.3.3.2 Management of maternal sepsis occurring around childbirth

Maternal bacterial sepsis around the time of birth is among the leading causes of preventable maternal morbidity and mortality globally. Prompt identification and appropriate treatment of sepsis during the intrapartum and immediate postpartum periods are critical to reducing associated severe maternal as well as fetal and newborn complications. As part of the Department’s efforts to consolidate evidence-based guidance on the provision of quality care around the time of birth, recommendations on the prevention and management of intrapartum and postpartum maternal sepsis are currently being developed.

Progress

Priority questions and outcomes for the recommendations were finalized in June 2014. Out of the 21 Cochrane reviews identified for developing this guideline, 11 have been updated and published (or accepted for publication) between September and October 2014, five reviews are currently undergoing editorial processes while four of the reviews do not require updating (see details of these Cochrane reviews in Annex B). The grading of evidence from all systematic reviews and preparation of draft narrative summaries are ongoing.

Planned activities

- The recommendations will be finalized and published in 2015 together with the publication of the remaining Cochrane systematic review updates.
- Evidence briefs will be developed and published in the second half of 2015.

3.3.3.3 Preterm birth

Preterm birth is the leading cause of death and severe, acute and long-term disabilities for the neonate. Evidence-based guidance on the effectiveness and safety of interventions to prevent preterm birth, as well as supportive health-system characteristics, is crucial to improving outcomes for mothers and babies. The RHR Department and the Maternal, Newborn, Child and Adolescent Health (MCA) Department are collaborating to develop a set of guidelines that address questions relating to the effectiveness and safety of interventions for managing women at imminent risk of preterm birth, as well as care for the preterm newborn infants. A group of international stakeholders prioritized key questions and outcomes relating to this guideline during a technical consultation in April 2013.

Progress

In 2014, the Department collaborated with the Cochrane Pregnancy and Childbirth Group to update or conduct afresh 23 Cochrane reviews, and with the National Center for Child Health and Development in Japan to conduct seven
new systematic reviews of non-randomized studies to inform recommendation questions relating to the management of the mother; and graded evidence according to the GRADE methodology. The technical consultation to agree on the final recommendations was held in May 2014 and recommendations covering antenatal corticosteroids, tocolytics, antibiotics and optimal mode of preterm delivery were formulated by the Guideline Development Group (GDG). The RHR and MCA Departments also hosted an electronic consultation among the GDG members in November 2014 to review implications of the recently published trial on antenatal corticosteroid use in developing country settings on the formulated recommendations (15). The final guideline document and evidence tables have been completed according to the WHO Guideline Review Committee guidelines.

**Planned activities**

- The recommendations will be published in 2015.
- Evidence briefs will be developed in collaboration with USAID and will be published along with the main guideline document.
- A commentary on the WHO recommendations – to further promote their dissemination and implementation – will also be published by the second half of 2015.

**3.3.3.4 Research synthesis and guideline development methods**

(i) Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (DECIDE) collaboration

The Department 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 policy decisions about health systems.

**Progress**

- A two-day workshop for policy-makers from eight European countries on the application of the DECIDE evidence-to-recommendation frameworks for WHO guidelines in task shifting was held in Slovenia in August 2014. The Department contributes to the development of evidence-to-recommendations and recommendations-to-decisions frameworks, in collaboration with the Norwegian Knowledge Centre for the Health Services. This occurs particularly through the ongoing use of DECIDE frameworks in guideline development, such as the forthcoming WHO recommendations on task shifting in the provision of abortion services, and WHO recommendations on ANC.
- Further evidence briefs derived from the 2012 OptimizeMNH guidance on health worker roles (22) have been developed, to support the dissemination and use of the guidance on task-shifting approaches in maternal and neonatal health by policy-makers (23, 24, 25). The Department is also contributing to the ongoing development of the interactive Evidence-to-Decision (iEtD) framework tool. We conducted a two-day workshop for WHO guideline developers in Geneva (October 2014) to use the DECIDE frameworks and test the iEtD tool.
(ii) The Confidence in the Evidence from Reviews of Qualitative research (CERQual) tool

- Qualitative research is especially valuable in exploring questions related to the acceptability and feasibility of an intervention, among other implementation considerations. Methods for systematically reviewing the results of multiple qualitative primary research studies are an emerging area of research within the health sciences. However, as with evidence of effectiveness, decision-makers need tools for assessing how much confidence they can place in findings from systematic reviews of qualitative evidence. The CERQual tool provides a transparent method for assessing the confidence level of evidence from reviews of qualitative research, and for indicating this confidence to end-users, such as guideline panels or decision-makers. CERQual uses a similar approach conceptually to other GRADE tools, but is intended for findings from systematic reviews of qualitative evidence.

**Progress**

- The development of CERQual is being taken forward through the CERQual subgroup of the GRADE Working Group, in close partnership with the RHR Department. A manuscript describing the tool entitled “Assessing how much confidence to place in the evidence from qualitative evidence syntheses: the CERQual approach” has been submitted for publication.

**Planned activities**

- The Department will continue working on further development of the CERQual tool in 2015.

3.3.4 Monitoring and evaluation

3.4.4.1 Maternal mortality

(i) Maternal mortality estimates

The Department leads the collaborative effort with UNICEF, UNFPA, the World Bank and the United Nations Population Division 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, between 1990 and 2015, the maternal mortality ratio by 75%). This collaboration is known as the Maternal Mortality Estimation Interagency Group (MMEIG) and it is advised by an external Technical Advisory Group (TAG). Critical to the maternal mortality estimation process is a country consultation with Member States to review draft estimates prior to publication. The Department leads this effort and it has served as a starting point to engage countries in improving the quality of data collection. This consultation process has been recognized as transparent and a good example of how "WHO estimates" should be undertaken.

**Progress**

In May 2014, the MMEIG published estimates of maternal mortality with trends from 1990 to 2013; the number of women dying due to complications during pregnancy and childbirth has decreased by 45% from an estimated 523 000 in 1990 to 289 000 in 2013 (26). With the addition of new data points and increased country engagement, it is now evident that the statistical model used to estimate maternal mortality requires additional refinement to better reflect good quality country-level data.
The process to refine the statistical model and improve the estimation process for the last round of MDG reporting was initiated in mid-2014. A MMEIG and TAG meeting was convened in October 2014 to discuss potential changes to the model and to plan for country consultation for estimates related to the 1990–2015 reporting period. These estimates will be used for the final MDG report.

**Planned activities**

- In 2015, the MMEIG will complete the country consultation and publish a report on maternal mortality estimation with trends for 1990–2015.
- The Department will support and participate in regional workshops related to improving measurement of maternal mortality in both the Eastern Mediterranean and Western Pacific Regions.
- In collaboration with the MMEIG, TAG, and the Health Statistics and Informatics Department of WHO, the Department will lead the technical development of a robust statistical model which will expand these estimates to incorporate both estimates of total numbers of maternal deaths as well as estimates of individual causes of maternal death.
- In collaboration with the MMEIG, TAG, and the Health Statistics and Informatics Department of WHO, the Department will elaborate specific country-level targets for the new Sustainable Development Goals (SDGs), using as a baseline figure the 2010 estimate for maternal mortality from the 1990–2015 estimation.

**(ii) Causes of maternal death**

Data on the causes of maternal deaths are needed to inform policies to improve maternal health.

**Progress**

WHO developed and analysed global, regional and subregional estimates of the causes of maternal death during 2003–2009 using a novel method, updating the previous WHO systematic review (27). The new analysis and estimates were published in Lancet Global Health (28).

The literature search for this analysis included specialized and general bibliographic databases for research articles and data published between 1 January 2003 and 31 December 2012, with no language restrictions, as well as the WHO mortality database for vital registration data. Estimates of causes of death by MDG regions and worldwide, for main and sub-causes of death categories with a Bayesian hierarchical model, were reported.

Overall, 417 datasets from 115 countries and including 60 799 maternal deaths were included in the analysis. Based on this analysis, 73% of all maternal deaths between 2003 and 2009 (i.e. 1 771 000 of 2 443 000) were estimated to be due to direct obstetric causes, while indirect causes accounted for 27.5%, haemorrhage for 27.1%, hypertensive disorders for 14.0% and sepsis for 10.7% of maternal deaths. The rest of these deaths were due to abortion (7.9%), embolism (3.2%) and all other direct causes of death (9.6%). Regional estimates varied substantially. These analyses will inform the prioritization of health policies, programmes and funding, to reduce maternal deaths at regional and global levels. Further efforts are needed to improve the availability and quality of data related to maternal mortality.
Planned activities

• The cause of maternal deaths will be analysed in categories specifically looking at the distribution of indirect causes of maternal deaths.

3.3.4.2 Maternal morbidity

(i) Maternal morbidity working group

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 is needed to inform policy and programme decisions and resource allocations. The Department received a grant from the Bill & 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 (MMWG) has been established, with representation from all WHO regions, relevant technical expertise in quantitative and qualitative measurement of maternal morbidities, and patient advocacy.

Progress

In 2014, the MMWG continued to refine the maternal morbidity framework to develop the basis for a community-based tool for measurement of morbidity. A stakeholders meeting was convened to share the progress of the MMWG and to receive their feedback and recommendations on the direction and scope of the work. The group reaffirmed the working definition and framework upon which a “tool” to measure maternal morbidity has been developed. The tool has undergone pre-testing in one country setting (Jamaica) and plans for pilot-testing in three countries are being finalized. A paper describing the methods and process of the MMWG was submitted for publication in a peer-reviewed journal and is under review.

Planned activities

• Pilot-testing of the tool will be completed in three country settings in 2015.

• Systematic reviews describing the magnitude of maternal morbidity related to psychiatric conditions and noncommunicable diseases, such as cardiovascular disease, and the impact of maternal morbidity on maternal function will be published.

• Indicators related to maternal morbidity will be developed

(ii) Maternal near-miss cases

Since its publication, the WHO maternal near-miss criteria and the audit tool have been applied in over 30 countries.

Progress

In collaboration with the Department, a number of countries, such as Brazil and Nigeria, have recently conducted national-level surveillance studies, and there are many other countries that would like to implement the near-miss tool at scale.

Planned activities

• The systematic review on maternal near-miss has been updated and is being prepared for submission to a peer-reviewed journal in 2015.
• Learning from the research and field experiences, the Department is planning a technical consultation entitled “WHO maternal near-miss approach and quality of care: research and Implementation” in January 2015, to examine the evidence on the current application of this tool and to identify ways to implement the near-miss approach at scale while establishing links between communities and facilities.

3.3.4.3 Perinatal mortality

The large number of perinatal death classifications in the literature suggests that none of them is accepted as a uniform system which can be applied in different environments. Recent efforts have focused on the development of a single, multi-layered system that can facilitate comparisons between and within diverse settings, including low-, middle- and high-income countries. This would allow benchmarking and the identification of trends, gaps and modifiable factors. In turn, this will help to focus local efforts on improving maternity care and developing strategies for prevention.

Especially following the recent publication of the ICD-Maternal Mortality (ICD-MM), systematically classifying maternal deaths, there is an urgent need for a high-quality global classification system for causes of perinatal death. The place to start in constructing such a system is a review of what currently exists and how current systems match up with important criteria for such a system.

Progress

WHO has been working with a number of research partners undertaking a literature review to provide background papers to inform the development of this global classification system. This review will include a comprehensive search (including non-English articles) and will base data extraction upon key criteria for a global system agreed by an expert panel. WHO will use the outcomes of this review to inform the development of a globally accepted system.

A technical consultation was convened (July 2014) on the WHO Application of ICD-10 to perinatal deaths: ICD-Perinatal Mortality (ICD-PM), modelled on the WHO Application of ICD-10 to deaths during pregnancy, childbirth and the puerperium: ICD-MM, on maternal mortality (29). The ICD-PM classification system has several unique features, necessary to optimize the classification of perinatal mortality across all settings. It identifies the time of death as the first step in classification (i.e. antepartum, intrapartum, early neonatal or late neonatal) and it is multi-layered such that the depth of classification can reflect the locally available information. The third important feature is the requirement that a maternal condition (healthy or otherwise) be documented for every perinatal death, such that the system reflects the inherently linked health outcomes of these two groups of patients.

Planned activities

• The ICD-PM draft document will be presented at the next ICD Genitourinary and Reproductive Medicine Technical Advisory Group meeting (date not yet known yet) in alignment with the ICD-11 revision process. The work on the document will continue incorporating feedback.

• The manuscripts on Delphi survey and the systematic review will be published in 2015.
3.3.5 Dissemination and partnerships

3.3.5.1 WHO statement on prevention and elimination of disrespect and abuse during facility-based childbirth

Progress

Following a technical consultation on disrespect and abuse experienced by women during facility-based childbirth in November 2013, the Department has initiated research activities on this important and under-researched area. To highlight the need for greater cooperation, research and action on this topic, in collaboration with international partners we developed and published the WHO statement on The prevention and elimination of disrespect and abuse during facility-based childbirth in September 2014 (11). The statement was launched at the UN General Assembly (New York, September 2014) and the Third Global Symposium on Health Systems Research (Cape Town, September 2014) and was widely disseminated to governments, healthcare providers, managers, professional associations, researchers, women’s advocates, international organizations and to the general public.

3.3.5.2 Shaping the research agenda – 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 report was published in Reproductive Health in 2014 (30). 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-raising 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%).

3.3.5.3 Dissemination of WHO guidelines and derivative products and improving the science of implementation

(i) The GREAT Network

The Department 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 Department has supported development of national policies and implementation research in the context of activities supported by the UN Commission for Life-Saving Commodities, as described below. These activities were conducted in collaboration with Member State governments and partner agencies within the UN Commission.
Progress

Within the GREAT Network and with support from the UN Commission on Life-Saving Commodities and the WHO Implementation Research Platform, the Department has conducted barrier assessments to implementation of maternal health guidelines in three countries (Myanmar, Tanzania and Uganda), with a fourth country to be concluded soon (Ethiopia). We are continuing to provide technical support to these knowledge translation initiatives in these countries, as well as developing and pilot-testing and evaluation methodology in Kosovo, for future application in all participating countries.

The GREAT Network held its second international collaborators’ meeting in South Africa in October 2014 to review ongoing projects and discuss new activities. With GREAT Network partners, we are currently developing a training-of-trainers course on knowledge translation methodologies, with online and face-to-face components. The course will be offered to up to 25 individuals across eight countries currently participating in the knowledge translation activities within the GREAT Network, and is intended to support ongoing knowledge translation activities in those countries and build local capacity in the science and practice of knowledge translation.

In 2014, The GREAT Network ran a seed grant competition for research groups in low- and middle-income countries working on knowledge translation activities in the area of maternal and perinatal health guideline implementation; two groups, from Sri Lanka and Uganda, were successful.

Planned activities

• The work of the successful research groups will continue in 2015.
• A second seed grant competition will be held in 2015.
• The Department has also mobilized support for capacity-building in knowledge translation and guideline implementation activities through H4+ funds; the capacity-building will be provided through the establishment of two centres of excellence in H4+ countries selected through competitive application (Cameroon, Côte d’Ivoire, Ethiopia, Guinea Bissau, Liberia and Zimbabwe). These funds will be awarded in January 2015.

(ii) Programme Reporting Standards (PRS) for maternal, sexual and reproductive health

Reporting of the key implementation elements of programmes in maternal, sexual and reproductive health is essential to understand the impact of the programmes, as well as to guide the efforts for future replication and scale-up. Indeed, readers of a programme publication need clear and complete information about the intervention process to be able to assess the evidence and its quality as well as replicate the model. However, there is growing recognition that the key variables for understanding programme implementation – how, when and under what conditions programmes are being implemented – is inadequately reported on in the scientific literature on maternal, sexual and reproductive health. Many programmes report on outcomes without describing the implementation process in sufficient detail. This limits the understanding of the intervention and the outcomes, and also limits replication of the programme in other contexts.

H4+ is an inter-agency mechanism aimed at harmonizing and accelerating actions to improve maternal and newborn health. The agencies are: UNFPA, UNICEF, WHO, the World Bank, UNAIDS and UN Women.
Progress

To address this gap, WHO is initiating a consultative process to review existing templates for process documentation and programme reporting, with the goal of developing Programme Reporting Standards (PRS) with a focus on maternal, sexual and reproductive health. Similar to the CONSORT 2010 guideline (CONsolidated Standards of Reporting Trials), a checklist and flowchart format can be employed, describing key elements for understanding the implementation process. The intent is that the PRS will be used by implementers and researchers to improve process documentation and facilitate comparison between programmes. It would also facilitate the use of implementation research as part of programme implementation, since many of the processes and contextual variables documented through this process are useful sources of data for implementation research studies.

The objectives of the project are three-fold:

i. to provide an overview of available process reporting tools (used by researchers, organizations, donors) and reporting guidance (used by journals, similar to CONSORT) for programmes in maternal, sexual and reproductive health;

ii. to develop PRS to be used by authors when reporting on implementation and results for programmes in maternal, sexual and reproductive health;

iii. to test the feasibility of the PRS for maternal, sexual and reproductive health programmes in a variety of platforms.

A departmental working group has been convened, including participation of the Implementation Research Platform, and the protocol for the scoping review has been completed in 2014. Of the 4596 citations identified, 163 full text articles are currently being assessed for inclusion.

Planned activities

• The systematic review will be submitted for publication and a technical consultation will be convened to develop consensus and produce the tool for dissemination and implementation.

3.3.6 References


Available at: http://www.consort-statement.org/consort-2010


3.4 Preventing unsafe abortion

3.4.1 Introduction
The activities of the Human Reproduction Programme (HRP) on preventing unsafe abortion in 2014, while maintaining its scope of work in all its core areas, saw a special focus on: innovations in implementation research to expand access to safe abortion care; conceptual and measurement-related developments in understanding and assessing abortion safety; and normative work on non-physician health-care providers.

Major achievements

- A special supplement issue on “Expanding access to medical abortion” was published by Reproductive Health Matters, with articles highlighting the findings of work supported by HRP.
- A study in Ethiopia, India and South Africa on the capability of community health workers to assess eligibility for medical abortion yielded mixed results, suggesting that they were more successful in ruling out ineligible cases.
- The study on abortion complications in Ghana, Lao People’s Democratic Republic, Myanmar, Nigeria and Sri Lanka generally showed low levels of severe morbidity.
- The Clinical practice handbook for safe abortion was launched to facilitate the implementation of the 2012 WHO Safe abortion guidelines.
- A series of briefings and workshops were conducted on the WHO Safe abortion guidance for a broad range of United Nations treaty monitoring bodies.

3.4.2 Research and development

3.4.2.1 Research on medical abortion

Progress
A special supplement issue of Reproductive Health Matters that highlights findings from work supported by HRP on social science and operational research studies on expanding access to medical abortion was finalized in 2014 (1). The articles report on findings from a range of middle- and low-income countries and cover themes ranging from the feasibility of abortion care by non-physician health-care providers, women’s experiences with post-abortion care in legally restricted contexts, and health system savings associated with the provision of medical abortion.

The three-country study (in Ethiopia, India and South Africa) looking at community health workers’ ability to assess eligibility for medial abortion using a checklist showed mixed results. The checklist was better at assisting these health workers to rule out ineligible cases.
than it was at helping them identify women who were eligible. Agreement between community health workers and more experienced facility-based clinicians was the highest with community health extension workers in Ethiopia. But even in India, community health workers with limited formal education and only three to four days of study-specific training were able to use the checklist reasonably well.

Data collection was initiated on the study to demonstrate the feasibility of nurse provision of mifepristone–misoprostol abortion in rural Kyrgyzstan. The study continues to face practical challenges in terms of ensuring the availability of the medication for study participants.

The protocol for the three-country randomized controlled trial (RCT) evaluating different options for pain management in early medical abortion in Nepal, South Africa and Viet Nam was finalized, but difficulties with medication exports and packaging delayed the initiation of this project.

**Planned activities**

- The study to demonstrate the feasibility of nurse provision of mifepristone–misoprostol abortion in rural Kyrgyzstan will be completed in 2015. Further scale-up of medical abortion is planned if the findings of this study are favourable.
- The three-country RCTs on pain management in early medical abortion will initiate recruitment of cases at all sites in early 2015.

### 3.4.2.2 Research on abortion morbidity and complications

**Progress**

- The five-country study (in Ghana, Lao People’s Democratic Republic, Myanmar, Nigeria and Sri Lanka) examining hospital-based morbidity related to unsafe abortion was concluded. The results are being finalized, but across sites in all the countries severe morbidity was low and the retrospective record review shows that presentation of severe complications appears to have decreased over the last five years. Qualitative in-depth interviews suggest that it is possible that the increased informal use of misoprostol in these settings is playing a role.
- A proposal is being developed to study the burden and severity of abortion-related complications among women presenting to secondary care and tertiary care facilities in 20–30 countries across all six WHO regions. Countries and facilities will be identified through a multi-stage sampling methodology similar to that used for the previous WHO Multicountry Survey on Maternal and Newborn Health. Cross-sectional data collection will include record review, and exit interviews with women in order to elicit pathways to care seeking. Secondary objectives include assessing the institutional readiness to deal with abortion complications and evaluating practices surrounding abortion provision and adherence to the 2012 WHO Safe abortion: technical and policy guidance for health systems, second edition (2).

**Planned activities**

- The results of the five-country study on hospital-based morbidity related to unsafe abortion will be published in 2015
- Multicountry study on the burden and severity of abortion-related complications among women presenting to secondary and tertiary care facilities will commence in 2015.
3.4.3 Norms, standards and tools

3.4.3.1 Guidelines on health worker roles in abortion care

Progress

During the year, as part of the process for developing these guidelines, a systematic process of search, retrieval and synthesis of evidence related to the roles of health workers was undertaken. Seven new systematic reviews were conducted and evidence from 32 studies that met inclusion criteria were evaluated using Grading of Recommendations Assessment, Development and Evaluation (GRADE) and Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (DECIDE) frameworks. Over half of the included studies came from low- and middle-income countries (Ethiopia, India, Mexico, Mozambique, Nepal, South Africa, Uganda and Viet Nam). Overall the evidence suggests that there may be little or no difference in effectiveness, safety or women’s satisfaction when early medical abortion or first trimester surgical abortion using manual vacuum aspiration is provided by non-physician facility-based providers (i.e. associate clinicians, nurses, midwives, auxiliary nurse midwives) compared to doctors. Serious adverse events were rare for any type of provider in any of the studies and several studies had no serious adverse events at all. Several studies also point to the safety and efficacy of service provision by community-based health workers in terms of their ability to play supportive roles in effectively identifying eligibility for early medical abortion or in assisting women to determine the need for follow-up care after an early medical abortion. The evidence also points to the safety and efficacy of self-assessment and self-management of parts of the early medical abortion process by women themselves, provided they have received appropriate information and have access to a trained health-care provider should they need assistance.

Additionally, in order to fully understand factors that influence successful implementation of “task shifting” approaches, five country case studies on task shifting in abortion care (Bangladesh, Ethiopia, Nepal, South Africa, Uruguay) and two systematic reviews of 85 qualitative studies on acceptability issues were completed. Information on country policies on non-physician providers of abortion care was also collated. The body of evidence was presented to the external group of technical experts who constitute the Guideline Development Group in October 2014 and recommendations were agreed. The guidelines will contain recommendations on the roles of facility-based and non-facility-based health workers in the provision of medical and surgical methods of abortion in both the first and second trimester.

Planned activities

- The guidelines are currently being finalized with an expected launch by mid-2015.
- A series of regional dissemination, adaptation and implementation workshops are planned for the third and fourth quarters of 2015.
- Several implementation research projects are also expected to be developed around the knowledge gaps identified in the guidelines.
3.4.3.2 Clinical practice handbook for safe abortion

Progress

The Clinical practice handbook for safe abortion, a derivative document of the Safe abortion guidance, was launched online in January 2014 and a print version was available in May 2014 (3). 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.

3.4.4 Monitoring and evaluation

3.4.4.1 Global and regional estimates of abortion incidence and safety

Progress

Work on the seventh edition of Unsafe abortion: global and regional estimates of the incidence of unsafe abortion and associated mortality, using updated methods of estimation (Bayesian Hierarchical Modelling), was initiated during 2014 to update the sixth edition, which was published in 2011 (4). The global and regional estimates of the incidence of abortion will be modelled in collaboration with the Guttmacher Institute. Abortions will be characterized along a safety spectrum based on a nuanced interpretation of the WHO definition of unsafe abortion and the evolving nature of abortion safety. Development of appropriate covariates, and a systematic search and collation of country statistics, as well as a review of published literature on the characteristics of abortion and associated outcomes is under way. Based on a systematic search strategy aimed at identifying literature from major databases as well as targeted grey literature searches, over 55 000 records in Chinese, English, French, Portuguese, Russian and Spanish (dated between 1990 and June 2014) were screened and approximately 1400 of these are being considered for possible inclusion in the model. The paucity of good quality data, especially from countries where unsafe abortion is a major problem, is proving to be a challenge in developing the model.

Planned activities

- The developments of the estimates are in progress and both the global and regional estimates of abortion incidence and the categorization of abortion incidence by safety will be completed in mid-2015.
- Several additional sub-analyses, such as on the global morbidity burden, are planned for 2015.

3.4.4.2 Mapping of global policies in relation to the WHO guidelines

Progress

The Global Abortion Policies Project was initiated in 2014 by HRP in collaboration with the United Nations Population Division (UNPD) with the aim of producing a global database and repository of current abortion laws, standards, policies and guidelines that can be periodically updated for all countries in the world. In addition to compiling and presenting this information, the project will undertake analysis and comparisons with key policy recommendations from the 2012 WHO Safe abortion guidelines (2). Analyses of country laws, health standards and policies may be interlinked with other indicators of safe/unsafe abortion, such as
WHO country estimates on maternal mortality, national contraceptive prevalence and unmet need for contraception.

**Planned activities**
- Narrative country profiles of all countries will be developed in 2015.

### 3.4.4.3 National evaluation of safe abortion care in Moldova

**Progress**

HRP initiated an external evaluation on comprehensive abortion services in Moldova. This is in follow up to the technical support HRP has provided to the Ministry of Health for scaling up of services in six public sector model centres for comprehensive abortion care from 2007 to 2014.

A team led by an independent expert in comprehensive abortion care will review data and visit each site to document achievements and gaps in strengthening this care and to assess the extent to which these sites comply with national abortion standards and guidelines, based on four key indicators:

- the proportion of abortions provided with recommended methods;
- the proportion of surgical abortions (vacuum aspiration and dilation and curettage) provided with recommended pain management;
- the proportion of women leaving the facility with post-abortion contraception;
- the rate of procedural complications.

In addition to the external evaluation of the six selected project intervention sites, a national evaluation is under way to examine the extent to which non-intervention sites have complied with national standards for safe abortion care, based on the same four key indicators. Data from the project intervention sites will be compared to data from non-intervention sites.

**Planned activities**
- In April 2015, the results of the evaluations will be presented at a national workshop, which will focus on scaling up comprehensive abortion care throughout the country.

### 3.4.5 Dissemination and partnerships

#### 3.4.5.1 Guideline dissemination activities

**Progress**

Both the 2012 Safe abortion guidelines and the 2014 Clinical practice handbook were disseminated through regional, sub-regional and national meetings, and training was provided through workshops in collaboration with partners. Specifically, WHO’s guidance and tools were presented as part of a panel at the International Federation of Professional Abortion and Contraception Associates (FIAPAC) and highlighted in a session moderated by WHO at the 13th Congress of the European Society of Contraception. A regional meeting hosted by WHO’s Regional Office for South-East Asia in New Delhi brought together 84 participants from nine countries to provide technical updates on safe abortion and to spotlight the Clinical practice handbook. Subregional and multinational training-of-trainers
workshops have also been held in Malaysia, Nepal and in the Caribbean, featuring the utility of the handbook in clinical settings.

Dissemination activities have included strong involvement of our regional offices as well as other partners like the International Planned Parenthood Federation (IPPF) and Ipas, and professional societies including the International Federation of Gynecology and Obstetrics (FIGO) Working Group on Unsafe Abortion. We have also engaged with other professional societies to increase uptake of this guidance; for example, a session during the Scientific annual conference of the East, Central and South African College of Nursing reviewed guidelines related to safe abortion and post-abortion contraception.

The 2012 Safe abortion guidelines were translated into Arabic, Chinese, Romanian and Ukrainian in addition to the existing translations in French, Japanese, Portuguese, Spanish and Russian. The Clinical practice handbook has been translated into Spanish.

Planned activities

- Translations of the Clinical practice handbook into Arabic, Chinese and French are under way and will be published in 2015.
- Two evidence briefs have been developed on safe abortion, derived from the Safe abortion guidelines and will be published in 2015.

3.4.5.2 Briefings on the WHO safe abortion guidance for UN treaty monitoring bodies

Progress

HRP organized a series of briefings on the 2012 WHO Safe abortion guidance for a range of UN treaty monitoring bodies, including the Committee on the Rights of the Child, the Committee on the Elimination of All Forms of Discrimination against Women, and the Committee on Elimination of Racial Discrimination. WHO standards have been specifically reflected in treaty monitoring recommendations following the workshops. HRP also organized a two-day capacity-building workshop for selected members of international and regional human rights bodies on 1–2 April 2014, titled “Strengthening health and human rights standards for prevention of unsafe abortion”; and convened a two-day workshop on “Sexual and reproductive health, violence, gender equality, and human rights of women and girls with disabilities”, which was attended by members of the Committee on the Rights of Persons with Disabilities (CRPD) and UN partners including OHCHR, UNFPA, UNICEF, UNAIDS and UN Women. Access to abortion for women living with disabilities, forced abortion, and health and human rights issues related to fetal impairment as a ground for abortion were discussed at the workshop.

3.4.5.3 Partnerships

Progress

Many of the activities listed in this section on preventing unsafe abortion are in active partnerships with WHO regional offices, nongovernmental organizations,

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academic institutions and professional societies such as FIGO. During 2014, HRP developed partnerships with the UNPD to work on abortion policies and with the Guttmacher Institute for work on measuring abortion incidence.

**Planned activities**

- An active collaboration with the INDEPTH Network is expected during 2015.11

### 3.4.6 References


### 3.5 Sexually transmitted infections (STIs) and reproductive tract infections (RTIs), including multipurpose prevention technologies (MPTs) and SRH–HIV linkages

#### 3.5.1 Introduction

Preliminary WHO global estimates for 2012 report over 400 million new cases of curable sexually transmitted infection (STIs), including chlamydia, gonorrhea, syphilis and trichomoniasis, in addition to 417 million prevalent herpes simplex virus (HSV-2) infections in adults, and 291 million prevalent human papillomavirus (HPV) infections in women.

Given the high prevalence and incidence, STIs persist as a major cause of morbidity and mortality throughout the world, both directly, through their impact on sexual and reproductive health (SRH) as well as neonatal health, and indirectly, through their role in facilitating sexual transmission of HIV infection, their impact on national and individual economies, and adverse effects on quality of life.

The Human Reproduction team at the RHR Department, which includes HRP, works to control STIs and other reproductive tract infections (RTIs) based on the Global Strategy for the Prevention and Control of Sexually Transmitted Infections: 2006–2015, approved by the World Health Assembly in May 2006 (WHA59.19).

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11 For more information on the INDEPTH Network, see: www.indepth-network.org
Major achievements

• The RHR and HIV Departments jointly launched *Global guidance on criteria and processes for validation: elimination of mother-to-child transmission (EMTCT) of HIV and syphilis*.

• The RHR Department established a global system of STI reporting on 10 core indicators within the Global AIDS Response Progress Reporting System (GARPR).

• The largest global community survey of the sexual and reproductive health and human rights of women living with HIV was conducted to inform the WHO normative guidance.

• *SRH and HIV linkages compendium: indicators and tools* were finalized and disseminated.

• The first peer-reviewed supplement on multipurpose prevention technologies was published and widely disseminated.

• The Department contributed to the development of the Target Product Profiles (TPPs) for point-of-care tests (POCTs) to detect *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, human papillomavirus and syphilis, as well as a comprehensive set of research questions for further validation/development of POCTs for STIs.

• Laboratory evaluation of the performance of a dual HIV/syphilis POCT was completed in two countries.

3.5.2 Research and development

3.5.2.1 Development and evaluation of new STI diagnostic tools

The high prevalence of asymptomatic STIs, as well as STI-related stigma and ostracism, are major barriers to strengthening health-seeking behaviours in all countries around the world. With regard to the early diagnosis and effective treatment strategy, the absence of reliable and affordable diagnostic tests is a critical obstacle to reducing the STI burden, given that “some 80% to 90% of the global burden of STIs occurs in the developing world where there is limited or no access to appropriate diagnostics” (1).

One of the major barriers to diagnostic testing for STIs is the unavailability of reliable, low-cost, point-of-care tests (POCTs). POCTs offer patients the opportunity to receive definitive diagnosis and appropriate treatment in a single visit. POCTs also include the home or site delivery of over-the-counter (OTC) tests to end-users by trained and untrained users, as well as via the Internet. Advancing the field of diagnostic testing for STIs can potentially improve STI surveillance and facilitate effective STI control.

Therefore, in 2014 the Department initiated a multi-year project designed to ensure universal access to high quality STI testing through the development and implementation of low-cost POCTs for STIs.

Progress

An international consultation on STI POCTs was conducted in 2014. The main outcomes of the consultation were:
• development of Target Product Profiles (TPPs) for POCTs to detect *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, human papillomavirus (HPV) and syphilis;

• a comprehensive set of research topics to be addressed through the research phase of the project such as: (a) analytical and operational characteristics of tests used for different purposes (e.g. STI case management, screening and surveillance), in different populations, anatomic sites and analytes; (b) test impact on acceptability, feasibility, field performance, uptake, prevalence in the community, contact testing/treatment and uptake of testing for other STIs; and (c) home-based testing approach – its role, psychological impact among users, use for surveillance within the context of mHealth, and the need for confirmatory testing.

• establishment of an International Advisory Group on STI POCTs.

The Department also completed the systematic review and landscape analysis of the promising STI POCTs and technologies to detect *N. gonorrhoeae*, *C. trachomatis*, *T. vaginalis*, HPV and syphilis.

All these achievements allowed the Department to initiate the development of a research protocol for an independent multi-country validation of promising tests and technologies. This validation is an essential step to advance our understanding of performance, feasibility, acceptability and utility of STI POCTs, as well as to develop an investment case for further implementation of STI POCTs within national STI control and prevention programmes. This validation exercise has been planned for 2015–2016.

**Planned activities**

• To finalize the research protocol for the independent multi-country validation of promising tests and technologies, and to implement it in the selected sites.

3.5.2.2 Implementation research to eliminate mother-to-child transmission (EMTCT) of HIV and syphilis

Global and regional initiatives have been launched for dual EMTCT of HIV and syphilis. One critical component of these initiatives is early detection and timely intervention for 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 (RDTs), which hold the potential to improve the coverage of syphilis and HIV testing, the efficiency of services, and the 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 RDTs.

**Progress**

WHO has worked with countries and other partners – including PATH, the London School of Hygiene and Tropical Medicine (LSHTM), University of Bristol, the United States Centers for Disease Control and Prevention (CDC), the Bill & Melinda Gates Foundation, etc. – to initiate a comprehensive package of studies to evaluate dual HIV/syphilis RDTs and to provide data for future WHO recommendations on appropriate use of these tests. Laboratory evaluations in China and Nigeria were completed in September 2014; results showed high performance of all three tests that were evaluated. Enrolment for an implementation study of one of these
tests in China and Colombia has begun, as has enrolment for a field performance evaluation in Zambia. All three studies are scheduled to be completed by March 2015. An additional introduction study in Nigeria is undergoing ethical review and is expected to begin enrolment in February 2015. A mathematical modelling exercise with LSHTM is being completed; this will evaluate the diagnostic and cost implications of using different syphilis testing strategies in pregnancy.

In addition, WHO collaborated with Tulane University, New Orleans, to develop a protocol for a randomized cluster trial in Zambia and a multifaceted intervention to control mother-to-child transmission of syphilis in the Democratic Republic of the Congo. This study received a three-year grant from the Bill & Melinda Gates Foundation in October 2014. Also under ethical review is a protocol for a semi-quantitative survey of clinicians and programme managers to assess barriers to diagnosis and treatment of infants for congenital syphilis.

**Planned activities**

- WHO prequalification of three dual RDTs is scheduled for early 2015.
- Finalization and publication of all WHO dual RDT studies is anticipated for 2015.
- Completion of probability assessment of WHO rapid advice on dual RDT use is anticipated in 2015, once study results are available.
- Collaboration with the Clinton Health Access Initiative (CHAI) on market shaping to reduce the price of dual RDTs is planned, if the results of the dual RDT studies are promising.
- Finalization of the ethical review and initiation of enrolment is expected for the multifaceted intervention study in the Democratic Republic of the Congo and Zambia.
- The Department will complete the analysis of barriers to diagnosis and treatment of infants for congenital syphilis, and use the findings to identify strategic next steps to overcome these barriers.

### 3.5.2.3 STI prevention

**(i) SIALON II**

The European Commission funded an integrated bio-behaviour study on STI/HIV/hepatitis C virus (HCV) prevalence and behaviour factors among men who have sex with men (MSM). The study, SIALON II (Capacity Building in Complementing Combined and Targeted Prevention with a Meaningful HIV/STI Surveillance among MSM), is being implemented in 15 western, central and eastern European countries. SIALON II aims to better understand the main bio-behavioural patterns of the HIV and STI epidemics among MSM by gathering up-to-date information to facilitate trend analysis and better inform decision-making processes to improve STI/HIV prevention in this key population. WHO’s RHR Department is an official partner of SIALON II throughout all phases of the project.

**Progress**

In 2014 all sites completed data collection and reached the expected sample size (n=5126). The preliminary results of the analysis, conducted according to the analysis protocol, are available. However, the SIALON II Group decided to make the preliminary results a subject of embargo until the final analysis, in early 2015.
It is clear from the proposed methodology that a cross-sectional integrated bio-behavioural survey is a feasible and useful tool to generate critical strategic information to inform targeted STI/HIV prevention in MSM. The peer-reviewed article on the SIALON II protocol was collectively developed and is expected to be published in early 2015.

**Planned activities**

- In 2015, the RHR Department expects to complete the data analysis for validation of the (a) RDTs for syphilis, (b) syphilis testing algorithms, (c) selected sexual health indicators within the behavioural component of the survey, as well as an analysis of syphilis prevalence.
- The results of the study will be published and disseminated.

(ii) Behaviour change interventions

Behaviour change interventions have consistently been seen as an essential part of comprehensive STI/HIV prevention. Throughout the last decade some substantial research has been undertaken to develop evidence-based behaviour change interventions that contribute to health outcomes from an STI/HIV-safer behaviour perspective (e.g. delay in sexual debut, consistent condom use, partner reduction strategy, HIV/STI testing), as well as promotion of sexual well-being through increasing self-esteem, self-regulation and a positive attitude towards one's own and other's sexuality. However, most of the studies have been conducted in the northern hemisphere and therefore results cannot be directly replicated in other countries. As sexual behaviour is very much driven by local norms, traditions and culture, the behaviour interventions must be adapted to local contexts.

Therefore, it would be timely to establish the validity of specific behaviour change interventions with proven effectiveness in high-income settings, for different population needs in low- and middle-income settings.

**Progress**

In 2014, the Department initiated a systematic review of techniques for the brief behaviour change interventions within the context of the primary STI/HIV prevention. The systematic review was accomplished and the main outcomes have been assessed according to the GRADE methodology, facilitating the development of an evidence-based list of techniques to be validated in low- and middle-income countries.

**Planned activities**

- In 2015, the Department intends to develop a multicountry research protocol to validate the promising techniques of the behaviour change interventions aimed at prevention of STIs and HIV in key populations and adolescents/young people in low- and middle-income countries.
- Once developed, the research protocol will be implemented in the selected sites.

3.5.2.4 Sexual and reproductive health (SRH) and HIV linkages, and multipurpose prevention technologies (MPTs)

- Sexual and reproductive health (SRH), human rights and HIV are intimately linked. The Department leads policy, programmatic and advocacy activities

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in this area, and supports national assessments of policy, systems and service delivery of integrated or linked interventions, since these contexts differ by political commitment; structure of the health system; sociocultural and socioeconomic determinants; availability of human and financial resources; the nature of the HIV epidemic; and the status of SRH and human rights in each country. In the past two years, the Department has initiated research related to new biomedical interventions that link the fields of SRH and HIV prevention.

(i) Temperature recording vaginal ring for accurate measurement of user adherence

The recording of vaginal temperature offers an alternative and interesting biomarker option for monitoring adherence to microbicide-releasing vaginal rings.

Progress

In collaboration with the University of Belfast, the RHR Department demonstrated proof-of-concept of a novel, vaginal temperature-recording device comprising a miniature temperature recording implant encapsulated within non-medicated silicone elastomer vaginal tubing.

Vaginal administration in cynomolgus macaques enabled accurate and continuous monitoring of body temperature, both the small changes associated with the normal diurnal pattern and the larger changes associated with removal and re-insertion of the vaginal device.

Planned activities

- A proposal is being developed for a three-year project at the School of Pharmacy, Queen's University Belfast, Northern Ireland, United Kingdom, to support preliminary clinical evaluation of a temperature-recording vaginal ring device in women. The proposal will be submitted to the Research Project Review Panel (RP2).

(ii) Injectable-type MPT products, with potential to provide simultaneous long-term hormonal contraception and antiretroviral-based prevention against HIV infection

The Department has undertaken to develop and test the preclinical feasibility of injectable-type MPT products (including investigations of drug type, drug loading, drug–drug interactions, drug stability, and animal model pharmacokinetics), to ascertain the practicalities and constraints of combining two active ingredients within a single injectable delivery system.

Progress

The project was approved by RP2 and initiated in 2014. A postgraduate student has been recruited to conduct the research. Two different formulation strategies will be assessed based upon the commercial depot medroxyprogesterone acetate (DMPA) injection products, Depo-Provera (DP) and Depo-subQ Provera 104 (DsQP), both of which take the form of injectable suspensions, to be administered with tenofovir or another antiretroviral (ARV)-based HIV prevention product.

Planned activities

- In 2015, the Department will conduct a literature review on sustained-release parentally administered products, including DP and DsQP, with particular focus
on "syringeable" platform technologies and slow release from subcutaneous and intramuscular tissues.

- There will also be clinical assessment of different in vitro release models (including sample and separate, continuous flow and dialysis methods) for commercial DP and DsQP products in conjunction with tenofovir or another ARV-based product.

(iii) Community survey to assess values and preferences on the sexual and reproductive health and human rights of women living with HIV

Prior to updating the 2006 WHO 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 (2), a community survey was developed and conducted to assess the SRH needs and priorities of women living with HIV.

**Progress**

The survey was conducted in March–June 2014 and is the largest global survey on SRH and human rights of women living with HIV to date, with participation of over 1000 women from 94 countries, ranging in age from 15 to 72 years.

In addition, cognizant that the "digital divide" is a huge issue for women and girls living with HIV, hard copy text versions of the survey were made available in all the languages in which the survey was conducted (English, French, Russian and Spanish).

Volunteers within networks of women living with HIV also translated the survey into Portuguese, Bahasa Indonesia and Chinese and made these versions available electronically and in hard copy, in order to reach out to more women with HIV who use those languages. Community dialogues focusing on specific issues such as disability, migration, sex work, imprisonment, drug use and old age were also conducted in Ethiopia, Jamaica, Nepal, Senegal, Thailand and the United Kingdom.

**Planned activities**

- The survey results will be disseminated in 2015, including through a special supplement issue of a peer-reviewed journal and sessions at international conferences.

- Systematic reviews will be developed.

3.5.2.5 STI vaccines

In 2014, the RHR Department and the Department of Immunization, Vaccines and Biologicals, together with the United States National Institutes of Health (NIH), published a special issue of the journal Vaccine focusing on vaccines for the following five STIs: herpes simplex virus, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Treponema pallidum* (3). The purpose of this special issue was: to review and evaluate the need, development status, and future prospects for new, effective vaccines against STIs; to identify critical gaps in knowledge and current barriers to development of effective STI vaccines; and to propose potential solutions and outline a global roadmap for the development and introduction of these vaccines. This roadmap outlines the critical next steps for STI vaccine development and introduction.

**Progress**

Plans have been developed and agreed on for individual-level meta-analysis of STI prevalence and incidence in low-income countries, using combined data from
18 clinical trials and prospective studies of HIV prevention interventions. This work will address the need to have better data in order to: understand the potential impact of future STI vaccines on STI burden; inform global estimates of the burden of STIs; and support decision-making related to STI management.

Four objectives were agreed on with the principal investigators of the 18 studies. The objectives are to assess: (a) the prevalence and incidence of five major STIs (chlamydia, gonorrhea, syphilis, trichomoniasis and HSV-2) and bacterial vaginosis (BV) by region, age, population type (high-risk versus general); (b) the association of individual prevalent and incident STIs and BV with genital symptom syndromes; (c) the effect of hormonal contraception on STI and BV incidence; and (d) the risk of HIV acquisition among women with and without individual prevalent and incident STIs and BV.

Each objective will be developed as an individual study with an analysis plan that describes in detail the methods for meta-analysis of individual-level participant data.

**Planned activities**

- Two to four papers will be developed on individual-level meta-analysis of STI prevalence and incidence in low-income countries.
- This data analysis approach will also be extended to other important databases in which STI data are available, such as male circumcision trials, HPV vaccine trails, etc.
- The Department will work on estimating the global burden of HSV-related disease (including genital ulcer disease, HIV infection, encephalitis) and related costs.
- The Department will collaborate with the Immunization, Vaccines and Biologicals Department to develop the preferred product characteristics for HSV vaccine.
- The Department will also prepare a business case for investment in the development of HSV vaccines.
- The Department will collaborate with the NIH to follow up on the progress related to the development of STI vaccines, in particular HSV and gonococcal vaccines.

### 3.5.3 Norms, standards and tools

#### 3.5.3.1 Guideline for the prevention, management and control of sexually transmitted infections

The Department initiated the process of updating the 2003 *WHO Guidelines for the management of sexually transmitted infections* (4), via a phased approach given the numerous components requiring different methodologies with limited resources.

Because of the emerging STI drug resistance, changing epidemiology of STIs, concerns about syndromic case management, and the global focus on elimination of mother-to-child transmission (EMTCT) of syphilis, phase 1 of this process will prioritize the following: treatment of major STIs, STI syndromic management, screening and treatment for syphilis in pregnant women, and an STI clinical management package. Phase 2 will address STI prevention, phase 3 will focus on treatment of other STIs, and phase 4 will cover STI screening and diagnosis.

**Progress**

(i) STI treatment

An extensive process to prioritize population, intervention, comparator and outcome (PICO) questions for treatment of gonorrhoea, chlamydial infection, genital
herpes and syphilis was undertaken. The scoping document was developed by the Guideline Development Committee. A review was conducted of the evidence for the safety of metronidazole use in pregnancy to inform recommendations for treatment of *Trichomonas vaginalis* among pregnant women.

**(ii) Syphilis screening and treatment among pregnant women**

A modelling exercise has also been initiated to determine the cost-effectiveness and the performance of different testing and treatment algorithms, which will be the basis for making recommendations.

**(iii) Syndromic case management**

The methodology for updating the syndromic management guidelines has been developed. Generic flowcharts were developed to highlight the key points for clarification in developing the PICOs and for which evidence will be needed. To inform the development of the syndromic management guidelines, the following were conducted:

- reviews of approach for managing vaginal discharge, and ano-rectal and genital ulcers;
- review of the role of *Mycoplasma genitalium* in recurrent urethral discharge and pelvic inflammatory disease (PID); and
- inventory of availability of STI health services detailing the basic medical devices (e.g. speculum) and drugs needed for provision of basic STI care.

**Planned activities**

- In 2015, the Department will conduct systematic reviews, assess quality and make recommendations on STI treatment and syphilis screening and treatment of pregnant women, and will also finalize and disseminate the relevant guidelines.
- The Department will also conduct systematic reviews, assess quality and make recommendations on STI syndromic case management and a clinical management package (i.e. condom use, partner management, follow up, clinic-based counselling).
- The Department will plan and work on phases 2 and 3 of the STI guideline development.

**3.5.3.2 Development of WHO normative guidance on topical pre-exposure prophylaxis**

Tenofovir vaginal gel (1%) and dapivirine intravaginal ring are in late stage clinical trials with results expected in early 2015 and 2016, respectively. If the trials confirm safety and effectiveness of the products in preventing HIV infection in women, licensure dossiers will be rapidly submitted to national drug regulatory authorities and WHO will then need to issue guidance to countries on whether and how these new products can be used within existing HIV prevention programmes.

As the phase 3 clinical trials of tenofovir gel and the dapivirine intravaginal ring near completion, the product sponsors must plan for rapid implementation of open-label extension studies in which all former study participants use the active product. These studies will provide more information on the safety of the method for prolonged periods of use as well as assess how the product can be delivered in an acceptable and sustainable manner to women at high risk of HIV infection.
**Progress**

Accordingly, the RHR Department convened a meeting of stakeholders in March 2014, in Durban, in collaboration with the Centre for AIDS Prevention and Research in Southern Africa (CAPRISA), and identified the highest priority implementation research questions that can and need to be addressed in advance of licensure. The studies on these research questions will form the evidence base for WHO guidance on topical pre-exposure prophylaxis, which must be developed in advance of product licensure.

One of the key issues identified at the March 2014 stakeholder consultation was the need to update and consolidate models of cost-effectiveness of topical microbicides. The Department convened a meeting of modellers in December 2014 to develop a set of core epidemic scenarios that can be included as base cases in all models for topical pre-exposure prophylaxis, and can be used as common output metrics to address policy-makers’ questions. The model outputs will also be used to inform investment decisions on scale-up of the new microbicide products and to determine design of implementation programmes.

**Planned activities**

- In 2015, the Department will undertake analysis of funding sources and criteria used for prioritizing support for new HIV prevention methods for women.
- A guideline development proposal will be submitted in early 2015.

### 3.5.4 Monitoring and evaluation

#### 3.5.4.1 The roadmap 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. In 2013, the Department published a roadmap for improving STI surveillance and a baseline report on global surveillance, 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 increased data collection, such that more countries report on more of the indicators. In response, WHO established a global system of STI reporting through the Global AIDS Response Progress Reporting (GARPR) system, incorporated STI data into the WHO Global Health Observatory Data Repository, and worked with regions to conduct national STI surveillance strengthening exercises.

**Progress**

In June 2014, the Department published its Report on global sexually transmitted infection surveillance 2013, summarizing the results and data from these efforts, and subsequently launched the WHO global HIV monitoring report, *Global update on the health sector response to HIV, in July 2014*. A global consultation on STI surveillance strengthening was held in August 2014. Recommendations were made: to more closely integrate STI surveillance strengthening work with the Gonococcal Antimicrobial Surveillance Programme (GASP); to use GASP as a platform for establishing a Global STI Surveillance System (GLOSS); and to build national STI surveillance systems and capacity to better inform

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13 Available at: [http://apps.who.int/gho/data/](http://apps.who.int/gho/data/)
STI programming, advocacy and STI estimation processes. A set of Powerpoint modules for an STI surveillance training course was produced in collaboration with the WHO Collaborating Center for HIV Surveillance at the University of Zagreb, Croatia.

**Planned activities**

- In 2015, the Department will finalize the tool for evaluation of national STI surveillance systems.
- The Department will also work with WHO regional and country offices and partners to establish GLOSS sites in one or two countries in 2015.
- **3.5.4.2 Antimicrobial resistance in N. gonorrhoeae**
  - The Gonococcal Antimicrobial Surveillance Programme (GASP) has detected the emergence of gonococcal resistance to extended spectrum cephalosporin (ESC), the last-line treatment. It is only a matter of time until gonorrhoea becomes untreatable as there are no vaccines or new drugs available.
  - To facilitate action against the spread of multidrug-resistant *N. gonorrhoeae*, WHO launched the Global Action Plan to Control the Spread and Impact of Antimicrobial Resistance in *Neisseria gonorrhoeae*.

**Progress**

This global action plan is being implemented within the context of GASP to facilitate early detection of emerging resistant strains. GASP has been maintained in 60 countries across all six of the WHO regions (see Table 3.5.1).

**Table 3.5.1: Number of countries participating in GASP**

<table>
<thead>
<tr>
<th>WHO regions</th>
<th>Number of participating countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region of the Americas</td>
<td>9</td>
</tr>
<tr>
<td>African Region</td>
<td>4</td>
</tr>
<tr>
<td>Eastern Mediterranean Region</td>
<td>2</td>
</tr>
<tr>
<td>European Region</td>
<td></td>
</tr>
<tr>
<td>- European Union (EU)</td>
<td>21</td>
</tr>
<tr>
<td>- Non EU</td>
<td>3</td>
</tr>
<tr>
<td>South-East Asia Region</td>
<td>7</td>
</tr>
<tr>
<td>Western Pacific Region</td>
<td>14</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>

WHO continues to map out patterns of antimicrobial resistance (AMR) in gonorrhoea based on the collated data from the regional GASP reference centres. The latest gonococcal AMR data are available on the RHR Department website.14 These data have been disseminated in: (a) *Report on global sexually transmitted infection surveillance 2013* (5), in section 5 on GASP; and (b) *Antimicrobial resistance: global report on surveillance* (7), in section 2.2.7 on decreased susceptibility of *Neisseria gonorrhoeae* to third-generation cephalosporins.

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14 Available at: http://www.who.int/reproductivehealth/topics/rtis/en/index.html
(i) Regional and country support

Because of the limited data on AMR in gonorrhoea in Africa, WHO has focused support in Africa to collect valid and comparable data. Three sub-regional reference centers are being supported: Institute Pasteur, Côte d'Ivoire; Medical Microbiology Department, University of Nairobi; and Zimbabwe Ministry of Health and Child Welfare. Gonococcal AMR monitoring protocols were developed and collection of gonorrhoea isolates were initiated.

The WHO Regional Office for the Americas was supported to develop a regional action plan on AMR in gonorrhoea, aligned to the regional AMR initiative, and to expand GASP from 9 countries currently to include 10 additional countries. The WHO Regional Office for Europe has also been supported to expand GASP to non-EU countries.

(ii) Coordination with the global AMR surveillance

The RHR Department has actively supported the development of the global action plan on AMR. Work under the global action plan on AMR initiative will impact AMR in gonorrhoea, and will increase commitment to addressing this issue. Additionally, the Department has provided substantial input into the development of the WHO global platform for collaborative surveillance of AMR, including the standards for antibacterial resistance surveillance and early implementation guidance. GASP is now linked to the global AMR surveillance platform, with gonorrhoea as one of the nine core bacteria that will be monitored.

(iii) Data collection and laboratory support

Work is being done to standardize and improve the quality of data for AMR monitoring. Sample size modelling to ensure representativeness of samples has been initiated.

Since the use of varied laboratory methodologies for antimicrobial susceptibility testing has resulted in non-standardized interpretation of resistance, WHO reference strain panels were developed in 2008 to address this. The WHO reference strain panels are being updated (2014 panels) to include resistant strains to cefixime, ceftriaxone and azithromycin, which are not included in 2008 panels. The resistant panel strains have been phenotypically and genetically characterized to standardize interpretative criteria for resistance.

Planned activities

- The Department’s Human Reproduction team will work with WHO’s global AMR team to support the early implementation phase of the global AMR surveillance, which links to gonococcal AMR monitoring.
- The Department will work to enhance GASP in selected countries to improve quality, comparability and timeliness of gonococcal AMR data and link to global sentinel surveillance in selected countries. Work will also be undertaken to improve laboratory and surveillance capacity of countries in GASP through developing and adapting a standardized training package on data collection and gonococcal antimicrobial susceptibility testing and strengthening external quality assessment.

3.5.4.3 Global and regional STI estimates for 2012

Strengthening surveillance, monitoring and estimation of the burden of STI 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.
The most recent WHO estimates for curable STIs were produced for 2008, and for herpes these were produced for 2003. Thus, a priority for 2014 has been updating these global and regional estimates.

**Progress**

In collaboration with the University of Bristol, United Kingdom, WHO global and regional estimates for 2012 for HSV-2 in 15- to 49-year-olds were published in PLOS ONE in 2014 (8). Reviews for global and regional estimates of HSV-1 and neonatal herpes were completed and final estimates should be available in early 2015.

WHO estimates of the global and regional prevalence and incidence of curable STIs (chlamydia, gonorrhoea, syphilis and trichomoniasis) for 2012 are being finalized and will be submitted for publication in a peer-reviewed journal in early 2015.

WHO global and regional estimates of syphilis in pregnancy and associated adverse outcomes for 2012 have been finalized and are undergoing final review.

**Planned activities**

- In 2015, the Department will publish peer-reviewed manuscripts on 2012 global burden of HSV-2, HSV-1 and neonatal herpes, 2012 global burden of syphilis in pregnancy and associated adverse outcomes, and 2012 global burden of curable STIs.

- The Department will also work with global partners to identify modelling strategies for incorporating alternative data sources, such as data from high risk groups and routine STI surveillance, into global estimation processes.

### 3.5.4.4 Validation of elimination of mother-to-child transmission (EMTCT) of HIV and syphilis

EMTCT of HIV and syphilis has been endorsed as a dual initiative in the Americas, in Asia and the Pacific, and in Africa, and targets have been set for 2015 and beyond. However, it is critical to have criteria and processes as to 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 *Global guidance on criteria and processes for validation of elimination of mother-to-child transmission (EMTCT) of HIV and syphilis*, which was launched in June 2014 (9). In September 2014 a global consultation was held to review draft tools to facilitate national validation exercises. The tools included those for: data quality and impact; laboratory quality assessment; human rights and gender equality; and community engagement. The Department supported the advancement of regional processes, including the establishment of a validation committee for the Region of the Americas, and development of draft strategies for validation in the Asia Pacific region (i.e. South-East Asia and Western Pacific Regions jointly), as well as in the Europe and Africa Regions.

**Planned activities**

- In 2015, the Department will nominate and convene the first global committee for validation of EMTCT of HIV and syphilis.

- Tools and processes for validation will be pilot-tested in at least two countries, and validation assessment will be conducted in at least one candidate country.
3.5.4.5 SRH and HIV linkages compendium, and development of a composite SRH and HIV Linkages Index

The focus of activities in 2014 for the Inter-agency Working Group on SRH and HIV Linkages, convened by WHO’s RHR Department and UNFPA, has been to complete the pilot-testing for the three new integration indicators in Botswana, Lesotho, Malawi, Namibia, Swaziland, Zambia and Zimbabwe.

**Progress**

The SRH and HIV linkages compendium: indicators and tools was finalized and disseminated in 2014 (10). An Expert Review Group was established to support the development of a composite SRH and HIV Linkages Index. While there are many separate indicators related to SRH and HIV, a key challenge has been the lack of internationally agreed indicators to measure progress in linking SRH and HIV. Based on a theory of change, this SRH and HIV linkages compendium contains a focused set of indicators and related assessment tools that have relevance to tracking the links between SRH and HIV programmes at national and sub-national levels. Each indicator includes an overview, a brief description of its relevance to SRH and HIV linkages, and a hyperlink to a detailed definition. All the indicators in this compendium have passed through a rigorous evaluation based on the indicator standards of the UNAIDS Monitoring and Evaluation Reference Group.

**ASSESSING THE EFFECT OF THE RAPID ASSESSMENT TOOL FOR SRH AND HIV LINKAGES**

**Background**

The tool was developed as part of an effort to define indicators for monitoring and evaluation of integrated SRH and HIV services. It was designed to inform the scale-up of services to women and girls, and to strengthen policy, systems and services. The tool was piloted in 2012–13 in the first 20 countries to implement SRH and HIV services.

**Rapid Assessment Tool**

The Rapid Assessment Tool for SRH and HIV is a flexible tool that can be used to assess the effects of integrating services. It was designed to increase SRH and HIV access for women and girls, and to strengthen policy, systems and services development.

**Lessons learned**

- Evidence required to advocate for change
- The development of action plans
- Strengthened implementation of policies and programmes
- Raising the profile of SRH and HIV
- Background documentation

**Assessment contributed to:**

- Research in relation to SRH and HIV
- National strategic plans for SRH and HIV
- Linkages at the national level
- Evaluation systems
- Policies and programmes and services
- National strategies
- Linkages at the policy, systems and services levels
- Integration of SRH and HIV
- Comprehensive services
- Bi-directional linkages between SRH and HIV

**Planned activities**

- In 2015, country profiles of SRH and HIV linkages will be produced for countries where the SRH/HIV assessment tool has been implemented.
• A composite SRH and HIV Linkages Index will be developed, as a way to “score” progress on SRH/HIV linkages.

3.5.5 Dissemination and partnerships

3.5.5.1 Initiative for Multipurpose Prevention Technologies

The Initiative for Multipurpose Prevention Technologies (IMPT) is an international collaboration of product developers, researchers, health-care providers, policymakers, epidemiologists, advocates and supporting agencies committed to safely and swiftly bringing new MPTs to market. The RHR Department plays an active role in the Steering Committee of the IMPT, provides technical support to the Scientific Advisory Working Group (SAWG), co-chairs the STI Working Group, and edited the first peer-reviewed supplement on this issue (11).

Progress

Target Product Profiles (TPPs) were developed, including a generalized TPP and TPPs for the prioritized dosage forms – i.e. on-demand, sustained-release, and injectable MPTs – that can serve as a tool to help assure that the appropriate products for maximum public health impact will be developed.

The SAWG established a sub-working group focused on STIs in response to a key gap identified in the field, namely the insufficiency in products that address STIs. The STI–MPT working group will conduct work that is complementary to the larger SAWG, focused on advancing MPT products and candidates that prevent STIs.

MPT Product Pipeline Database was developed to serve as a comprehensive resource outlining information on MPT products and product candidates.15

Technical webinars were held on topics such as MPT manufacturing and regulatory issues.

Planned activities

• In 2015, there will be a stakeholder consultation to better understand the future of tenofovir gel, dapivirine ring and MPTs in the context of the phase 3 clinical trials that might confirm the safety and efficacy of these products for HIV prevention for women.

• The Department will establish priorities among the gaps in hormonal contraceptive knowledge to best inform MPT design, such as on-demand and long-acting formulations for MPTs.

• The Department will assess the gaps in socio-behavioral knowledge as it relates to MPT development.

• The Department will also assessing the environmental impact issues that need to be taken into consideration for the development of MPT intravaginal rings and other formulations.

• The Department will conduct IMPT outreach within WHO and to other UN agencies and EU donors.

15 Available at: http://www.mpts101.org/mpt-database
3.5.5.2 Gonococcal Antimicrobial Surveillance Programme (GASP) Network

The GASP network is a worldwide laboratory network coordinated by WHO and consisting of regional coordinating centres, focal points and partner countries. Each designated regional focal point, in partnership with WHO regional offices, collates data on antimicrobial susceptibility patterns in gonorrhoea in different countries and provides laboratory support and external quality assessment.

Progress

A partners meeting on AMR in gonorrhoea and STI surveillance was organized in August 2014 to review implementation of the global action plan on AMR in gonorrhoea, including strengthening the GASP network collaboration and linkages with the global AMR initiative. Teleconferences with GASP regional focal points were organized quarterly to facilitate information sharing on monitoring AMR and on recent laboratory and treatment advances. The regular forum enabled standardization of gonococcal AMR surveillance and sharing of tools and resistant gonococcal isolates for genetic sequencing.

Planned activities

• In 2015, the Department will maintain regular teleconferences with the regional coordinating centres and focal points and organize an annual meeting of the GASP network.
• The GASP website platform will be improved, to strengthen international collaboration and information sharing.

3.5.5.3 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. The RHR Department is working jointly with the HIV Department to engage partners to attain dual EMTCT of HIV and syphilis.

Progress

In 2014, WHO continued a project called “Dual testing for elimination of congenital syphilis” (DTECS) with PATH, funded by the Bill & Melinda Gates Foundation. The goal was 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,\(^{16}\) 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 to engage in-country partners. WHO is also working with priority countries such as Indonesia and Myanmar on strategies to accelerate elimination.

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, which in 2014 was transformed into a listserv.

WHO worked with the CDC to revamp and put online the WHO Syphilis Serology Proficiency Programme.\(^ {17}\) This programme is now focused on improving the capacity and quality of syphilis testing for national reference laboratories in low- and middle-income countries (see Figure 3.5.1).

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\(^{16}\) Available at: http://www.who.int/reproductivehealth/topics/rtis/syphilis/measurement_tool/en/

\(^{17}\) More information at: www.who.int/reproductivehealth/topics/rtis/syphilis/spt-program/en
WHO is also leading production of a special issue of the *International Journal of Gynaecology and Obstetrics* focused on how new diagnostics and innovative tools can accelerate the dual EMTCT of syphilis and HIV. Currently 14 submissions from collaborators around the world have been approved for development and inclusion in the full manuscript.

**Planned activities**

- In 2015, the RHR Department will work with PATH to finalize and disseminate the investment cases for dual EMTCT of HIV and syphilis in India, Nigeria and Zambia.
- The Department will launch the special issue of the *International Journal of Gynaecology and Obstetrics* on EMTCT of syphilis at the 2015 Conference of the International Federation of Gynecology and Obstetrics (FIGO) in Vancouver, Canada.
- The Department will continue efforts to increase membership of the BASTA listserve.
- The Department will support the CDC to develop standard operating procedures for countries participating in the Syphilis Serology Proficiency Programme.

### 3.5.6 References

3.6 Cervical cancer

3.6.1 Introduction

Cervical cancer is the fourth most common cancer in women, and the seventh overall, with an estimated 528,000 new cases in 2012. A large majority (around 85%) of the global burden occurs in the less developed regions, where it accounts for almost 12% of all female cancers. There were an estimated 266,000 deaths from cervical cancer worldwide in 2012, accounting for 7.5% of all female cancer deaths. Almost 9 out of 10 (87%) cervical cancer deaths occur in the less developed regions. Mortality varies 18-fold between the different regions of the world, with rates ranging from less than 2 per 100,000 in western Asia, western Europe and Australia/New Zealand to more than 20 per 100,000 in Melanesia (20.6), central Africa (22.2) and eastern Africa (27.6) (1). The RHR Department, including HRP, in collaboration with other relevant WHO departments – such as the Departments of Immunization, Vaccines and Biologicals (IVB), Maternal, Newborn, Child and Adolescent Health (MCA), and Noncommunicable Diseases, Disability, Violence and Injury Prevention (NVI) – gave priority to addressing and responding to the 2013 World Health Assembly resolution that identified cervical cancer as among the priority interventions in the Global Action Plan for the Prevention and Control of Noncommunicable Diseases in 2013–2020. This must be seen as a global opportunity to improve women’s health and address inequity.
Major achievements

- The Departments of RHR, IVB and NVI jointly launched the new WHO guidelines *Comprehensive cervical cancer control: a guide to essential practice* in December. It has been welcomed by countries, partners and a wide range of stakeholders.

- An important HRP–IARC research collaboration was established on the validation of new HPV rapid tests, new screening strategies for cervical cancer prevention and control, and operations research to strengthen cervical cancer prevention and control programmes in countries with the introduction of new tools.

3.6.2 Research and development

3.6.2.1 ESTAMPA: multicentre study of cervical cancer screening and triage with HPV testing

Human papillomavirus (HPV) testing for primary cervical cancer screening of women over 30 years of age is likely to become the standard of care in the near future in many areas of the world. Its high sensitivity can significantly improve the effectiveness of screening programmes and its prolonged negative predictive value can allow extension of screening intervals. However, a single HPV test has low positive predictive value and can lead to unnecessary workup and overtreatment and thus can generate unnecessary distress in patients. Hence, more research is needed to develop optimal screening approaches. The RHR Department, in collaboration with the International Agency for Research on Cancer (IARC) is conducting a multicentre screening study among 50 000 women in 10 Latin American countries to compare visual, cytological and molecular screening methods, or combinations of these methods, in terms of their performance and cost-effectiveness in cervical cancer screening programmes.

Progress

Five study sites in three countries have recruited 4160 women: 68% in Colombia, 17% in Honduras and 15% in Paraguay. Two additional sites – in Costa Rica and Mexico – began recruitment in September. Sites in Argentina and Uruguay started recruitment in December. Additional sites in Argentina, Brazil, Chile, Costa Rica and Peru may start in 2015, and researchers from countries including Bolivia, Ecuador, Guatemala, Nicaragua, Panama, Puerto Rico and Venezuela have also shown interest in carrying out the study. The sites in Apartadó (Colombia) and in Honduras have completed the recruitment phase of a pilot study involving 500 women.

The training team from the RHR Department visits each study site the week it starts recruiting participants. The team spends one full week with each local team making sure all standard operating procedures are fully understood and well implemented. Regular training activities include: (i) initial training at the start of recruitment, offered at the study site by the ESTAMPA IARC team; (ii) training on the colposcopy protocol offered at the Colombian National Institute of Cancer in Bogotá; and (iii) training on visual inspection of the cervix with acetic acid (VIA) offered at the Peruvian National Cancer Institute (INEN) in Lima. So far, five colposcopists have been trained in Bogotá, and one general doctor and two nurses have been trained on VIA in Lima.

The first Data Safety and Monitoring Board (DSMB) meeting was held at IARC on 24 February 2014, and the study protocol was discussed. The DSMB gave a number
of recommendations, in particular related to the clinical management of HPV-positive women taking into consideration the high likelihood of losing women to follow-up. Following the DSMB report, a protocol amendment has been submitted to the IARC Ethics Committee.

Planned activities

- During 2015, the second round of screening will start, with the recall of the study participants in Colombia, Honduras and Paraguay. We will also start the study in four more sites in the following countries: Argentina, Costa Rica, Mexico and Peru.
- Nurses, medical doctors, colposcopists and pathologists from these new sites will be given the training required prior to their participation in the study.
- We are also planning to start using the pscyhoESTAMPA tool, a questionnaire to evaluate the impact of receiving a positive HPV test result. The protocol to validate this tool has recently been submitted for ethical approval in Colombia where the validation will take place.
- In all sites, the first exercise of external quality control of HPV testing will be carried out during 2015. Sites will join an international scheme through which samples are retested at each centre. In addition, a comprehensive quality assurance programme is under development by ESTAMPA researchers with expertise in HPV testing services and laboratory quality assurance.
- Finally, in May 2015, the second DSMB meeting will be held at IARC in Lyon.

3.6.2.2 AISHA: an implementation study on rapid HPV testing in Tanzania

This is a cross-sectional, multicentre study to be carried out in 10 centres in Tanzania to assess the reproducibility, feasibility and acceptability of rapid HPV testing at each level of the health system. Cervical specimens from 255 women will be processed at field sites, regional expert laboratories and the national reference laboratory. The agreement between test results from the different laboratories will indicate if rapid HPV testing is a feasible and reliable screening test when operated at different levels within the health system. The use of VIA and rapid HPV testing in the follow-up care of treated women will be assessed at a one-year follow-up visit.

Progress

The study protocol has been revised and approved by the ethical review committees at WHO headquarters and in Tanzania. An assessment of study sites was performed and the Dar es Salaam, Kilimanjaro and Morogoro regions were selected for the study. The intensity and quality of VIA screening differs mainly according to the level of the health infrastructure. The quality was particularly poor at most of the primary health centres that were visited. This will be overcome by organizing a comprehensive VIA training session for the nurses involved in the study. Likewise, the laboratories will need support, especially those at the primary health centres.

The collaboration between the Tanzania Ministry of Health and Muhimbili Hospital, the main organizing partners, and the WHO Africa Regional Office was efficient and smooth. The need for additional study staff was discussed and a national data manager was identified.
The MOU between the Tanzanian Ministry of Health and Qiagen, regarding the donation of careHPV tests for this study, was signed in October 2014, and the study is expected to start in February 2015.

**Planned activities**

- The study will be implementation in Dar es Salaam in February–May 2015.
- A workshop will be organized on implementation of cervical cancer screening in Tanzania, including all the national stakeholders and organizations active in the field.
- Implementation will begin consecutively in the other regions:
  - Kilimanjaro: June–September 2015

### 3.6.2.3 Randomized trial comparing cervical cancer screening algorithms in Africa

The 2013 *WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention concluded that there was an important research gap for clinically relevant studies* (2). In order to provide this much-needed evidence, a randomized trial is being planned to compare the performance of the different screening algorithms of interest. The main objective of the trial is to compare the efficacy of VIA with rapid HPV testing (with or without triage by VIA) in reducing histologic high-grade squamous intraepithelial lesions two years after screening and treatment of women aged 30–49 years.

**Progress**

Several meetings have been held at IARC and WHO to discuss the proposal for this study. Following these meetings, a draft protocol for a multicentre randomized trial has been completed.

Discussions were also held with the WHO African Region regional advisor on cervical cancer control, as well as country representatives and potential donors, during the African Region’s Regional Consultation on Cervical Cancer Prevention and Control Meeting, in Yaoundé, Cameroon, 24–26 March 2014. Subsequently, at the 5th International Workshop on Prevention, Screening of Cervical Cancer and Colposcopy in Buea, Cameroon, 27–28 March 2014, the objectives and draft design of the trial were presented to a selected audience of stakeholders in cervical cancer prevention.

An advisory expert group meeting was held at IARC, Lyon, 27–28 October 2014. Among the participants were 13 external experts, 5 experts from WHO headquarters and 11 from IARC. The draft protocol was discussed and representatives from Kenya, Uganda and Zambia presented the capacities of their candidate sites to carry out the study.

**Planned activities**

- In 2015, the Department will undertake the elaboration of the study protocol and tools.
- Site visits will be made to assess the candidate study sites.
- Meetings will be organized with the principal investigators of the participating study sites to discuss and finalize the study protocol and tools.
• Before the end of 2015, preparations to implement the study will start in one country.

3.6.2.4 Human papillomavirus vaccines and adolescent health

Working in conjunction with the Department of Immunization, Vaccines and Biologicals, the RHR Department supported the Faculty of Infectious and Tropical Diseases, at the London School of Hygiene and Tropical Medicine, London, United Kingdom, and the Mwanza Intervention Trials Unit, at the National Institute for Medical Research, Mwanza, Tanzania, to carry out formative research for a proposed intervention trial to test the feasibility and acceptability of delivering adolescent health interventions alongside vaccinations for HPV in Tanzania. For full information on this initiative, please see sub-section 3.2.2.1 (iv) in section 3.2: Adolescent sexual and reproductive health.

3.6.3 Norms, standards and tools

3.6.3.1 Comprehensive cervical cancer control: a guide to essential practice, second edition

Progress

The newly published second edition of the C4-GEP (replacing the 2006 edition) provides a comprehensive cervical cancer control and prevention approach for governments and health-care providers in developing country settings. Also known as the “pink book”, the guidance underlines recent developments in technology and strategy that can improve women’s access to health services in order to better prevent and control cervical cancer (3).

The new guidance identifies key opportunities and ages throughout a woman’s life when cervical cancer control and prevention can be put into action, especially for:

• Primary prevention: HPV vaccination targets girls aged 9–13 years, aiming to reach them before they become sexually active.

• Secondary prevention: This refers to access to screening technology, followed by treatment of detected precancerous lesions, which may develop into cervical cancer.

• Tertiary prevention: This includes cancer treatment in women of any age, including surgery and radiotherapy, as well as palliative care.

The new guidance also calls for greater collaboration across organizations, programmes and partners to improve women’s health. It also shows how cervical cancer control and prevention can be integrated into existing health-care delivery systems, including family planning, postpartum care and HIV/AIDS. The delivery of vaccinations to girls, for example, opens the door to reaching adolescents with additional health information and services (see section 3.6.2.4).

The C4-GEP was launched at the Union Internationale Contre le Cancer, World Cancer Congress (UICC WCC) in Melbourne, Australia, on 3 December 2014. Coinciding with the launch, several media activities took place to gain more exposure for the guideline.

Planned activities

• The guideline will be translated into all WHO official languages in 2015.

• Sub-regional and country workshops will be held to adapt and introduce the guideline within national cancer prevention and control programmes.
• The guideline will be introduced in 10 African countries through 10 country consultations that will take place throughout 2015. The guideline is the pillar for much of the work outlined in sections 3.6.2.2, 3.6.2.3 and 3.6.2.4; the revised guideline will be introduced within all of these research programmes.

• The impact of the introduction of the guideline will be monitored.

3.6.4 Monitoring and evaluation

The RHR Department plays a key role in guiding, supporting and transferring knowledge and practices across several health projects linked to the introduction of cervical cancer screening and treatment in a health system (see below). These projects share commonalities in identifying and providing information, and tools to facilitate political, systemic and individual support for monitoring and evaluation, yet they differ in their approaches.

3.6.4.1 Integrating cervical cancer screening and prevention into reproductive health services

The “Cervical cancer screening and prevention therapy via reproductive health networks” project specifically sets out to explore approaches for integration and adaptation of VIA followed by cryotherapy within existing semi-public family planning services models. This will provide many insights into how best to integrate the screen-and-treat approach to cervical pre-cancer into reproductive health services.

This project is being implemented in Kenya, Nigeria, Tanzania and Uganda. The project partners include WHO, Marie Stopes International (MSI), Population Services International (PSI) and the International Planned Parenthood Federation (IPPF).

Progress

More than 400,000 women aged 30–49 have been screened so far.

Planned activities

• Screen-and-treat rates will be increased, and steps are now being taken to improve quality and to scale up reach; results should be available in 2015.

3.6.4.2 Reducing cervical cancer burden in selected high-burden countries in the African Region

The objective of the project is to increase screen-and-treat coverage and capacity through engaging partners, improving training and quality assurance. Continuous process evaluation will be used to identify barriers and implement strategies to overcome these challenges. A series of reports will be developed, including reports on lessons learnt and evidence-based models for “best practice”, as well as tools for strategic planning, VIA/cryotherapy training, advocacy, and information, education and communication.

This project is being implemented in Ghana, Guinea, Kenya, Madagascar, Malawi, Nigeria, Senegal, Sierra Leone, Zambia and Zimbabwe. It is a partnership between WHO headquarters and the WHO African Regional Office.

Progress

A country capacity survey has been completed and a draft baseline report developed. A country consultation to review the baseline report was scheduled for 25 September, but has been postponed until 2015. Strategic planning training tools and an advocacy toolkit have been developed and sent to external experts for review.
Planned activities

• The tools will be developed and finalized
• The tools will be disseminated and a series of training workshops will be held.

3.6.4.3 Improving data for decision-making in global cervical cancer programmes (IDCCP)

The objective of the IDCCP project is to develop a series of reports evaluating current data systems, facilities and patient outcomes. The project also includes development of tools for population-based surveillance and monitoring and for costing for the scale-up of the screen-and-treat approach. This project is being implemented in Botswana, Ethiopia, Guatemala, Kenya, Tanzania and Zambia. The partners include WHO, IARC, United States Centers for Disease Control and Prevention (CDC), CDC Foundation, and the Pink Ribbon Red Ribbon (PRRR) global health initiative of the George W. Bush Institute.

Progress

A population-based surveillance consultation meeting was held in August 2014 with experts from the fields of cervical cancer, epidemiology, and monitoring and surveillance. Working groups to develop population-based surveillance tools have been established. WHO costing tools have been expanded to include the screen-and-treat approach to cervical pre-cancer. Training for the data assessment team has been completed and data collection in the field has commenced in the first country, Botswana.

Planned activities

• The costing tools will be piloted in Ethiopia in 2015.
• Data assessment will continue in Ethiopia, Guatemala, Kenya, Tanzania and Zambia.
• Web-based knowledge platform (a contractor will be identified).
• A patient outcome protocol will be developed by IARC.
• Facilities-based assessment will be conducted, and a tool will be developed for monitoring programmes and patients.

3.6.5 Dissemination and partnerships

All projects outlined above are engaged in activities for the dissemination of results and tools. These activities include country consultations and workshops, peer-reviewed publications and posting of information online.

As summarized above, the RHR Department collaborates with a diverse range of partners in the area of cervical cancer prevention and control. These include but are not limited to: CDC, CDC Foundation, George W. Bush Institute, IARC, IPPF, MSI, PSI, ministries of health and other partners within countries. Partners provide funding, resources and expert knowledge. The chief role of the RHR Department within these partnerships is: to ensure synergy between the various projects, cross-collaboration and sharing of information on progress and lessons learnt; to ensure that protocols, policies and tools are informed by and align with WHO guidelines; and to provide expert guidance. These roles are carried out through direct and frequent discussions with partners, and success depends on the good rapport of the RHR Department staff with our partners.
Planned activities

- A Regional Consultation will be held in Brazzaville, Congo, in April 2015. The following countries will be invited to attend: Botswana, Ethiopia, Ghana, Guatemala, Guinea, Kenya, Madagascar, Nigeria, Sierra Leone, Senegal, Tanzania, Zambia and Zimbabwe. The objectives of the meeting are: to disseminate, discuss and identify opportunities to improve current cervical cancer prevention and control plans using the completed baseline assessment information and implementing strategies in the C4-GEP; and to introduce tools for strategic planning, advocacy and information, education and communication.

- A Global Consultation in Botswana in June 2015 will include the countries listed above in addition to representatives from the six WHO regions as well as partners including CDC, CDC Foundation, George W. Bush Institute (PRRR initiative), IARC, IPPF, MSI and PSI, among others. The objectives of this meeting are to present the tools developed as part of the IDCCP project, and to seek feedback before finalization and dissemination of the tools.

- The Department will present projects at the XXI World Congress of the International Federation of Gynecology and Obstetrics (FIGO) in October 2015.

- Further regional consultations are undergoing planning for late 2015.

3.6.6 References


3.7 Violence against women and harmful practices, including female genital mutilation and early marriage

3.7.1 Introduction

As part of its work in supporting improved sexual and reproductive health of populations, the RHR Department, including HRP, places special emphasis on responding to the needs of women and girls who have been subject to gender-based violence, including female genital mutilation (FGM) and early marriage. Research activities include strengthening the evidence base on the magnitude of the problems, testing interventions to reduce violence and harmful practices or mitigate their consequences, as well as synthesizing evidence to develop evidence-based tools, guidelines and activities that contribute to strengthening health policy and health care delivery for addressing the unique needs of women and girls affected by these issues.
The following sections summarize key activities carried out and key products delivered during 2014 as well as plans for 2015 to achieve the above goals and related mission of the Department.

Major achievements

• Three scientific papers were published on: (i) research gaps in the care of women with female genital mutilation (FGM); (ii) a systematic review of the evidence on clitoral reconstruction after FGM/cutting, and (iii) case studies on clitoral reconstruction after FGM/cutting.

• The Department developed a research protocol to evaluate the safety and efficacy of clitoral reconstruction following FGM, and the impact of comprehensive psychosexual care on health outcomes.

• A clinical handbook, *Health care for women subjected to intimate partner violence or sexual violence* (a derivative of the 2013 WHO clinical and policy guidelines *Responding to intimate partner violence and sexual violence against women*) was published in November 2014 and has been disseminated in several countries.

• A Lancet Series on violence against women and girls was coordinated by the Department and the London School of Hygiene and Tropical Medicine’s Centre for Gender, Violence and Health, and was launched on 21 November 2014 to mark the “International Day for the Elimination of Violence Against Women”.

• The Department supported the development and adoption of a Member-State-led World Health Assembly Resolution 67.15 on “Strengthening the role of health systems in addressing violence, in particular against women and girls and against children”.

3.7.2 Research and development

3.7.2.1 Violence against women

*Progress*

(i) Addressing intimate partner violence against pregnant women

The Department is supporting a study in three public antenatal care clinics in Johannesburg, South Africa, to test an empowerment counselling intervention for women exposed to intimate partner violence during pregnancy. Funded by the Flemish Government, the study is being carried out in collaboration with Wits Reproductive Health and HIV Institute (WRHI) in Johannesburg, and it aims to improve women’s mental health outcomes and self-efficacy, and increase safety behaviours (e.g. preparing an escape or having a safety plan in the event of escalating violence) and the rate of accessing community resources, thereby reducing recurrence of intimate partner violence and mitigating its consequences. Recruitment into the randomized controlled trial began in April 2014 at all three clinics and will continue until the desired sample size (n=504 women) is reached and follow-up interviews have been conducted at postpartum clinic visits. Results from the formative research using qualitative research methods have been published, showing that antenatal care patients and providers are well aware of the bi-directional links between intimate partner violence and HIV (1).
(ii) Correlates of violence against sex workers

A systematic review, published in March 2014, presents the global prevalence and risk factors for violence faced by sex workers (2). The findings suggest that sex workers face a high burden of violence, both in the workplace and beyond. Individual risk factors, such as drug and alcohol use and work environment (i.e. indoor versus street-based sex work), as well as more structural risk factors, such as unequal gender and power dynamics and socioeconomic inequality, trafficking, migration, forced labour, and policy and practices around policing and criminalization of sex work, are important in understanding risk of violence and developing policies and programmes to address it.

(iii) Sexual Violence Research Initiative (SVRI)

The SVRI is a network of researchers, policy-makers, donors and other stakeholders concerned with raising awareness about sexual violence as a public health issue and promoting research and building research capacity on this issue, particularly in low- and middle-income countries. The Department continued to play a leading role in this global initiative in 2014.

(iv) WHO Multi-country Study (MCS) on Women’s Health and Domestic Violence against Women

A meeting was held in June with some of the international partners and country principal investigators who were involved with the development of the WHO MCS questionnaire to discuss revisions to the questionnaire for publication of an updated version. The methodology continues to be used by researchers in many countries and has informed the development of guidelines for the measurement of violence against women by the UN Statistics Commission. The database of the WHO MCS continues to be used; for example, for the burden of disease estimates, and for an analysis of the data for adolescents, which was published in 2014 (3).

Planned activities

• The Department will continue to oversee and monitor the study among pregnant women experiencing intimate partner violence in South Africa.

• Building on the existing one-week training curriculum on research on violence against women, the Department will develop a longer training programme on this issue for researchers (including a module on interventions research) in collaboration with other UN agencies and will also develop partnerships with a couple of the Department’s collaborating centres to implement this training course.

• Sites are being identified for pilot-testing in 2015 of questionnaire tools for measuring sexual violence in conflict situations, including both victimization and perpetration of sexual violence.

• The Department will assist with preparations for the SVRI Forum 2015 to be held in September in South Africa, and support it in additional ways, including chairing the Scientific Committee, reviewing abstracts and shaping the agenda.

• The Department will contribute to a Cochrane review of interventions to address unequal and harmful gender norms, to be undertaken in 2015. This will build on a systematic review of determinants of gender norms among adolescents that was conducted in 2014 by the Johns Hopkins University in collaboration with the Department.
• An expert consultation will be convened in the first half of 2015 to review and identify interventions for children of women who have been subjected to intimate partner violence.

• The Department will publish an updated version of the WHO Multi-country Study questionnaire and manual.

3.7.2.2 Female genital mutilation

Progress

(i) Analysis of research gaps in the care of women with FGM

A literature review on the knowledge gaps in the clinical care of women with FGM was prepared and presented to the WHO FGM Steering Committee last year, and research priorities developed. The review and priorities were prepared as a research manuscript, and have been accepted for publication by *BJOG: An International Journal of Obstetrics & Gynaecology* (4). Four priority research areas have been identified for WHO and the global community to improve evidence-based health care for girls and women living with FGM. These include: (a) obstetric outcome and postpartum perineal re-education; (b) defibulation outside of pregnancy or labour; (c) clitoral reconstruction; and (d) training, skills and confidence of health-care providers.

(ii) The safety and efficacy of clitoral reconstruction in women with FGM – a case series and systematic review

The safety and efficacy of clitoral reconstruction in women with FGM was identified as a priority in 2013 by the WHO FGM Steering Committee. A systematic review was conducted on this topic and accepted for publication by the *International Journal of Obstetrics and Gynaecology* (5). Only four poor-quality studies, with limited follow-up periods, address the safety and efficacy of clitoral reconstruction surgery alone in improving sexual health outcomes for women with FGM. This highlights a critical research gap, as clitoral reconstruction surgery is being broadly scaled up in private hospitals and directly advertised to women with FGM as an effective cure for sexual dysfunction, pain and gender identity issues. A case series, presenting the need for comprehensive psychosexual care in clitoral reconstruction, was undertaken. This manuscript has been accepted for publication by the *Journal of Sexual Medicine* (6).

(iii) The safety and efficacy of clitoral reconstruction in women with FGM – a clinical research protocol

Clitoral reconstruction surgery is being widely offered in private clinics and hospitals in Europe and Africa, and marketed to women with FGM as a cure for a range of disorders. Limited evidence exists to substantiate claims of safety or efficacy. Importantly, no study has investigated the impact of comprehensive psychosexual care, including sexual therapy, in addressing the needs of women with FGM who request clitoral reconstruction. A clinical research protocol to investigate the safety and efficacy of clitoral reconstruction – and the impact of comprehensive psychosexual care in women requesting the surgery – has been developed. The protocol was submitted to the Swiss Foundation for funding. It is being developed as a multicountry study. Input on the psychosexual component of the research is being gathered from a multi-disciplinary team of experts from European and African settings.
(iv) Psychological consequences of FGM

A WHO-sponsored study in Nigeria will provide information on the psychological experience and consequences of FGM. The objective of the study is to inform guidelines for the management of FGM complications related to mental health. In January 2015 the research team met in Geneva to review preliminary analyses of the study results and to draft manuscripts.

Planned Activities

- The clinical research protocol for the multicountry study on clitoral reconstruction in women with FGM will be revised to meet WHO requirements and then submitted to the Research Project Review Panel (RP2) and the WHO Ethics Review Committee (WHO-ERC). Sites for the multicountry trial will be identified and visited in 2015.

- Manuscripts on the study findings from Nigeria on the psychological consequences of FGM will be submitted for publication in the first half of 2015.

- The Department will develop a research proposal on the development and testing of a package of interventions for use by health-care providers to improve health care for women who have undergone FGM.

3.7.3 Norms, standards and tools

3.7.3.1 Violence against women: tools to strengthen health systems response and interventions

Progress

A clinical handbook, Health care for women subjected to intimate partner violence or sexual violence (derived from the 2013 WHO clinical and policy guidelines on Responding to intimate partner violence and sexual violence against women; 7), was developed and published in November 2014 (8). This practical reference tool is aimed at supporting providers in identifying and responding to the needs of patients who have experienced these forms of violence. Field-testing methodology was also developed and planning is in progress for field-testing the handbook in three countries.

In addition, as a companion to the clinical handbook, a health systems manual for health managers on responding to intimate partner violence and sexual violence was also drafted.

A toolkit to strengthen medico-legal evidence for conflict-related sexual violence, with job aides for practitioners on the collection and use of forensic data, and including guidance on coordinating the engagement of other stakeholders in the medico-legal response, was finalized in 2014. This toolkit was developed to respond to the practical challenges of collecting forensic evidence in conflict-affected settings.

A manual for a brief structured psychological intervention for survivors of adversity has also been developed and will be tested among survivors of conflict-related sexual violence (in collaboration with WHO’s Department of Mental Health and Substance Abuse and UNHCR).

Training curricula (one modular and one electronic) for both pre- and in-service training of health-care providers to respond to violence against women are being developed. In 2014, in collaboration with PAHO, a comprehensive review of existing training curricula on violence against women aimed at health-care providers was completed.
**Planned activities**

- In 2015, field-testing of the clinical handbook on intimate partner violence and sexual violence against women will be undertaken in three countries, based on the methodology developed in 2014.

- The health systems manual for responding to intimate partner violence and sexual violence aimed at health managers, which was drafted in 2014, will be finalized in 2015.

- Training curricula for both pre- and in-service training of health-care providers to respond to violence against women will be developed in 2015, including an electronic format. In early 2015, building on the review of existing training curricula, an expert consultation will be convened to develop the draft content of the curricula.

- The toolkit for strengthening medico-legal systems will be published and field-tested in Kenya (with Physicians for Human Rights) and Somaliland (with UNODC).

- The Department will initiate the development of clinical and policy guidelines for responding to sexual violence against children and adolescents. Children and adolescents constitute a significant proportion of sexual violence cases seen by health services. The current WHO guidelines on intimate partner violence and sexual violence address only adult women. A scoping document, identification of PICO questions and a first meeting of the Guidelines Development Group will be undertaken in 2015.

3.7.3.2 Female genital mutilation: WHO guidelines on optimizing care for women and girls living with FGM

**Progress**

It is currently estimated that between 100 and 140 million girls and women worldwide are living with the effects of FGM. Despite enormous efforts to eradicate the practice, every year over 3 million women and girls in Africa and elsewhere are at risk of being mutilated and are therefore exposed to the health consequences of this harmful practice.

Recent studies indicate that although health-care professionals are aware of the existence of FGM and some of its health consequences, their ability to identify the condition and its associated morbidity remains suboptimal. Some providers consider certain forms of FGM non-harmful and a large proportion of them do not manifest a clear position when confronted with crucial issues like requests for performing FGM (medicalization of the practice) or re-infibulation. Additionally, there is a growing understanding that this harmful practice is no longer limited to African and Middle Eastern countries, due to increasing immigration from countries with a high prevalence of FGM to high-income countries. As a result, health-care providers across the globe, many of whom have received little or no formal education on the issues related to FGM, may find themselves ill prepared to treat and care for patients with FGM-related complications.

WHO published a guideline with recommendations regarding the management of FGM-related health complications in 2001 (9). Since then, no updates have been made and new evidence and information on the subject have not been included in any new WHO publications. In collaboration with the UNFPA–UNICEF Joint Programme on Female Genital Mutilation/Cutting (FGM/C), WHO will update and
publish a guideline on the management of FGM complications to optimize the health of women and girls living with FGM.

In 2014, the proposal for this guideline was drafted and accepted through the WHO Guideline Review Committee process.

**Planned activities**

- A Guideline Development Steering Committee meeting will be convened in February 2015.
- The subsequent processes of developing the FGM guideline – involving scoping, conduct of systematic reviews, and reviewing and assessing the evidence – will be undertaken in 2015.
- It is anticipated that this guideline will be published in late 2015/early 2016.

### 3.7.4 Monitoring and evaluation

#### 3.7.4.1 Violence against women

**Progress**

The following activities for strengthening monitoring and evaluation of violence against women and its health consequences were carried out in 2014.

The RHR Department convened a meeting of high-level international experts and UN partners in June 2014 to develop and build consensus on indicators of violence against women for global monitoring in support of the post-2015 development framework. The group recommended four indicators for consideration. A meeting report has been disseminated to participants.

In June 2014, the national prevalence study of violence against women in Cambodia was launched officially with UN and government partners. This study uses the methodology of the WHO Multi-Country Study on Women’s Health and Domestic Violence against Women. Activities in 2014 included establishing the research team, the sample size, and agreeing on the country adaptations of the questionnaire.

Prevalence estimates for non-partner sexual violence were published in *The Lancet* (10).

**Planned activities**

- Data collection for the prevalence study in Cambodia is expected to begin in 2015.
- Updated prevalence estimates on global intimate partner violence will be released in the first quarter of 2015 on the Global Health Observatory of the WHO.

#### 3.7.4.2 Support for monitoring of vulnerabilities and morbidities: ICD-11 revision

**Progress**

The International Statistical Classification of Diseases and Related Health Problems (ICD) is a key instrument of WHO. The ICD 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 10th revision of the ICD (ICD-10) came into use in 1994, and a revision process is currently under way, with the ICD-11 scheduled for release in 2017.

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) for the ICD-11. The Department also coordinates a genito/urinary and reproductive medicine (GURM) Topic Advisory Group (TAG) to support the revision, and has a seat on the Small Executive (oversight) Group of the ICD-11 revision process. The Department also co-leads, with the Department of Mental Health and Substance Abuse, on development of a new chapter on conditions related to sexuality and sexual health. The Department was also involved in a paper on the declassification of disease categories related to sexual orientation in the ICD-11 (11).

A meeting of the GURM TAG was convened in December 2014 to review progress and to continue discussions with overlapping areas of work (i.e. paediatrics, dermatology, neoplasm, endocrine). The TAG reviewed proposals submitted on the official ICD-11 commenting website\(^\text{18}\) as well as the new proposed chapter on “sexual health”, comprising conditions previously classified within mental health (e.g. gender identity disorders) and other conditions which may affect sexual health or well-being (e.g. sexual pain disorders).

**Planned activities**

- In 2015, the Department will continue working with the TAG to review proposals and provide advice for the ICD-11 revision process for the chapters it is responsible for.

### 3.7.5 Dissemination and partnerships

#### 3.7.5.1 Violence against women

**Progress**

In 2014, the following activities for dissemination of products and evidence on violence against women and its health consequences were carried out.

The Department supported the development and adoption of a Member-State-led World Health Assembly Resolution 67.15 on “Strengthening the role of health systems in addressing violence, in particular against women and girls and against children”. This resolution was adopted after a long and heavily debated process.

The WHO clinical and policy guidelines for *Responding to intimate partner violence and sexual violence against women* have been widely disseminated, including to nearly 40 countries through regional workshops aimed at strengthening capacity for a public health approach to prevention and response (7). These workshops have included 12 countries in the South-East Asia and Western Pacific Regions, as well as 24 countries in the African Region (7 in East Africa, 11 in southern Africa, and 6 in West Africa). A number of countries that have participated in these workshops have undertaken development or updating of their national health sector protocols and guidelines for responding to violence against women.

A Lancet Series on violence against women and girls was coordinated by the Department and the London School of Hygiene and Tropical Medicine’s Centre

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\(^{18}\) Available at: [http://www.who.int/classifications/icd/revision/en/](http://www.who.int/classifications/icd/revision/en/)
for Gender, Violence and Health (12). This special issue includes several papers co-authored by department staff, including an article on the health system response as well as a call to action (13, 14). It was launched on 21 November 2014 at LSHTM to mark the International Day for the Elimination of Violence Against Women, held every year on 25 November.

The Department supported several countries to develop and launch their national protocols for health sector response to violence against women (e.g. Afghanistan, Cambodia and India) or to revise their existing ones in line with the WHO guidelines and clinical handbook (Viet Nam) or to strengthen capacity of health-care providers in addressing violence against women (Syria).

The Department supported the WHO Country Office and the Ministry of Health in Uganda to improve the policy capacity and response to violence against women. This involved a readiness assessment, looking at the policy strengths and gaps, strengthening capacity of health-care providers and other stakeholders for a public health approach to preventing violence, evidence-informed advocacy with high-level policy-makers, and updating the Ministry of Health’s training package for addressing violence against women based on 2013 WHO clinical and policy guidelines (7).

The Department is leading the development of a global plan of action on strengthening the role of health systems in addressing interpersonal violence, in particular against women and girls and against children. This plan of action was requested by Member States from the WHO Secretariat in the World Health Assembly Resolution 67.15 on “Strengthening the role of health systems in addressing violence, in particular against women and girls and against children” in May 2014. In late 2014, the Department convened a Core Group, including members of other WHO Departments, and has developed a preliminary Discussion Paper as a basis for consultation and development in 2015.

Planned activities

• In 2015, WHO guidelines on violence against women will continue to be disseminated to WHO regions and other partners like UNFPA and UN Women. Support will continue to be provided to countries, as requested by countries and regional offices, in implementation of the WHO guidelines, norms and tools on violence against women, including in the uptake of the new clinical handbook for health-care providers

• The Department will continue to provide technical assistance for the implementation of the WHO multicountry study methodology, including in Cambodia and in Latin America and the Caribbean.

• The Discussion Paper on the global plan of action on strengthening the role of health systems in addressing interpersonal violence, in particular against women and girls and against children will be disseminated widely for consultations in 2015 with Member States and other stakeholders and partners, including a global web-based consultation. After this, in the second half of 2015, the global plan of action will be drafted and reviewed by Member States. In January 2016, the global plan of action will be submitted to the Executive Board and finally presented at the World Health Assembly for endorsement in May 2016.
3.7.5.2 The Girl Summit – a future free from FGM/C and child, early and forced marriage (CEFM)

Progress

The Department contributed to the Girl Summit, which was co-hosted by the Government of the United Kingdom and UNICEF, and held in London on 22 July 2014. The objectives of the Summit were to galvanize support and inspire local, national and international efforts to end FGM/C and CEFM in one generation. It brought together over 500 participants from high-, medium- and low-income countries from around the world. The participants included young people, nongovernmental organizations (NGOs) and government officials involved in FGM/C and CEFM work, as well as others involved in work addressing girls, including academics, representatives of multilateral organizations, bilateral agencies and foundations. It also included senior government officials – including presidents and prime ministers, their deputies, health and social welfare/community development ministers and first ladies.

A number of high- and middle/low-income countries governments, foundations, NGOs and UN agencies pledged their commitments in terms of the actions they will take and the funds they will make available for domestic and international work. Furthermore, over 250 individuals, organizations and countries signed up to the 10-point charter on ending FGM and CEFM.19

The below commitments for WHO were communicated by Dr Flavia Bustreo, the Assistant Director-General for the Family, Women’s and Children’s Health Cluster:

- WHO will coordinate and carry out research to enhance the evidence base for efforts to prevent and address the health consequences of child marriage and FGM/C. In doing so, WHO will also help to strengthen research capacity in low resource settings and facilitate and South–South and North–South collaboration (mainly through the WHO FGM/C research network).
- WHO will support the implementation of the recommendations on prevention of early marriage and addressing adverse health outcomes (15).
- WHO will develop policy and programmatic guidelines to manage adverse health consequences of FGM/C and improve the care for women and girls living with FGM/C.
- WHO will support countries in planning, implementing and monitoring policies and programmes to prevent and respond to child marriage and FGM/C.

A day prior to the Girl Summit, in conjunction with the United Kingdom’s Government’s Department for International Development and UNICEF, the Department convened a meeting to discuss existing evidence and share priorities and opportunities for future research on issues that are cross-cutting as well as those that are specific to FGM/C and CEFM, and to start the conversation on mechanisms that will enable research/policy coordination and collaboration.

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19 Available at: www.girlsummit2014.org/content/docs/CharterEnglish.pdf
Thematic areas

109

Planned activities

• In 2015, the Department will follow up on the conclusions of the meeting to update a review of the evidence and to initiate research on selected areas of early marriage and FGM/C prevention and response.

3.7.6 References


3.8 Sexual and reproductive health in humanitarian settings

3.8.1 Introduction

The RHR Department, including HRP, supports the provision and continuation of sexual and reproductive health (SRH) information and services in humanitarian settings through (i) collaborating with partners to respond to sudden-onset crises which pose threats to the accessibility and availability of SRH services, thus impacting the health of the affected population; (ii) developing and adjusting WHO guidance on SRH issues into digestible and usable resources for field situations; and (iii) disseminating these resources.

Starting in September 2014, the Department’s Humanitarian Settings team shifted to focus primarily on the growing outbreak of Ebola virus disease (EVD). Through a combination of fieldwork in outbreak regions, as well as ongoing research and coordination of global efforts from WHO headquarters, the Department has served as the SRH focal point for the EVD outbreak, collaborating with partners around the world affected by and working on the EVD outbreak to ensure that the latest correct, and appropriate evidence-based information and guidance is issued.

The following sections summarize the key activities that were carried out and products that were delivered in 2014, as well as those planned for 2015.

Major achievements

- The Department collaborated with UNICEF and Save the Children in publishing a guidance document for safe delivery and newborn care in regions affected by EVD, and this was disseminated widely.

- The Department published an evidence brief on EVD and seminal fluids, collating the current scientific knowledge surrounding the length of time EVD can be traced in seminal fluid, the infectiousness of such fluid, and any documentation of secondary infection cases.
3.8.2 Research and development

3.8.2.1 Minimum Initial Service Package (MISP) for reproductive health in crises

Progress

Prior to the EVD outbreak, which has now taken precedence over other work in the Humanitarian Settings portfolio, the Department had undertaken a comparative analysis and evidence-based update of the MISP for reproductive health in crisis settings. This analysis compared the current MISP guidance against that of the current WHO guidance and recommendations. The analysis highlighted areas where the MISP is not completely in line with WHO guidelines.

Planned activities

• This work will recommence in 2015 as the EVD outbreak eases. It is seen as integral to improving services and availability of SRH in humanitarian crises.

• A short rapid review may need to be conducted to ensure that new WHO guidelines and recommendations are still in line with the findings of the analysis.

3.8.2.2 Ebola virus disease and bodily fluids

Progress

The EVD outbreak that is affecting parts of West Africa began in March 2014 and is the largest outbreak of EVD in history. Previous outbreaks of Ebola have generated some research into the specificities of the modes of transmission as well as some documentation into the delicate situation surrounding pregnancy and EVD infection. However, there remain many unanswered questions. As the rates of survival are increasing in some areas, and thus more and more people are discharged having recovered, questions have been raised around the length of time for which bodily fluids remain infectious, even after the blood has become EVD-free.

It is known that the shedding of the Ebola virus can be found in a variety of bodily fluids, including sweat, vomit, urine, semen, vaginal fluid and breast-milk, among others. However, what is not known is the infectiousness of these fluids, and the length of time such shedding can be found in these fluids. Of particular interest are (a) seminal and vaginal fluids, which may pose the threat of sexual transmission of the virus from convalescent patients, and (b) fetal transmission and the management of pregnant EVD patients. The latter refers to two components: firstly, to the safety of health workers, specifically midwives and nurses, during pregnancy-related complications or during labour, and secondly, to the communities at large when pregnant women are released from an Ebola treatment centre to deliver at home or in another location, which may pose a threat of transmission. Additionally, as the infectiousness of bodily fluids is not well understood, there is growing stigma and fear surrounding all pregnant women regardless of EVD infection, in light of the volume of fluids involved in delivery or pregnancy-related complications.

The Department reviewed and synthesized scarce evidence on this topic. A one-page evidence brief on EVD and seminal fluids, collating the current scientific knowledge surrounding the length of time EVD can be traced in seminal fluid, the infectiousness of such fluid, and any documentation of secondary infection cases, and the use of condoms as a precaution was published (1).
**Planned activities**

- In 2015, the Department will finalize a condom efficacy review as well as potential mechanical studies into EVD and condom permeation, slippage and breakage consequences (if seminal and vaginal fluids are found to be infectious).

- Collaborations with partners from a variety of organizations, including those on the ground in EVD-affected regions, will continue to identify research questions and develop studies to establish a solid evidence base for the questions surrounding the sexual transmission of EVD via convalescent patients’ bodily fluids, namely seminal and vaginal fluids.

- In partnership with the Pandemic and Epidemic Diseases (PED) Department, the RHR Department will be involved in the development of clinical standards on the care and management of pregnancy and EVD.

- The RHR Department will also participate in ongoing discussions regarding EVD in breast-milk, as well as provide support to a three-country research mechanism that has been established to assist in the delivery of much-needed data to clarify these questions.

- The Department will develop priority research questions and carry out research on key priorities on reproductive, maternal, newborn and child health in the context of the Ebola outbreak.

**3.8.3 Norms, standards and tools**

**3.8.3.1 WHO/UNICEF/Save the Children global guidance for safe delivery and newborn care in Ebola-affected countries**

**Progress**

Across EVD-affected regions, entire maternity wards have been closed down and many health-care facilities and programmes that were previously available to pregnant women have been suspended, causing serious threats to the health of EVD-negative women who were in need of medical attention. Further, many symptoms associated with pregnancy and labour can be mistaken for the early symptoms of EVD infection. The need for global guidance on safe delivery and newborn care arose from the increasing stigma and fear surrounding all pregnant women in the EVD-affected regions due to the large volumes of bodily fluids involved in childbirth and pregnancy-related complications. The Department collaborated with UNICEF and Save the Children in publishing this guidance, which was disseminated widely (2).

**Planned activities**

- In 2015, the Department will continue to answer calls for documentation and guidance related to the EVD response through the development of WHO guidance for pregnant women with EVD.
3.8.4 Dissemination and partnerships

3.8.4.1 Ebola virus disease outbreak

Progress

The Department deployed the staff member working on humanitarian settings to Liberia for a total of 10 weeks in 2014, to provide support to Member States and partners in strengthening their efforts to respond to the sexual and reproductive health aspects of the EVD outbreak. As part of this support, publication of a national clinical management manual for pregnant and breastfeeding women was supported (3).

Planned activities

• In 2015, the Department will continue involvement in the EVD outbreak response through supporting the building of resilient reproductive, maternal, newborn and child health systems and services in Ebola-affected and neighbouring countries.

• The Department will also continue collaborative efforts with external partners; for example, contributing its expertise to a UNFPA meeting on the impact of EVD on the reproductive health of women in Dakar, Senegal, planned for March 2015.

3.8.5 References


3.9 Infertility

3.9.1 Introduction

WHO estimates that 186 million ever-married women of reproductive age – one in every four couples in developing countries – are unable to become pregnant when they desire to have a child (1). More recent WHO analysis reported that this estimated overall burden of infertility in women from 190 countries has not significantly changed from 1990 to 2010, and the burden remains highest in developing countries – paradoxically in the regions with the highest unmet need for contraception (2).

Infertility is not merely defined as the inability to become pregnant, but to maintain that pregnancy. In the male, if no motile or viable sperm can be found in
an ejaculate, this is defined as male sterility; and, if there is a low or very low viable sperm count, then the risk of pregnancy in their partner is not zero, thus the male is defined as “subfertile” (3). The term “subfertility” is often used as an equivalent, but more patient-friendly, term for infertility, for example in some countries in Europe and sub-Saharan Africa. WHO recognizes both terms; however, where interchangeable, this report uses the term “infertility”.

Over the past 20 years, the evidence base for best practice has expanded tremendously and clinical practices have changed significantly in the field of infertility, often defined as “reproductive medicine”. Unregulated and non-evidence-based practices occur worldwide in this field. Some of these have potentially fatal outcomes, e.g. multiple pregnancies that can lead to premature births and potentially fatal ovarian hyper-stimulation syndrome (OHSS). Also, HIV-affected serodiscordant couples are living longer and requesting access to reproductive health interventions that avoid transmission to a partner and future child. However, the diagnosis, management and treatment of infertility are complex. They require analysis of not just one individual since the successful outcomes of reproductive medicine interventions are healthy partners, parents and children. The RHR Department, including HRP, has begun conducting systematic analysis and research to assess the conditions that impinge on fertility and best practice interventions.

Lastly, policies, systems and services for infertility care are often extremely limited or non-existent in public health, especially in low- and middle-income countries. The Department is therefore undertaking research to develop self-explanatory tools that will assist countries to independently integrate the upcoming infertility guidelines and best practice for fertility care with an objective to ensure healthy outcomes for partners, mothers and newborn babies.

Major achievements

• The current basic Consolidated Standards of Reporting Trials (CONSORT) guidelines for clinical trials have been identified for modification when reporting studies with interventions to resolve infertility. In 2014, as a founding member of the Infertility Harbin Consensus Group, the Department provided technical support in the generation of the SHORT and LONG versions and adaptations of the basic CONSORT guidelines for clinical trials, defined as “Improving the reporting of clinical trials of infertility treatments” (IMPRINT). These IMPRINT CONSORT guidelines are being endorsed by journals that publish reproductive medicine studies.

3.9.2 Research and development

3.9.2.1 Development and pilot study of the Rapid Assessment Tool

Fertility problems can be a result of medical, genetic, congenital, environmental and/or lifestyle factors. Because of this, multiple programmes are needed to diagnosis, manage and treat infertility, spanning different health systems. Simple fertility-awareness methods are needed, targeted at the individual, community and primary-care levels for appropriate referral, as fertility problems can be prevented or efficiently managed early through affordable and timely interventions. There is a need for mid-level interventions (i.e. basic semen evaluation, techniques such as vaginal insemination), and, advanced methods associated with in vitro fertilization
(IVF) are required to resolve male factor and female tubal factor infertility, the most common fertility problems in low- and middle-income countries. Implementation research is required to develop an adaptable self-explanatory tool for governments to be able to introduce infertility guidelines that cover fertility-care awareness, and an assessment to provide affordable infertility interventions within health policies, systems and services.

**Progress**

The Department technically supported consultations to scope the requirements for successfully integrating in/fertility care into existing health systems. Following the success of the innovative Rapid Assessment Tool for sexual and reproductive health and HIV links in 2009 (4), in 2012, a decision was made to begin research to develop a new Rapid Assessment Tool for the integration of in/fertility care into their health policies, systems and services. The first research protocol was developed in 2012 and subsequently approved by the Research Project Review Panel. Following a call for grants, funds were secured and, in late 2013, a Steering Committee was convened to begin drafting the Tool.

During 2014, the Department collaborated with the Zambia WHO Country Office and held two discussions with the country's Ministry of Health. This resulted in support for Zambia to field-test the Rapid Assessment Tool, as soon as additional funding is secured in the Department. New drafts of the Tool were generated during side-meetings with American Society for Reproductive Medicine (ASRM) and the European Society for Reproduction and Embryology, and discussions concluded that the WHO best-practice algorithms and guidelines, currently being developed by the Department's Infertility Guidelines Development Groups, would need to be incorporated into the tool before any field-testing could be initiated.

**Planned activities**

- The Rapid Assessment Tool for the integration of in/fertility care into policy, systems and services will be finalized and field-tested in 2015, once funding is secured.
- A third consultation of the Steering Committee will be held in 2015 to prepare the final tool capable of adaptability and Member State self-assessment.

**3.9.2.2 Infertility and intimate partner violence**

Although many factors negatively influence women's health, violence is one whose importance cannot be overstated as it is a fundamental violation of women's rights. In 2013, WHO released a report on global and regional estimates of violence against women (5). This report recommends that previously unidentified risk factors for intimate partner violence (IPV) be identified and systematically reviewed, so that appropriate interventions can be designed and implemented within health systems.

**Progress**

The body of evidence that has been amassed suggests that infertility may be a formerly unrecognized risk factor in IPV. The Department undertook a systematic assessment of the available evidence on associations between infertility in women of reproductive age and the risk of experiencing IPV. This confirmed that infertility is a risk factor for IPV in low- and middle-income countries, and potential drivers of
this are likely to include the social, cultural and economic consequences that often accompany female infertility.

Additional research is required to explore this association further. Prospective studies should establish a temporal sequence between the diagnosis of infertility and the onset of IPV, and segregate outcomes based upon whether the man or the woman is the infertile partner. These findings, submitted by the Department as an abstract, were granted an oral presentation at the European Society for Reproduction and Embryology, in Munich, Germany.

**Planned activities**

- The manuscript reporting results from this review will be submitted to a journal for peer-review and publication in January 2015.

**3.9.2.3 Research protocol development for HIV-serodiscordant couples who desire a child**

Recent WHO prevalence data has found that infertility prevalence remains high in low- and middle-income countries, and within settings of high HIV prevalence (2). The burden of infertility or fertility problems in HIV-affected individuals is unknown. Health-care providers can be reticent in recommending a fertility evaluation or access to care for HIV-affected individuals desiring a child.

**Progress**

The Scientific and Technical Advisory Group (STAG) recommended more research on how to expand safe reproductive options for HIV-serodiscordant couples desiring a child. In 2014, the Department co-authored and published two research articles: “Promoting reproductive options for HIV-affected couples in sub-Saharan Africa” (6) and “Achieving pregnancy safely with a perspective on timed vaginal insemination among HIV-serodiscordant couples and health care providers” (7).

In 2014, after a successful research application, the Department provided technical support for a consultation dedicated to addressing key research questions for fertility interventions for HIV-affected serodiscordant couples. Barriers to care and research gaps that address gender, rights, ethical and social issues were identified.

**Planned activities**

- A commentary entitled “Safer conception for HIV-affected couples: a new strategy to help eliminate mother-to-child transmission of HIV” has been written and will be submitted to a journal for peer-review and publication in early 2015.
- After providing technical support for a research analysis that showed an extended time-to-pregnancy in HIV-positive women attempting pregnancy, additional research is under way to modify and extend this analysis to a further 11 high-burden HIV countries.

**3.9.3 Norms, standards and tools**

**3.9.3.1 Development of comprehensive evidence-based guidelines for the diagnosis, management and treatment of infertility**

The mandate for providers of reproductive health care includes fertility care for desired pregnancy. The Department is in the process of a systematic review of the clinical
research literature to assist in the development of evidence-based comprehensive guidelines in the field of infertility and identification of key research gaps.

**Progress**

A Guidelines Development Group (GDG) Steering Committee was formed and has scoped the field into 26 topics, which cover all aspects of comprehensive infertility care. Prioritizing these topics, and scoping and prioritizing researchable questions, has been accomplished through a WHO-approved global consensus process. This process had incorporated a broad spectrum of reproductive medicine specialists through WHO side-consultations at annual regional and international conferences, as well as, the process being incorporated into an online infertility evidence-based course for 86 developing country participants during 2013 and 2014, run in collaboration with a nongovernmental organization (NGO) in official relations with WHO.

During 2013 and 2014, the Department developed Guidelines Development sub-Groups and supported systematic research reviews in the following seven priority areas: female infertility, diagnosis and management; male subfertility diagnosis and management; controlled ovarian stimulation (COS) for assisted fertility; intrauterine insemination (IUI) with and without COS; IVF and intracytoplasmic sperm injection (ICSI); polycystic ovary syndrome (PCOS); and interventions for HIV-affected serodiscordant couples who desire a child.

The GDG Steering Committee held side-meetings with Guidelines Development sub-Groups during regional and international meetings in 2014, as well as an official WHO meeting in Geneva, from 1–5 December 2014. The Committee and Chairs of prioritized sub-groups met to assess the current status of systematic reviews, meta-analyses, draft recommendations, GRADE tables and algorithms, evidence tables and identification of research gaps. The editor-in-chief of *Human Reproduction Update* worked with the GDG Steering Committee to develop a format for presenting the seven prioritized topic areas for submission to the journal and for discussion of additional future peer-reviewed publications.

As part of the Infertility Harbin Consensus Group, the Department developed two articles to address the reporting requirements for clinical research trials in infertility – with a critical requirement to ensure that the health of the newborn child is an outcome indicator. The basic CONSORT guidelines contain several areas of uncertainty about what to report, given the multiple individuals involved (i.e. donating partners, man, woman, child). As a result of deliberations with the Harbin Group, new CONSORT adaptations were developed and published in two simultaneous articles in journals, and endorsed by other journals in the field: (i) SHORT: Improving the reporting of clinical trials of infertility treatments (IMPRINT): modifying the CONSORT statement and (ii) LONG: Improving the reporting of clinical trials of infertility treatments (IMPRINT): explanation and elaboration of the modification of the CONSORT statement (8, 9). Adherence to IMPRINT guidelines on trial reporting will significantly help in generating more robust evidence in the field of in/fertility in future, and will include critical outcome indicators addressing the health of partners, men, women and children.

**3.9.3.2 Female diagnosis and management for infertility and subfertility**

Trials addressing the clinical diagnosis of infertile females are sparse, so collecting data to support evidence-based recommendations for diagnosis is challenging.
Progress

Thirteen systematic reviews (with meta-analysis where appropriate) were either completed or ongoing in 2014. A new algorithm has been developed for managing the female with fertility problems, within which each review has been strategically positioned to ensure any WHO recommendations address key interventions at decision-making stages and are able to highlight critical research gaps.

In 2014, the Department’s Gender and Rights Advisory Panel (GAP) recommended that the Department hold a consultation and prepare a background paper to develop a research agenda on the gender and rights dimensions and implications of surrogacy – a transnational gender and human rights phenomenon. The GDG Committee tasked the female infertility GDG sub-group to prepare the basis for this discussion on surrogacy and provide a systematic review of the evidence.

3.9.3.3 Male diagnosis and management for infertility and subfertility

Most causes of male infertility are due to low sperm counts, poor sperm quality (motility) and abnormalities in the sperm found in semen, in addition to genetic defects, hormonal aberrations and anatomical problems. Age, lifestyle, complications caused by HIV and sexually transmitted infections (STIs), and environmental impacts also contribute to male infertility.

Progress

In 2014 six systematic reviews (with meta-analysis where appropriate) were initiated. A draft algorithm for the clinical management of the male was initiated, two additional systematic reviews begun, and research began to revise the baseline semen values required for designating male fertility.

3.9.3.4 Polycystic ovary syndrome

In approximately 80% of females with anovulatory infertility, this is suspected to be due to the presence of polycystic ovary syndrome (PCOS). PCOS has been estimated to be present in 12–21% of females of reproductive age (10). Not all women with PCOS are infertile, but those who have it often experience a significantly longer time to pregnancy, thus complicated by a decrease in ovarian reserve due to aging that may affect pregnancy success and child outcomes.

Progress

The PCOS Australian Alliance recently published Evidence-based guidelines for the assessment and management of PCOS (11). The WHO analysis was built upon this review. The WHO scoping and prioritization process prioritized 17 clinical research questions; if the question had already been addressed by the Alliance, a systematic research analysis was performed in 2014 using the same search strategy. If the clinical research question was not previously addressed, a new search strategy was developed and performed. Although many research reviews and meta-analyses were completed in 2014, additional reviews and identification of key research gaps are in progress.
Intruterine insemination (IUI) is a procedure for treating: females with ovulation problems; a male partner who is unable to ejaculate or experiences premature ejaculation; a female without a male partner; and couples with unexplained infertility. It includes couples with physical disabilities or couples wishing to avoid a chronic and non-curable STI.

In vitro fertilization (IVF) procedures incorporate the collection of eggs from the ovaries and sperm from semen, leading to co-culture outside the uterus, which results in fertilization. ICSI involves identifying and isolating a single sperm, which is injected into the cytoplasm of the egg in an attempt at fertilization – a procedure that has revolutionized treatment for male infertility.

Success rates for IVF for females have greatly improved. This is mostly due to COS, which induces multiple follicle development, followed by the use of mid-luteal phase gonadotropin-releasing hormone agonists to achieve pituitary down-regulation. Multiple COS protocols exist to address the high rates of heterogeneity in female ovarian responses, and to avoid overstimulation of ovaries – thus avoiding potentially fatal OHSS.

**Progress**

(i) IUI with and without COS

Fourteen research questions were prioritized. Ten systematic reviews have been completed in 2014, the data collated and analysed, and, where possible, meta-analysis completed. Draft algorithms are being linked to the male and female algorithms for diagnosis, management and treatments.

(ii) IVF and ICSI

Out of 11 research questions prioritized, nine systematic reviews of the evidence were completed. Draft algorithms developed in 2014 are being linked to both the male and female algorithms for diagnosis, management and treatment.

The indications for using IVF have expanded beyond female tubal disorders (its original purpose) to many causes of subfertility, including unexplained infertility. To highlight these issues, an article entitled “Are we overusing IVF?” was written by the Evidence-Based IVF Group (of which the Department is a member) and published in the British Medical Journal in 2014 (12).

(iii) COS

Four out of seven systematic reviews were completed, the data collated and analysed, and, where possible, meta-analysis completed in 2014. A draft algorithm is in process of being developed and will link to the female diagnosis, management and treatment algorithm, IUI and IVF/ICSI.
3.9.3.6 Fertility assessment interventions for HIV-serodiscordant couples

If antiretroviral therapy is able to suppress the expression and transmission of the virus in an HIV-affected individual or an HIV-affected partner, then unprotected sex between HIV-serodiscordant couples presents a low risk of transmission to the unaffected partner and fetus. However, the ability to fully suppress viral load and the realistic management of HIV are less than optimal in many high-burden low- and middle-income countries. Thus, HIV-serodiscordant couples, and HIV-affected individuals with partners of unknown status, in these countries knowingly risk HIV transmission to a potentially uninfected partner in order to achieve pregnancy. This has been identified as a contributing factor in the HIV epidemic, particularly in HIV high-burden countries.

Progress

The Department secured external funding to partially support a cross-disciplinary meeting in December 2014 on pre-pregnancy and fertility care for HIV-affected individuals and HIV-serodiscordant couples – addressing both pharmaceutical options (antiretroviral drugs) as well as fertility interventions in order to reach zero transmission of HIV. Three systematic reviews with meta-analysis were discussed, and additional key research questions scoped and prioritized. Addressing “values and preferences” was identified as especially important in future research evaluation of the evidence, when research gaps are identified, and the importance of being based within concepts of rights, gender and social issues was also highlighted.

3.9.3.7 Planned activities for all norms and guidelines in infertility

- The Department will finalize all research questions through the completion of all relevant systematic reviews and identification of reviews to be developed for peer-reviewed publications.

- A final review of systematic reviews and research evidence and the identification of research gaps will be undertaken, and the integration of algorithms of best-practice and accompanying documentation will be reviewed and debated during a global consensus meeting in 2015.

- During regional fertility congresses in June and October in 2015, additional side-meetings and consultations will be held to finalize all documents and articles, and prepare for dissemination.

- A process will be developed to scope and prioritize the research gaps identified – within and across these sets of infertility guidelines – including those associated with HIV-affected individuals, in collaboration with the HIV Department.

- In 2014, STAG recommended that the psychosocial, gender, equity and rights issues be highlighted in in/fertility care initiatives. The human rights advisor in the RHR Director’s Office contributed to the December 2014 meetings, and will continue to assist to address gender, equity and rights issues, with priority given to the topic of surrogacy (as recommended by GAP).
3.9.4 Monitoring and evaluation

Progress

The Department is providing technical support to the International Federation of Fertility Societies (IFFS) for a global survey to monitor trends based on data collected in past surveys, specifically a comparison with the 2010 and 2013 surveys (13, 14). Information collected includes the current status of national policies and regulations associated with assisted reproductive interventions worldwide.

Planned activities

• The Department will provide technical support during the collection of data in late 2015. The results of this latest survey will also inform the final development of the Department's Rapid Assessment Tool for integration of in/fertility care.

3.9.5 Dissemination and partnerships

Progress

• In May 2014, the Department participated in a World Health Assembly (WHA) side-consultation on medical products of human origin (MPHO, which include human products derived from or utilized within reproductive medicine technologies). This led to an early draft of the WHO document Medical products of human origin, which is slated for debate during the Executive Board meeting 136, in January 2015.

• The Department together with the International Committee Monitoring Assisted Reproductive Technologies (ICMART) has developed and is revising a set of terms for monitoring and collection of data from IVF centres worldwide (15, 16).

Planned activities

• As a member of the International Organization for Obstetrics and Gynaecology's Reproductive Medicine Committee (FIGO-RMC), the Department will review the FIGO Fertility Tool Box, a manual of best practice (17). This will be evaluated for consistency with the Department's infertility systematic review outcomes.

• The ASRM was approved at the WHO Executive Board meeting, January 2014, to become the fourth "NGO in official relations to WHO" covering the field of infertility in collaboration with the Department (the other three official WHO NGOs are FIGO-RMC, ICMART and IFFS). Part of the ASRM Plan of Work is to update a joint online course on WHO evidence-based medicine and 16 modules covering the field of infertility. This will be made freely accessible.

3.9.6 References


3.10 Sexual Health

3.10.1 Introduction

The work on sexual health in the RHR Department, including HRP, is an integral part of several key thematic areas such as adolescent sexual and reproductive health, prevention of sexually transmitted infections, elimination of female genital mutilation, and other cross-cutting work such as updating the sexual health aspects of International Statistical Classification of Diseases and Related Health Problems (ICD), 10th revision (ICD-10), and development of ICD-11. A range of sexual-health-related activities are therefore included in the relevant sections of this Annual Technical Report. Two specific activities, exclusively focusing on sexual health are reported in this brief section.

Major achievements

- A WHO guideline was developed: Brief sexuality-related communication: recommendations for a public health approach.
- A report on sexual health, human rights and the law was developed.

3.10.2 Norms, standards and tools

3.10.2.1 Sexuality-related communication guidelines

- In 2010, WHO convened an expert consultation on sexual health to make recommendations on strategic directions for the Department's work in this area. One of the recommended priorities was the development of sexuality counselling guidelines, to be used as a tool to facilitate the integration of this counselling into health services, mainly by primary health-care providers (physicians, nurses and others) and in the context of sexual and reproductive health services.
- The ultimate goal of this initiative is to ensure access to sexual and reproductive health services for all and to ensure promotion of sexual health rather than mere treatment of sexually transmitted infections.

Progress

- The development of this guide required an evidence-informed process and had to be carried out according to the WHO Guidelines Review Committee's (GRC's) standards. This work was conducted throughout 2013 and 2014.
- The systematic review of existing evidence helped in the shaping of recommendations and led the internal review of the draft guidelines at WHO, as well as by an external peer review group.
In 2014, the systematic reviews on interventions to improve sexuality-related communication were finalized, the Guideline Development Group was convened and discussed the range and strength of the evidence and formulated recommendations. The final version of the guidelines have been approved by the GRC and prepared for publication.

**Planned activities**

- Brief sexuality-related communication: recommendations for a public health approach will be published and widely disseminated in 2015.
- The research gaps identified during the development of the guideline will be reviewed for development of further research on the effectiveness of sexuality-related communication techniques for low- and middle-income settings.

### 3.10.2.2 Development of the ICD-11

The process of reviewing the current 10th revision of the ICD-10 to develop the ICD-11 presents a key opportunity. The Department worked with the ICD Secretariat at WHO and the WHO Department of Mental Health and Substance Abuse in facilitating the updates on sexual-health-related conditions within the ICD.

**Progress**

Proposals are being developed jointly with the WHO Department of Mental Health and Substance Abuse and they are being field-tested in five low- and middle-income countries. In addition to the field-testing of the ICD proposals, reviews of national laws, regulation and policies related to proposals for the classification of “Gender Incongruence” and “Paraphilic Disorders” in ICD-11 are being conducted in the five field-testing countries (Brazil, India, Lebanon, Mexico and South Africa), recognizing that medical diagnostic classifications are embedded in a complex legal, regulatory and policy environment. The Department also led the process of developing a new proposed chapter on “sexual health”, comprising conditions previously classified within mental health (e.g. gender identity disorders) and other conditions which may affect sexual health or well-being (e.g. sexual pain disorders). The genito/urinary and reproductive medicine (GURM) Topic Advisory Group (TAG) convened by the Department reviewed this proposal prior to submission to the official ICD-11 commenting website.20

**Planned activities**

- In 2015, the Department will continue working with the TAG to review and incorporate, as appropriate, comments on the new sexual health chapter proposed for ICD-11.

### 3.10.2.3 Sexual health, human rights and the law

In 2010, a report was initiated to elaborate the intersections between sexual health, human rights and laws, and to identify relevant international, regional and national human rights standards that promote sexual health. The report also contributes to the application of international, regional and national laws and human rights standards to sexuality and sexual health. The report is aimed at health policy-makers, researchers and academics.

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20 Available at: http://www.who.int/classifications/icd/revision/en/
**Progress**

An expert consultation reviewed the first draft of the report in 2013, and its recommendations were incorporated during 2014.

**Planned activities**

- The report on sexual health, human rights and the law will be published in early 2015.
4. Cross-cutting topics

4.1 Human rights and gender equality

4.1.1 Introduction

While significant gains have been accomplished in different areas of sexual and reproductive health and human rights and gender equality, challenges remain. The 20th anniversary of the 1994 International Conference on Population and Development (ICPD) Programme of Action and of the 1995 Beijing Declaration and Platform for Action has provided a unique opportunity during 2014 to reflect on the role of the RHR Department, including HRP, in the promotion and protection of human rights and gender equality in relation to sexual and reproductive health (SRH), and to plan for the future.

In 2014, as part of the reorganization process at the Department, the work on human rights and gender equality was moved to the Office of the Director of the RHR Department. This included the appointment of the human rights adviser, who is located in the Director’s Office. This move strengthens the mainstreaming of human rights and gender equality work across different teams in the Department and moves towards realization of the WHO Director-General’s vision of integrating human rights and gender equality into the DNA of everyone.

As an inter-agency body with expertise in SRH, human rights and gender equality, the Department is an authoritative source when it comes to making a contribution to the development, clarification and interpretation of international standards.

Strategic directions and priorities of the Department’s work on SRH and human rights and gender equality are identified to include:

• incorporating human rights and gender equality into the work of the Department, with specific focus on addressing the SRH needs and human rights of vulnerable/marginalized populations;
• developing research on SRH, human rights and gender equality in relation to SRH policy-making, implementation and monitoring and accountability;
• developing tools to support the development of national laws, policies and programmes on SRH;
• providing technical input in response to requests from international, regional and national human rights and other bodies on issues related to SRH, human rights and gender equality; and
• providing assistance in response to requests from governments on incorporation of SRH, human rights and gender equality into their development processes for national laws, policies, programmes and health standards.

Major achievements

• The RHR Department, including HRP, is a key actor on human rights and sexual and reproductive health (SRH) among development partners, including international and regional nongovernmental organizations and academic institutions, and has built partnerships with these actors at the international, regional and national levels.
The Department has contributed to normative development at the international and regional levels on SRH, human rights and gender equality, and remains a significant actor in strengthening the content and meaning of sexual and reproductive health and rights.

The Department has been assisting UN human rights bodies to ensure that their interpretations of international human rights standards are evidence-based and thereby contribute to the improvement of SRH worldwide.

In order to foster the respect, protection and fulfilment of human rights related to SRH, the Department has developed tools that can assist stakeholders to integrate human rights and gender equality into SRH law, policy and programme development and implementation.

The Department has played a leadership role by underscoring the need to achieve and exceed all health-related Millennium Development Goals (MDGs), which include ending preventable maternal deaths and improving SRH, and to ensure that the new development framework, including the Sustainable Development Goals, highlights these priorities as part of completing the unfinished work of the health-related MDGs.

4.1.2 Research and development

A key area of the Department’s work in 2014 related to the development of a research agenda on sexual and reproductive health, gender equality and human rights.

4.1.2.1 Identify research priorities on sexual and reproductive health, gender equality and human rights

As a premiere research institution, the RHR Department, including HRP, makes a unique contribution to the development and advancement of a research agenda on SRH. In 2014, the Department has focused on identifying research priorities and needs in relation to SRH, human rights and gender equality.

Progress

In 2014 formative research was done for this activity and a methodology was finalized to identify research priorities relating to SRH using a human rights and gender equality analysis. Further, discussions were initiated with the Programme on Tropical Disease Research (TDR) to develop joint activities in relation to research on human rights and gender equality as it relates to the work of the two programmes.

Planned activities

- An expert group meeting is planned for January 2015 to identify domains and develop questions for a survey on SRH research priorities using a human rights and gender equality analysis. This will be followed up with a survey in 2015 and a subsequent meeting of experts. The report will be finalized in 2015.

- Further discussions to develop a joint research project with the TDR Programme on human rights and gender equality are planned for 2015.

4.1.2.2 Generic guidance for implementation of sexual and reproductive health programmes based on a human rights based approach

The Department aims to develop action-oriented generic guidance on the operationalization and implementation of SRH programmes based on
human rights and gender equality. The need for such guidance was a key recommendation of the Gender and Rights Advisory Panel (GAP) in January 2014.

**Progress**
Formative research and discussions with key partners were undertaken in 2014 for the conceptual development of the project. Also, linkages were identified with the "knowledge translation for implementation" work led by the Department's Maternal and Perinatal Health and Preventing Unsafe Abortion (MPA) team. Activities for development of the guidance are scheduled for 2015.

**Planned activities**
- Development of generic guidance for implementation of SRH programmes based on human rights and gender equality is planned for 2015. This will include development of a module based on human rights and gender equality for the knowledge translation work led by the MPA team.

**4.1.2.3 Explore the impact of laws and policies on the realization of sexual and reproductive health and human rights**
This is identified as a key overarching priority for 2014–2015 and was also a recommendation of the GAP. This activity will also focus on developing cross-issue dialogue and research on the impact of laws and policies on the realization of sexual and reproductive health and human rights.

**Progress**
The impact of laws and policies on the realization of sexual and reproductive health and rights is being systematically integrated across different areas of work. In particular, research was undertaken to explore the impact of laws and policies in two key areas of work related to SRH: female genital mutilation (FGM), and child, early and forced marriage (CEFM).

**Planned activities**
- A report on laws and policies related to CEFM will be finalized in 2015.

**4.1.3 Norms, standards and tools**

**4.1.3.1 Integrating human rights in key areas of research and normative work for the RHR Department, including HRP**
Great progress has been made in a number of areas in incorporating human rights and gender equality into the technical areas of the Department's work.

**Progress**

(i) Ending preventable maternal mortality
In April 2014, representatives from UN agencies, country governments, development partners and other stakeholders came together in Bangkok at a meeting organized by the RHR Department in collaboration with the UNFPA, the United States Agency for International Development (USAID), the Maternal Health Task Force (MHTF), and the Maternal and Child Health Integrated Program (MCHIP). The meeting was a “Consultation on targets and strategies for ending preventable maternal mortality (EPMM)”. Specifically, the consultation was aimed at forging consensus on maternal mortality reduction targets for inclusion in the post-2015
development agenda, as well as identifying maternal health strategies that will assist countries to achieve those targets. The consensus statement recognizes human rights and gender equality as guiding principles and also identifies the need to ensure accountability to improve quality of care and equity (1).

(ii) Contraception/family planning and human rights

Unmet need for contraception remains high in many settings, and is highest among the most vulnerable in society: adolescents, the poor, those living in rural areas and urban slums, people living with HIV, and internally displaced people. The latest estimates are that 222 million women have an unmet need for modern contraception, and the need is greatest where the risks of maternal mortality are highest (2).

In order to accelerate progress towards attainment of international development goals and targets in SRH, and in particular to contribute to meeting unmet need for contraceptive information and services, WHO has developed guidelines and recommendations on Ensuring human rights in the provision of contraceptive information and services (3). WHO has also finalized a process for using quantitative indicators for rights-based monitoring of contraceptive services and information; a report has been published (4). A joint implementation guide for the WHO guidelines is being developed with UNFPA and will be released in 2015. WHO is also working closely with partners on the Denmark-led initiative on family planning and contraception at the Human Rights Council.

(iii) Adolescent sexual and reproductive health

An estimated 16 million births occur to young women aged 15–19 years, representing 11% of all births. About 12% of adolescent girls in low- and middle-income countries are married by the age of 15, and as many as 30% are married by the age of 18, increasing their risk for adverse health consequences of early pregnancy.

The Department is leading on key initiatives in this regard. The Department led on an initiative to document best practice examples of large-scale and sustained implementation of programmes providing SRH education and services to adolescents. As a flagship project, the Department is working on developing an intervention study to prevent adolescent pregnancy. The Department is also leading on a study to examine the nature of sexual development in early adolescence, including gender socialization, and its effect on relationship formation and sexual behaviour in later adolescence (for further details see section 3.2: Adolescent reproductive and sexual health).

The Department also led an initiative to review the effect of legislation on the practice of child marriage in Africa. A report on this subject was submitted to the Inter-Parliamentary Union (IPU). The Department is also working on identifying research priorities on child marriage. The initiative focuses on identification of research priorities on levels and trends, causes and consequences, effective approaches to prevent child marriage and to respond to child brides, and understanding child marriage in a broader context. The Department also supports an ongoing initiative in this regard at the UN Human Rights Council.

(iv) Prevention of unsafe abortion

HRP has been disseminating the 2012 WHO safe abortion guidance document to UN treaty monitoring bodies (5). A successful meeting was organized with the
Committee Against Torture (April 2014) and WHO’s recommendations are reflected in recent concluding observations (6).

A technical meeting was organized for international and regional human rights bodies in April 2014. A meeting was also organized with members of the Committee on the Rights of Persons with Disabilities (CRPD) to discuss issues related to SRH, particularly abortion and sterilization in relation to women with disabilities (June 2014).

**Planned activities**

- Key priorities for the work on integration of human rights and gender equality for 2015 include the development of guidelines on: women living with HIV or other sexually transmitted infections (STIs); SRH; quality of care; FGM; and contraception and family planning.

- A report on sexual health, human rights and the law will be published in early 2015 (see sub-section 3.10.2.3, in section 3.10: Sexual health).

**4.1.3.2 Contribution to the development and interpretation of human rights standards in relation to sexual and reproductive health**

2014 saw some key developments regarding the promotion and protection of SRH and human rights by ensuring integration of these issues across the key international human rights and developmental processes.

**Progress**

The RHR Department continued to support treaty monitoring bodies (TMBs) in their work on SRH. This included ongoing support to the UN Committee on Economic, Social and Cultural Rights (CESCR) in the development of their draft General Comment on the right to sexual and reproductive health.

The Department also contributed to the development of the Committee on the Rights of the Child’s General Comment on the right of the child to the highest attainable standard of health, which was adopted by the Committee in February 2014 (7).

HRP collaborated with the Office of the UN High Commissioner for Human Rights (OHCHR), including attending a session at the Human Rights Council on criminalization and unsafe abortion, organized by Action Canada for Population and Development and the Center for Reproductive Rights.

Significant contribution has been provided to the implementation of the 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, developed by OHCHR and its partners (8). The Department is actively contributing to the country implementation of the guidance. The guidance is being applied in four countries in southern Africa (Malawi, South Africa, Tanzania and Uganda).

The Department developed a series of briefs21 on different areas related to SRH in the context of the “ICPD Beyond 2014” review process and also a position paper (9). We also organized a regional briefing at the WHO Regional Office for Africa on ICPD Beyond 2014, linking also to the discussions on the post-2015 development agenda.

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21 Available at: http://www.who.int/reproductivehealth/icpd/en/
Presently, we are working on the “Beijing+20” review in relation to women’s health for the next WHO Executive Board, in 2015.

**Planned activities**

- In 2015 continued support and engagement with OHCHR is planned for implementation of the technical guidance on human-rights-based approach to maternal mortality and morbidity and the development of the CESCR General Comment on sexual and reproductive health and the CRPD General Comment on women with disabilities.
- Dialogue is planned with UN TMBs on the issue of criminalization of sexual and reproductive health services and information.
- Continued engagement is planned for the work on Beijing+20 at the World Health Assembly on women and health and on sexual and reproductive health and rights in the context of the discussions on the post-2015 development agenda.

**4.1.3.3 Finalization and dissemination of the RMNCH and human rights toolbox, and the interagency statement on forced sterilization**

**Progress**

- In 2014, the Department released *Reproductive, maternal, newborn and child health and human rights: a toolbox for examining laws, regulations and policies* (10). The first module specifically focuses on sexual and reproductive health and rights. Field-test reports from Moldova, Sri Lanka and Tajikistan have been launched at the country level and are being published nationally. The Toolbox was disseminated to Member States, UN agencies, international and regional organizations, donor agencies and civil society organizations. It has already been used by the Population Council as part of their Strengthening Evidence for Programming on Unintended Pregnancy (STEP UP) project. In addition, the Toolbox will be used to assist the implementation of the OHCHR technical guidance on preventable maternal mortality in several countries, with special attention to eastern Africa.
- An interagency statement on *Eliminating forced, coercive or otherwise involuntary sterilization* was finalized and published by WHO in 2014 (11). At WHO, the RHR Department worked on this statement in collaboration with the Department for NCDs, Disability, Violence and Injury Prevention (NVI), following an expert consultation on this issue. The guidance has been disseminated to different TMBs and other partners.

**Planned activities**

- A checklist and accompanying module on newborn and child health are under development for the RMNCH and human rights toolbox.

**4.1.4 Dissemination and partnerships**

**4.1.4.1 Partnerships with UN agencies and other partners on human rights and gender equality**

Developing and strengthening close partnerships and establishing joint programmes of work on human rights and gender equality has been core to this area of the RHR Department’s work in 2014.
Progress

The Department participated regularly in the ICPD Geneva Network, jointly organized by Ethiopia and the Netherlands. The Network facilitated close partnership with different actors for promotion and protection of SRH, human rights and gender equality. The Department also organized several joint activities (side-events at the World Health Assembly, Commission on Population and Development, United Nations General Assembly) with OHCHR, UNFPA and other partners, and a close partnership was developed with a range of stakeholders on different projects related to SRH, human rights and gender equality.

Planned activities

- Enhanced partnership and collaboration is planned with partners for 2015. Joint activities and partnerships have been identified to support different areas of work linking SRH to human rights and gender equality.

4.1.5 References

4.2 Innovations

4.2.1 Introduction

Reproductive health innovations can: reduce barriers to accessing reproductive health services; improve the quality and/or reduce the cost of services, making critical services and timely information more accessible; and improve the efficiency and effectiveness of health-care providers. Innovations play a critical role in helping to realize universal coverage of reproductive health, and often provide the tools needed to monitor progress towards the Millennium Development Goals (MDGs) and the post-2015 Sustainable Development Goals (SDGs).

To support health systems innovations, the RHR Department, including HRP, aims to:

• foster the development and validation of innovations that improve sexual and reproductive health in populations with the greatest need;

• develop and support mechanisms that improve the awareness, availability and use of innovations that improve sexual and reproductive health; and

• support research that aims to understand and overcome barriers that prevent innovations from achieving widespread adoption.

The following sections summarize the key activities and products carried out and delivered during 2014, and the plans for 2015 to achieve the Department’s goals and mission. This section focuses on the Department’s work related to the use of digital innovations, while specific health intervention innovations are reported in sections covered by other health domain areas in the report.

Major achievements

• The RHR Department launched the Technologies for Health Registries, Information, and Vital Events (THRIVE) Multi-site Study.

• The mRegistry web platform was launched by the RHR Department, the UN Innovations Working Group, UNICEF, and other partners, for systematically registering and cataloguing mHealth initiatives for reproductive, maternal, newborn and child health (RMNCH) and other health areas.
• The Department and partners launched the Open Smart Register Platform website\(^\text{22}\) – the smartphone-specific version of an application focused on civil registration and vital statistics (CRVS).

• Articles reporting on the Department’s work in this area were published in Science, PLOS ONE and Politico, as well as a chapter in a book published by Oxford University Press.

4.2.2 Research and development

4.2.2.1 mHealth innovations

Progress

(i) Dristhi research project

The Dristhi research project, initiated in 2012, used formative research and user-focused design to develop the “Dristhi mHealth intervention” in Karnataka, India. This was undertaken in collaboration with Columbia University and the Foundation for Research in Health Systems, with support from the Wellcome Trust, the Bill & Melinda Gates Foundation, WHO HRP and Norad, and in partnership with India’s Ministry of Health and Family Welfare, ThoughtWorks and Ona. Initiated in 2014, the cluster-randomized controlled study part of the project focuses on understanding the implementation requirements and effect of the intervention on coverage and quality improvements of routine RMNCH interventions among auxiliary nurse midwives in a disadvantaged region of Karnataka.

(ii) Technologies for Health Registries, Information and Vital Events (THRIVE) Multi-site Study

The THRIVE Multi-site Study is a formative research study that focuses on needs assessment, adaptation and pilot evaluation for deploying the Open Smart Register Platform (OpenSRP) across four sites. The OpenSRP is a digitized electronic register system that combines data collection, client management, and reporting workflows into one activity for frontline health workers. This multi-site formative research aims to generate the information needed to test and adapt the OpenSRP, and the technical and coordination mechanisms to facilitate this in a sustainable manner. The research results will be used to refine the OpenSRP for use across diverse health systems, and across interventions in the RMNCH continuum of care. The findings will also identify factors affecting the deployment of the Platform, the necessary steps for adaption, and the development of subsequent rigorous evaluations for measuring its impact, cost-effectiveness and scalability. The first phase (which will last two years) of the two-phase research study commenced in late 2014 in three research sites: Bangladesh, Indonesia and Pakistan. The Department is actively searching for funds and a research site to be able to include a site in the WHO African Region.

(iii) UN Innovations Working Group mHealth catalytic grant mechanism implementation research

The Department continues to play a leading role in this global initiative, which is a partnership with the UN Every Woman Every Child Innovations Working Group (IWG) and the UN Foundation. The Department’s role is to provide technical and research

\(^{22}\) http://smartregister.org/
assistance to 26 mobile technologies for health (mHealth) projects on maternal and child health that began in 2012. The Department strengthens the capacity for innovative mHealth projects to generate and use evidence to realize positive effects on women’s and children’s health at scale, while becoming financially sustainable. In 2014, the Department held three workshops with project grantees. The first, held in Bangladesh, concentrated on partnering with government to achieve institutionalization. The second was held in South Africa and looked at measuring costs, as well as the economic benefits of mHealth interventions. The third, held in the USA, focused on building new partnerships with financial and donor institutions.

**Planned activities**

- In 2015, the Department will conduct information and workflow mapping of the civil registration and vital statistics (CRVS) systems among frontline health workers in Bangladesh, Indonesia and Pakistan, in order to understand mechanisms to strengthen CRVS from the health sector.
- The Department will also conduct costing and health economics research for three or more IWG grantee mHealth projects that are focused on reproductive health, in order to develop a standardized costing tool, and generate evidence of the cost–benefit of mHealth interventions in RMNCH.

### 4.2.3 Norms, standards and tools

#### 4.2.3.1 mHealth for RMNCH

**Progress**

(i) Evidence synthesis and guidance development

The Department commissioned three separate studies to evaluate: the evidence in support of mHealth strategies for strengthening adolescent sexual and reproductive health; the role and effect of mHealth interventions on health provider effectiveness for facility-based delivery; and the role and effect of mHealth strategies on supply chain management, using evidence-grading criteria developed by the RHR Department’s mHealth Technical and Evidence Review Group mechanism.

The Department also convened the second meeting of the Technical and Evidence Review Group on mHealth for RMNCH (mTERG). The mTERG group conducted systematic reviews, revised mTERG methodologies, and outlined the scope of a WHO guidance document on using mHealth strategies to catalyse the potential for universal coverage of RMNCH interventions (i.e. the “Green Book” guidance document).

(ii) mRegistry

The Department supported the development and launch of “mRegistry”\(^{23}\), a web-based tool to uniquely register, categorize and classify all mHealth projects. This allows any user to submit a project and obtain a unique identification number. They will also have the data detailing their RMNCH mHealth project plotted and visualized on a standardized framework aligned to essential RMNCH interventions and defined common health systems constraints.

\(^{23}\) Available at: www.mregistry.org
Cross-cutting topics

(iii) mHealth for Assessment and Planning for Scale (MAPS) tool

The Department developed the mHealth for Assessment and Planning for Scale (MAPS) tool to provide a structure for the assessment and planning activities that are critical for successfully scaling up mHealth for RMNCH deployments. The tool helps project teams to put the factors that influence scale into operation. These include: assessing an innovation’s scalability; identifying areas that require further investment; and using tools that facilitate the planning of future activities. The MAPS tool was introduced at an IWG workshop (October 2014) to gather feedback from mHealth implementers and further inform and refine the domains of relevance to measurement and assessments of mHealth project scale-up. The MAPS tool will be further refined with expert groups and validated with additional projects in 2015 before publication in the third quarter of 2015.

Planned activities

- In 2015, the Department will further refine, validate and finalize the MAPS tool by using mHealth projects to test the relevance of specific domains that are critical to assessment of scale up, among IWG grantees.
- The Department will produce the second iteration of “mRegistry” to include geographic information systems (GIS) mapping and project management, and also integrate other tools for costing as well as the MAPS tool.
- The Department will work with WHO colleagues in other departments to integrate mHealth as a module into the WHO OneHealth financial planning tool.
- Three additional areas of evidence classification and systematic evidence synthesis will be developed: ASRH, demand generation, and decision-support tools.
- The Department will develop a WHO guidance document on mHealth for RMNCH universal health coverage (UHC) (“Green Book”).
- Through the mTERG, the Department will collaborate with other parts of WHO and UN partners and partner agencies in the creation of an interagency technical mechanism to support Member States investments in the informed use of mHealth strategies towards strengthening achievement of RMNCH and UHC goals.

4.2.4 Monitoring and evaluation

Progress

(i) IWG catalytic grant mechanism

The Department provided monitoring and evaluation (M&E) technical assistance to the 18 remaining grantees in partnership with the UN Foundation, as requested by the IWG mHealth project grantees. This covered areas including evidence claims alignment and status review, and indicator development and alignment.

(ii) Process and coverage indicators for RMNCH essential interventions

The Department worked with the Norwegian Institute of Public Health to develop standardized process and coverage indicators for each essential RMNCH

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intervention. These are appropriate for use by mHealth and information and communication technology (ICT) systems, including reproductive registries.

**Planned activities**

- In 2015, the Department will provide M&E technical assistance to 10 selected IWG grantees. A critical output from this will be the development of an M&E workbook that draws on experiences of providing M&E support to IWG projects. This will facilitate the robust use of M&E approaches, and will include specific indicators linking mHealth tools to performance metrics to guide M&E among the wider mHealth community. Johns Hopkins University Global mHealth Institute (JHU-GmI), a partner in this effort, will support a sample of grantees in the following areas: impact assessment; costing and cost-effectiveness analysis; process documentation and evaluation; and other areas identified by partners.

- The Department will create a standardized costing tool specific to mHealth, to allow projects to track financial costs and plan and model the scaling up of mHealth approaches.

**4.2.5 Dissemination and partnerships**

**4.2.5.1 UN Innovations Working Group**

**Progress**

The Department led a panel discussion on “Knowledge sharing mechanisms, implementation research tools, and lessons learned from grantees of the UN Innovations Working Group Catalytic mHealth Grant Mechanism for MDGs 4 and 5” at the Third Global Symposium on Health Systems Research, Cape Town South Africa in September 2014. This highlighted the grantee projects’ experiences of scaling, making projects sustainable, and institutionalizing maternal and child health mHealth innovations. The emphasis of these meetings were on the value of partnerships in achieving scale. Drawing on these experiences and on research related to the 24 mHealth projects within the grantee learning community, the panel showcased three mature projects (Interactive Research and Development [IRD], Mobile Alliance for Maternal Action [MAMA], and mTrac) to detail elements critical to scaling and institutionalizing mHealth within a health system.

In 2014, Department staff published the following, related to mHealth innovations:

- “Prioritizing integrated mHealth strategies for universal health coverage”, an article published in Science magazine’s September 2014 special issue on global health (1). The article outlines a way for global stakeholders to view and prioritize how the use of mHealth can help to achieve universal health coverage.

- “Harnessing mHealth in low-resource settings to overcome health system constraints and achieve universal access to health”, a chapter in the book Behavioral health care and technology: using science-based innovations to transform practice (2).

- “Using the Lives Saved Tool (LiST) to model mHealth impact on neonatal survival in resource-limited settings”, and article published in the journal PLOS ONE (3, 4).

**Planned activities**

In 2015, the Department will publish:
• three mTERG documents: the mHealth grading criteria; the mHealth taxonomy; and the evidence synthesis of three systematic reviews on the role of mHealth on specific maternal and adolescent health priority areas;

• WHO guidance on mHealth for strengthening the potential for RMNCH UHC; and

• guidance on mHealth project engagement with mobile service operators to drive scale.

4.2.6 References


4.3 Biostatistics and data management

4.3.1 Introduction
The Biostatistics and Data Management Unit provides support for statistical and data management to research projects of the RHR Department, including HRP, and supports research capacity-strengthening in biostatistics and data management. The services of the Unit contribute to the quality of the Department’s research projects. The work is focused on technical support for research projects, and capacity-building for collaborating institutions in low- and middle-income countries.

Major achievements
• Statistics, data-management, research-coordination and monitoring support was provided for 16 clinical trials and epidemiological studies during 2014.

• The Unit conducted on-site research training on data entry and data management for staff in three collaborating centres participating in projects with the Department, in Kyrgyzstan, Mozambique (twice) and South Africa.

4.3.2 Support for research activities
The Biostatistics and Data Management Unit provides technical support in biostatistics and data management for protocol development and review, including: advice on study design (including case-report forms); 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 Unit also develops and deploys a comprehensive monitoring and data quality-assurance programme, and trains project research teams in these areas.

4.3.2.1 Technical support for clinical trials and epidemiological studies

Progress

During 2014, support was mainly provided to 15 projects of the Department. The following is a summary of the statistics and data-management support that has been and/or is being provided to each of these research studies.

• **Peri-coital oral contraception with levonorgestrel: a prospective, open-label, single-arm, multicentre study to evaluate efficacy, safety and acceptability:** Data collection and analysis were completed in 2014. The data set has been cleaned and final analysis has started. The principal investigators meeting is planned for January 2015 to discuss the trial results.

• **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 final analysis of the data set was completed and the first draft of the manuscript is being discussed by the research team members. The Unit participated in the principal investigators meeting in Morgon, France (May 2014), and in the writing of the manuscript.

• **A demonstration project for the implementation of the WHO antenatal care model in Mozambique: a cluster randomized controlled trial:** Data collection is ongoing at 10 clinics. Nearly 100 000 antenatal care visits have been registered in the study logbook and copies have been uploaded to Dropbox. The trial intervention has been deployed in four clinics. On-site monitoring and refresher training sessions by our Unit for the local data management teams were conducted twice in the country during 2014.

• **Non-inferiority of short-term catheterization following fistula repair surgery:** The manuscript has been accepted for publication by The Lancet, but not yet published. The Unit was also involved in a secondary analysis with the objective of trying a new fistula classification using cluster analysis; a data set from another observational study will be included in this secondary analysis.

• **Feasibility and safety study of a new device (Odón device) for assisted vaginal delivery (phase I trial):** Data collection is ongoing in Argentina to test the safety and feasibility of the device. Data sets for the first and second recruitment periods are completed and ready for data analyses.

• **A randomized, placebo-controlled study of prophylactic ibuprofen in addition to a pain-control regimen for early medical abortion with mifepristone and misoprostol:** The revised protocol was approved (including revised sample size and randomization procedure), and the design of the data collection forms was completed. The data management system is being developed using the OpenClinica system.

• **Training midwives in Kyrgyzstan to provide safe abortion care with mifepristol and misoprostol:** Study material is complete, including data
forms, data-management system, standard operating procedures and a study manual. Data-management training was conducted in August 2014 and data collection started in early September 2014.

- **Addressing violence against women in antenatal care: testing an intervention in South Africa and Mozambique:** Data collection started in May 2014. A data-management system and study materials have been developed. The recent change in the data collection system (Open Data Kit) suggested by the Steering Committee – to add the Audio Computer-Assisted Self-Interview (ACASI) system – is being implemented. Utility to transfer data from the data-collection system to the data-management system (OpenClinica) is being developed. Data collection is being continuously monitored.

- **WHO randomized trial of calcium supplementation before pregnancy to reduce recurrent pre-eclampsia:** Data management has been outsourced to Centro Rosarino de Estudios Perinatales (CREP), Argentina, and is being supervised by the Unit; the Unit has also been involved in a secondary analysis to assess the possible effect of calcium on prepregnancy blood pressure.

- **The introduction and impact of the careHPV™ test into cervical cancer prevention and control programmes based on visual inspection with acetic acid (VIA) and cryotherapy:** The Unit participated in the finalization of study materials (data forms and standard operating procedures). The International Agency for Research on Cancer (IARC) data-management system was evaluated, and recommendations were made to enhance the system with additional audit trail and correction modules.

- **Carbetocin RTS (room temperature stable) for preventing postpartum haemorrhage: a randomized non-inferiority controlled trial.** The principal investigators meeting was held in September 2014 to discuss the protocol and the conduct of the trial in 12 collaborating countries. The protocol has been revised and submitted for approval. The data management for this trial was outsourced to CREP; however, the overall management of the trial data and the control of the data quality as well as the data management system will be the Unit’s responsibility.

- **Multicentre randomized clinical trial of two implantable contraceptives for women, Jadelle® and Implanon**: A revised statistical analysis plan (SAP) was prepared to account for the censoring process at the planned three-year follow-up and end of study. Final analysis of the revised SAP is ongoing and should be completed by mid-2015. Preliminary results were obtained for the post-three-year data and presented at the 13th European Society of Contraception and Reproductive Health Congress (Lisbon, Portugal, May 2014).

- **“UPTAKE” – A context-specific health sector and community-based participatory approach in a human rights framework, to address unmet need for contraception:** The Unit has been involved in the design of the study.

- **Multicentre study on cervical cancer screening algorithms with human papillomavirus testing and triage in Africa. A collaboration between IARC Prevention and Intervention Group and WHO’s RHR Department:** The Unit has been involved in the design of the study.

- **Adolescent Health Experience After Delivery (AHEAD): decreasing rapid repeat pregnancy:** The Unit has been involved in the design of the study.
• **Sperm suppression and contraceptive protection provided by norethisterone enanthate (NET-EN) combined with testosterone undecanoate (TU) in healthy men**: Final analyses were discussed with the project manager and primary author in September 2014. A few additional secondary analyses are ongoing.

As part of their statistics support to research conducted by the Department and elsewhere, the members of the Unit co-authored three papers published in 2014 in the *Bulletin of the World Health Organization, Contraception* and *MEDICC Review* (1, 2, 3).

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

**Planned activities**

• In 2015, the Unit 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 develop specific products, particularly methodological papers.

• In 2015, the Unit will work on several important trials with decentralized data management. Several statistical and data-management activities will continue to be outsourced during the year.

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

**Progress**

The Unit has a commitment to support research capacity-strengthening activities at the country level. In 2014, on-site training was provided to staff participating in research projects at three sites at collaborating centres, which helped these sites to improve compliance with Good Clinical Practices and to improve the quality of the data collected and of the corresponding statistical analyses.

**4.3.3 References**


**4.4 Advocacy and communications**

**4.4.1 Introduction**

Through its advocacy and communications work, the RHR Department, including HRP, 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, WHO and other agencies and partners.

**Major achievements**

- A new communications strategy for the RHR Department, including HRP, was developed in 2014, with the participation of partners, funders and staff, and with the support and guidance of a leading global communications firm. The new strategy is focusing our communications work on a smaller number of key events, but with much more intensive communications for each, including social media.

- In 2014, 49 new publications in English were produced and distributed (see Annex B).

- The Department produced and distributed 41 translations of existing RHR Department publications (see Annex B).

- Research results and knowledge synthesis were published in the scientific press, in 123 peer-reviewed articles (see Annex B). There was a sharp increase in the number of times these articles were cited by others, indicating increased relevance and impact.

- There were 2 million page views of the Department’s “Reproductive health” webpage, 2.8 million of the WHO Reproductive Health Library (RHL) website and 239 000 video views on the HRP YouTube channel.

- The Department’s outputs were widely disseminated, and high-level advocacy for sexual and reproductive health was carried out, at 28 different conferences, symposia and international meetings (see Annex B).

- A number of international days were marked by the Department, including International Day of Zero Tolerance to Female Genital Mutilation; Obstetric Fistula Day; World Contraception Day; International Day of the Girl Child; International Day for the Elimination of Violence against Women; World AIDS Day; Human Rights Day and World Prematurity Day. Web features were prepared for these days which were well supported by the WHO central web services. The WHO home page also regularly highlighted aspects of the Department’s work throughout 2014.

- A new Twitter channel was opened for HRP in mid-September, with the @HRPresearch handle. The number of followers had reached 310 by the end of 2014 and is growing steadily.

- During 2014, 10 issues of the Department's electronic newsletter were sent out.

- The Reproductive Health Update newsletter was redesigned and re-launched in December 2014 as *HRP News: Sexual and Reproductive Health*. The number of subscribers, who have all “opted in” to this newsletter, now stands at over 3000.

**4.4.2 Achievements in advocacy and communications**

**4.4.2.1 Communications strategy**

In 2014, on the advice of the Scientific and Technical Advisory Group (STAG), the Department started developing a new communications strategy for the period 2014–2016. Following an open public tendering process, the Department engaged Grayling, a global communications firm, to support strategy development activities. The methodology was based on a consultative process both within the Department and externally, in order to develop a first-hand and thorough understanding of the
current situation, aspirations and needs. Subsequently, Grayling analysed the input and provided ideas and suggestions, in close collaboration with the Department and on the basis of its own knowledge and expertise.

To understand the Department’s interests and concerns, Grayling carried out an internal survey of all 69 employees to gather their views and feedback. In addition, Grayling held a dozen days of face-to-face meetings with Department staff as well as with representatives from the office of the Assistant Director-General for Family, Women’s and Children’s Health and from the WHO Department of Communications. Likewise, gathering the views and interests of external stakeholders was equally important in order to build the strategy. Grayling reached out to 465 external stakeholders via an online survey and carried out one-on-one phone interviews with a selected number of donors and close collaborators to gather more detailed feedback on current perceptions and suggestions for the future.

The overarching framework of the new communications strategy is for the Department’s research outputs to inform policy and practice in sexual and reproductive health and rights. The strategy’s key objectives are:

i. to distinguish the Department as an innovator and a leading organization for sexual and reproductive health research;

ii. to promote evidence and game-changing research produced by the Department to maintain and strengthen the Department’s role as a knowledge broker and leader in the development of evidenced-based guidelines, norms, standards and tools on sexual and reproductive health and rights;

iii. to create ownership and commitment from co-sponsors; and

iv. to improve internal communications.

A three-pillar communications strategy was developed to effectively house the actions proposed and ensure there is a coherent framework. The pillars, which can each stand alone, are also mutually reinforcing.

Pillar 1: Build up relationships internally, within the co-sponsored Special Programme (HRP), to achieve better impact externally.

Pillar 2: Qualify the Department’s research as distinctive and credible in nature.

Pillar 3: Distinguish the Department as “unique”.

The new strategy has not abandoned the good communications work already undertaken, but it has mapped out a new pathway providing both specific processes and tools to communicate more effectively and in an impact/results-driven fashion. It requires a culture shift by all staff in the Department to accept that communication is one of the Department’s core functions, that they need to embrace digital technology, and that results need to be measured in order to be evaluated. Specific actions resulting from the new strategy include:

(i) development and launch of a new logo and tag line (see image on this page); (ii) changes to the content and approach of the RHR Department and HRP newsletters; (iii) engagement with digital media; and (iv) development
of a communications toolbox which will represent the foundations of the Department’s communications, and will ensure a coordinated and aligned thread to communications across all teams.

The strategy includes a complete implementation plan for the period June–December 2014, providing HRP with a concrete roadmap for launching the strategy, and with a number of initial actions to use as a starting point.

Grayling have acknowledged that this new strategy is ambitious, and in order to implement this successfully the Department will need to “do less but do it better”.

4.4.2.2 Peer-reviewed publications: trends and impact

Results of research by the Department were published in the peer-reviewed scientific press in 123 articles in 2014 (see Annex B: Indicator report). These articles were analysed by Thomson Reuters Evidence, a firm specialized in bibliometric analysis, following the same methodology used in recent years, beginning with the HRP external evaluation 2008–2012 (1). This rate of publication represents an increase over previous years, as shown in Figure 4.4.1.

The Department is now fully compliant with the WHO-supported open access publishing policy, so that all peer-reviewed articles are now freely accessible worldwide, regardless of region, academic affiliation or institutional membership.

Figure 4.4.1: Number of scientific papers published by the Department, 1990–2013

Number of papers

Normalized citation data for 2014 will not be available until well into 2015, so the citation impact analysis and author analysis presented in Figures 4.4.2–4.4.4 covers the period ending in 2013.

Department papers averaged 1.42 during the period 1990–2007 and then rose to 2.2 during the period 2008–2012, already more than twice the global average. In 2013, the Department’s citation impact dipped slightly, due to the issuance of a number of extremely highly cited papers in 2012, but nevertheless remained well above the global average. Trends in citation impact are shown in Figure 4.4.2.
An analysis of the categories of journal in which the Department published research articles revealed that obstetrics and gynaecology journals account for the highest share, with more than one third (40.9%) of the papers falling into this category in 2013. This research is well cited within its category, with a citation impact approaching twice the world average, as shown in Figure 4.4.3.

Figure 4.4.3: Output and citation impact in 10 most frequently used Web of Science journal categories, 1990–2013

The percentage of research papers published for which all the authors are from low- or middle-income countries has decreased since 1990, as shown in Figure 4.4.4. This trend is a reflection of the fact that the Department’s collaborating centres have been instrumental partners in the Department’s global research agenda, with a corresponding reduction in purely independent research.
Figure 4.4.4: Percentage of papers with authors from developing countries, 1990–2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage of Papers</th>
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</thead>
<tbody>
<tr>
<td>1990-2002</td>
<td></td>
</tr>
<tr>
<td>2003-2007</td>
<td></td>
</tr>
<tr>
<td>2008-2011</td>
<td></td>
</tr>
<tr>
<td>2012-2013</td>
<td></td>
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</tbody>
</table>

- Papers where all authors are from developing countries
- Papers where any author is from a developing country
- Papers where first author is from a developing country

Data & analysis: Thomson Reuters

Taken together, these indicators of research performance are significantly above the world average, and are indicative of research that is of strong international standing.

In 2014, the Department and Special Programme will aim to increase the participation of authors from developing countries, in particular under the HRP Academic Alliance.

4.4.2.3 New technical publications

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 2014, 49 new technical publications in English were produced and distributed (see Annex B).

(i) Guidelines

The Department issued six new guidelines (including handbooks and decision-making tools) in 2014. These were introduced and demonstrated at 25 workshops, with participants including ministry of health staff, programme managers, and health-care providers.

(ii) Global and regional estimates and projections

The Department issued one new document of estimates, on maternal mortality.

(iii) Technical publications including evidence briefs, fact sheets and statements

In addition to the above guidelines and estimates, the Department issued 23 other technical publications on a range of subjects in 2014, as well as two Programme Reports (the 2013 Annual Technical Report and Highlights of 2013) and the External evaluation of the Gender and Rights Advisory Panel 2002–2012 (see Annex B).
4.4.2.4 Electronic newsletter

The Department’s electronic newsletter – Reproductive Health Update – was also produced regularly during the year. Ten issues were sent out during 2014. Reproductive Health Update is a monthly email bulletin highlighting recently published research from the Department, including publications in peer-reviewed journals, and notable events. 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 Department’s website and a high rate of downloads of electronic copies of publications, as well as high interest in externally published research articles authored by staff of the Department. The Reproductive Health Update newsletter was redesigned and re-launched in December 2014 as HRP News: Sexual and Reproductive Health.

4.4.2.5 Language versions

The Department published 41 translations of existing RHR documents in languages other than English (see Annex B). In addition, requests by external partners to translate the Department’s publications into non-official languages were managed.

4.4.2.6 Web-based communication

(i) WHO Reproductive Health Library

The WHO Reproductive Health Library (RHL) has been published by the RHR Department since 1997. In 2014, the focus has been primarily on improving the quality and breadth of RHL, and expanding to include non-Cochrane systematic reviews of interest to RHL users, who are primarily reproductive health care providers working in low- and middle-income countries. User testing with students and junior doctors working in public health has been conducted and a raft of improvements to the site are under way. Greater emphasis is now placed on WHO guidelines and recommendations. Translations into official UN languages are updated on an ongoing basis.

In 2014, RHL has been updated each week with two new or updated Cochrane reviews and corresponding RHL summaries. An iPad version of RHL has been developed and is now available via the Apple Store. RHL content is also included in the new HRP newsletter and Twitter feed. These recent initiatives have been very successful in promoting RHL – in 2014 RHL had over 2.1 million visitors and nearly 2.8 million page views. By comparison, in 2013 RHL received 1.2 million visitors and 1.7 million page views. RHL continues to be very popular in developing countries, making up 6 of the top 10 countries using RHL. Spanish language content is also very popular, representing one third of RHL’s usage.

Several activities are planned for 2015 with a view to improving RHL, including:

• further user testing of the RHL website and iPad app with clinicians in low- and middle-income countries;
• dissemination and promotion of RHL via social media;
• development of further RHL platforms, including smartphone and Android tablet versions; and

• development of RHL interface for languages other than official UN languages.

(ii) Departmental website

In addition to the RHL website, the Department maintains a technical website that includes information and publications on the health topics that make up the area of sexual and reproductive health and rights. This information is updated daily. Prior to 2014, the work had been split into two websites with a generic “Reproductive health” site containing technical information and a smaller HRP website describing the role of HRP and its governance and programme reports. During October to December 2014, these two websites were merged into one consolidated site with the aim of improving coherence and making navigation much easier for site visitors.

The “What’s new?” section, which includes the latest publications, research articles and events, was regularly promoted in the Reproductive Health Update and HRP News newsletters.

In 2014, for the first time, WHO included “Preventing unsafe abortion” in the list of WHO health topics and a fact sheet was developed on this issue.25

WHO has been using Google Analytics for two years now to generate and analyse its statistics on website visits and page views. Thus we are able to show trends from 2013 through 2014 (see Figure 4.4.5). There was continued growth in the number of both website visits and page views in 2014. The number of visits rose from 607 000 in 2013 to 766 000 in 2014, as shown in Figure 4.4.5. This, in turn, resulted in a higher number of page views, up from 1.8 million in 2013 to 2 million in 2014. These figures exclude RHL, which are reported separately above.

**Figure 4.4.5: Number of HRP website visits and page views, 2011–2014**

<table>
<thead>
<tr>
<th>Visits</th>
<th>Page views</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>607 000</td>
</tr>
<tr>
<td>2014</td>
<td>766 000</td>
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The Department’s 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 (see Figure 4.4.6). Continuing a trend observed in 2013, the number of visitors seeking information on sexual and reproductive health and rights continued to grow in 2014, with Spanish now representing almost 20% of the total number of web sessions. The most visited page in 2014 was the Spanish version of the “Reproductive health” home page, which showed a 28% increase in visitors from 2013.

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25 Available at: http://www.who.int/topics/preventing_unsafe_abortion/en/
Given that over a third of visitors seek sites in languages other than English, this is an area that will continue to be important for the Department in 2015.

Figure 4.4.6: Visitors to the Department’s “Reproductive health” website by language, 2014

Table 4.4.1. Most frequently downloaded publications in 2014

<table>
<thead>
<tr>
<th>Title</th>
<th>Number of downloads</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO laboratory manual for the examination and processing of human semen, fifth edition</td>
<td>10 178</td>
</tr>
<tr>
<td>Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence</td>
<td>9 424</td>
</tr>
<tr>
<td>Clinical practice handbook for safe abortion</td>
<td>5 277</td>
</tr>
<tr>
<td>Unsafe abortion: global and regional estimates of incidence of unsafe abortion and associated mortality in 2008</td>
<td>5 277</td>
</tr>
<tr>
<td>Prevention and elimination of disrespect and abuse during childbirth (online since September 2014)</td>
<td>4 523</td>
</tr>
<tr>
<td>Family planning: a global handbook for providers: 2011 update: evidence-based guidance developed through worldwide collaboration</td>
<td>4 523</td>
</tr>
</tbody>
</table>
Traditionally the Department has prepared CDs of our publications for people who may have difficulty in accessing material through the web. In 2014, however, the Department switched to using USB keys. These were distributed at conferences and other events during the year.

The HRP YouTube channel also continues to enjoy a large degree of success, with 239,000 views in 2014.

4.4.2.7 Social media

2014 saw a marked increase in the social media activities of the Department. All major outputs and international days, as well as other key events, were promoted through social media during the year. HRP also launched its own Twitter account on 16 September 2014. It sent out 228 tweets during the remainder of 2014. At year end it had 310 followers and is increasing its following steadily.

There is evidence that this tool is helping the Department in its communication efforts. A series of tweets issued in December 2014 to highlight the issue of female genital mutilation (FGM) and the publication in BJOG: An International Journal of Obstetrics & Gynaecology of an analysis of the research gaps in the care of women with FGM saw 373 people clicking through to read the web story, 172 accessing the journal article and 423 reading the WHO fact sheet on FGM.

4.4.2.8 International days

A number of international days were marked by the Department in 2014:

- International Day of Zero Tolerance to Female Genital Mutilation, 6 February
- Obstetric Fistula Day, 23 May
- World Contraception Day, 26 September
- International Day of the Girl Child, 11 October
- International Day for the Elimination of Violence against Women, 25 November
- World AIDS Day, 1 December
- World Prematurity Day, 17 November
- Human Rights Day, 10 December
For each of these days, we created web-based stories on the home page of the WHO website. We also used social media (WHO’s Facebook page and Twitter account, as well as HRP’s Twitter account) to promote the issue and the Department’s work on the thematic area (see example in Box 4.4.1). All of the stories were also highlighted on the WHO home page.

Box 4.4.1: International Day of Zero Tolerance to Female Genital Mutilation (FGM)

As an example, for the International Day of Zero Tolerance to Female Genital Mutilation (FGM) on 6 February, the Department ran a story on Facebook and put out a series of tweets on Twitter during the day. The activities garnered a high degree of engagement on social media with 1878 “likes” on Facebook for the story and 1798 “shares”. On Twitter, the main message was retweeted over 600 times, which is around 10 times the average.

The web statistics for the 24-hour period were 2247 page views to our FGM home page with a total of 1555 visits and 523 page views for the interview with University Hospitals of Geneva (HUG). This represents a 12-fold increase in page views and a 16-fold increase in the number of visits compared to the average number per day during January 2014 (the average number of page views was 183 per day and average number of visits was 94 per day for the period 1–31 January 2014).

4.4.2.9 Planned activities

- The Department’s work in communications will continue in 2015, as guided by its new communications strategy.

- Major new directions identified within the new communications strategy include: (i) completing the consolidated web presence for the RHR Department and HRP, (ii) continuing to build on successes in social media, including Twitter, and branching out using additional new media channels, and (iii) integrating
communications within all the work of the Department, including research and development and standard setting.

4.4.3 References

4.5 Research project review

4.5.1 Introduction
The RHR Department, including HRP, ensures the assessment and completion of the scientific, technical, financial and ethical review of all new proposals, and the annual review of all multi-year projects. The Research Project Review Panel (RP2) assists the Department by providing independent, external reviews of the scientific, technical and financial/budgetary aspects of projects. This fosters recognition of the universal scientific principles of good research and clinical research practice in the development and implementation of studies, and in the implementation of guidelines. The purpose 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), Resolution 41.9, specific to the field of reproductive health and research. As of the third quarter of 2014, the Department uses the WHO Ethics Review Committee (WHO-ERC) to provide ethical review.

Major achievements
- Overall, RP2 conducted 43 successful project reviews during 2014, as either a "First submission", a "Resubmission" or for "Continuing review".
- Fourteen new projects were submitted to the RP2, and an additional six projects were resubmitted, following a first review by the RP2 in 2013. Of these new projects, 10 were initially only reviewed electronically (i.e. a technical and budgetary/financial review, but no meeting review) when first submitted, and then forwarded to the WHO-ERC for ethical review.
- Twenty-nine RP2 members were involved in committee review meetings (face-to-face, video or teleconferencing). For continuous and repeated assessments, the RP2 ensured that the same members were involved in subsequent committee reviews of a project.

4.5.2 Research Project Review Panel membership
The RP2 is an independent body whose members have included multidisciplinary external experts in the field of sexual and reproductive health (SRH) with proven capacity to assess and evaluate research protocols with regard to scientific, technical, financial/budgetary and ethical considerations. These experts are not involved in the development of the Department’s projects, and if any other conflict of interest is declared this negates their ability to participate in particular project reviews.

The RP2 was formed by the Department in 2010 by consolidating five specialist technical panels and the former Scientific and Ethical Review Group (SERG), which
were together responsible for strengthening concept notes as well as reviewing research projects. After taking over these roles, the RP2 reviewed projects at various stages of development.

During 2014, the terms of most RP2 members expired. Out of 53 RP2 members, 10 had their membership renewed, including renewal of the RP2 Chair’s position for one year. The Vice-Chair’s position was also renewed for one year, after which she will act as Chair for three years. In addition, eight members of the former Regional Advisory Panel and one new expert from Zimbabwe were invited and agreed to join RP2 during the third quarter of 2014. During the fourth quarter, a call for new members was released through the Department’s communication channels, with the aim of expanding RP2 membership during the first half of 2015.

With these changes in membership, the RP2 took the opportunity to revise its structure and function. For example, major concerns about duplication in ethics review by the RP2 and the WHO-ERC have been debated in the Scientific and Technical Advisory Group (STAG) and the Policy and Coordination Committee (PCC) for over 10 years. In 2014, the Department decided to defer to the WHO-ERC for full ethics review of all projects, while the RP2 will continue scientific, technical and finance/budgetary reviews. When appropriate (as science and ethics discussions are often integrated) the RP2 will suggest key ethical considerations, which will then be covered during full ethical assessment by the WHO-ERC.

To accelerate reviews through the Department’s processes, all research projects (where feasible) will form a dedicated research project steering committee or oversight project planning committee, comprising internal staff and external research experts. Following assessment and approval by senior management at the Department, research projects will be reviewed by RP2 members electronically. New and resubmitted projects will continue to follow an electronic review procedure that is similar to the previous face-to-face meeting review format. New terms of reference and rules of procedure have been drawn up to reflect all logistical and process changes within the RP2 review process.

4.5.3 Project review outcomes

All projects submitted to the RP2 Secretariat up until the third quarter of 2014 were reviewed under the previous terms of reference and rules of procedure. Therefore, during this period, new projects and those requiring major alterations following a previous first review (and thus requiring resubmission to RP2) were reviewed during the face-to-face RP2 meeting in March 2014. The new rules of procedures were instituted during the third quarter of 2014, and all projects submitted to RP2 from this time onwards were reviewed electronically. Throughout the year, approved multi-year projects requesting annual assessment (“Continuing review”) were reviewed electronically.

Fourteen new projects were submitted to the RP2 in 2014, and six projects from 2013 were resubmitted following a first RP2 review in 2013. Of the new projects, 10 were reviewed electronically for technical and budgetary/financial review at their first submission, and then forwarded to the WHO-ERC for ethical review. Overall, 43 project reviews were conducted as either a “First submission”, a “Resubmission” or for a “Continuing review” (see Table 4.5.1).

During 2014, 29 external experts were involved in committee review meetings (face-to-face, video or teleconferencing), with care taken that the same RP2
members provided continuous and repeated assessments of the same protocols in the context of any required subsequent committee reviews. In March 2014, five RP2 members attended a face-to-face meeting, with seven RP2 members contributing on teleconference, for technical, budget and ethics review of 10 new proposals or proposals that required resubmission. Throughout 2014, the review process – from “First submission” to completion of an RP2 review that resulted in “Final approval” – was usually completed within four to six weeks.

Table 4.5.1. New and multi-year RHR Department and HRP projects reviewed by RP2 in 2014, using either a face-to-face or electronic meeting format

<table>
<thead>
<tr>
<th>Type of review (meeting or interim)</th>
<th>Number of projects submitted</th>
<th>“Final approval”</th>
<th>“Conditional approval” with recommendations, amendments and clarifications</th>
<th>“Resubmission” required</th>
<th>“Disapproved” or “Exempt”</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP2 face-to-face meeting (March)</td>
<td>10</td>
<td>0</td>
<td>4</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>RP2 electronic meetings</td>
<td>10</td>
<td>0</td>
<td>5</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Interim/ “Continuing review”</td>
<td>23</td>
<td>17</td>
<td>1</td>
<td>2</td>
<td>2/1</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
<td>17</td>
<td>10</td>
<td>12</td>
<td>4</td>
</tr>
</tbody>
</table>
5. Research capacity strengthening, including the HRP Alliance

5.1. Introduction

The Human Reproduction Programme (HRP) is the only body within the United Nations system with a global mandate to lead research in sexual and reproductive health and rights, and to conduct research capacity strengthening (RCS) as a core activity. Since HRP’s inception in 1972, it has allocated grants for institutional capacity strengthening. These have been the main instrument for promoting essential national research to address priority needs in sexual and reproductive health and rights (SRHR) in low- and middle-income countries. During this period, HRP has provided long-term support to 103 institutions in 55 countries, helping them to develop their research capacity.

Major achievements

- In 2014, HRP awarded Long-term Institutional Development (LID) grants to 12 institutions. Four of these completed their research projects and disseminated results as publications and at regional seminars and conferences.
- HRP awarded 21 individual research training grants. Most of these were within the WHO regions, ensuring cost-effective participation at the country level and South–South collaboration.
- HRP established new partnerships to strengthen research capacity by joining ESSENCE on Health Research (Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts). This network of funding agencies aims to improve the coordination and harmonization of research capacity strengthening investments.

5.2. The HRP Alliance

Following the functional review of the RHR Department in 2013, it was necessary to organize and adapt RCS activities, although many grant mechanisms will remain unchanged. As part of this process, the “HRP Alliance” was created to enhance regional networking with RCS in sexual and reproductive health (SRH), taking advantage of HRP partnerships and collaborations that had not been specifically used for RCS. The HRP Alliance comprises:

- institutions receiving support from HRP under its RCS schemes (these primarily include LID grants and Research Mentoring Grant [RMG] recipients); official WHO collaborating centres (WHOCC) working with the RHR Department, including HRP, and WHO regional offices;
- institutions and individuals who have engaged strongly with HRP on various research initiatives.

It is envisaged that regional research and RCS activities will be better integrated under the Alliance and existing networks will be used more efficiently.

Following the 2014 recommendation from the Scientific and Technical Advisory Group (STAG), the Department reviewed other RCS initiatives relevant to SRHR, collaborated with other entities, and had extensive discussions with regional partners and regional SRH advisors. These interactions helped to finalize the HRP Alliance concept and operational plans.
The rationale behind the HRP Alliance is: to bring together entities working with HRP; to strengthen RCS work by maximizing resources; and to strengthen regional networks by providing better support to regional offices and grantee institutions. This is the first time that official WHOCC, working with the RHR Department (including HRP) and individuals who have worked with HRP (the HRP Alumni) are formally integrated into its RCS work. HRP anticipates that this will enhance regional RCS work significantly. In addition, several activities and initiatives are planned to strengthen RCS work in general. These are described below.

5.2.1 Formation of the HRP Alliance plan

Progress

In 2014, following STAG advice, several activities were undertaken, which formed the basis of the current HRP Alliance plan. These included a meeting organized jointly by the Latin America Perinatology Center/Women's and Reproductive Health (CLAP/SMR), a regional centre in Uruguay, and the WHO Regional Office for the Americas/PAHO. The meeting, held in São Paulo, Brazil, on 19–20 August, was used to plan collaboration and coordination on RCS in SRH. Attendees included members of the Latin American Association of Human Reproduction Researchers (ALIRH) and the Latin-American Program of Research in Sexual and Reproductive Health (PLISSER).

Following the São Paulo meeting, further consultations took place with the WHO regional offices and plans for initiating the Alliance activities were finalized. Work will continue on regional networking for RCS in SRH to enable the timely identification of regional priorities and emerging research institutions, and to promote South–South collaboration. A similar meeting is scheduled to take place in the African Region in the first quarter of 2015.

5.2.2 External partnerships

Progress

Acknowledging that RCS activities are undertaken by a wide range of institutions, including donors, HRP participated in two significant activities in 2014.

• ESSENCE on Health Research (1) is an initiative of funding agencies that aims to improve the coordination and harmonization of RCS investments. HRP formally joined ESSENCE in 2014 and participated in their meeting in Cape Town, South Africa, in October 2014, which coincided with the Third Global Symposium on Health Systems Research. One of the ESSENCE partners, the United Kingdom Collaboration on Development Studies (UK CDS), RCS Group is currently mapping all RCS institutions, which are estimated to number around 300.

• Discussions are ongoing with the Special Programme for Research and Training in Tropical Diseases (TDR), which is based at WHO, and within the Implementation Research Platform to access funds and enhance the impact of RCS in implementation research.

5.2.3 The HRP Alliance e-platform

Progress

HRP is developing the HRP Alliance e-platform to promote knowledge sharing, engagement and communication among organizations and researchers involved
in research and RCS on SRH. This platform will include profiles of the LID grantees to improve their visibility. Institutional achievements will appear in a monthly “what’s new in RCS” section.

HRP is also collaborating with TDR to set up a cost-effective portal based on a research networking tool (such as Harvard Profiles RNS, VIVO or Elsevier’s PURE Experts Portal) to facilitate collaboration and partnerships. The objective of the e-platform is to map regional expertise on RCS for SRHR and improve the visibility of researchers from low- and middle-income countries by linking them to existing research networking directories and retrieval of their profiles through commonly used search engines, such as Google.

5.2.4 Integrating RCS with multicountry global research

Progress

HRP is actively looking to collaborate with its RCS grantees in its large, centrally coordinated, multi-country studies. In 2014, Cellule de Recherche en Santé de la Reproduction, an LID grantee institution based in Conakry, Guinea, was included as the fourth site for the multicountry study on disrespect and abuse during childbirth.

HRP is also collaborating with LID grantees from Burkina Faso (Institut de Recherche en Sciences de la Santé, based in Ouagadougou) and the Democratic Republic of the Congo (Université de Kinshasa, Faculté de Medecine Département de Gyneco-Obstetrique, based in Kinshasa) to develop a research protocol on postpartum family planning. It is anticipated that the project will be implemented in 2015.

To promote regional mentoring and stimulate new work on the quality of care, HRP announced a call for proposals on “Strategies to improve quality of care in SRHR” in January 2015. These will be awarded as a competitive, intra-regional grant. Concept notes are invited from LID grantees in partnership with a mature research centre.

5.2.5 Governance

Progress

The HRP Alliance Steering Committee and four Regional Research Committees were established to oversee and provide guidance on HRP Alliance and RCS activities. The Steering Committee, comprising eight members, will meet once a year. It will provide strategic guidance and direction to the HRP Alliance and its broader RCS mandate, and advise on regional and global priorities and emerging themes in the field of RCS. Its work will be reported to HRP governing bodies including the STAG and the Policy Coordination Committee (PCC).

The Regional Research Committees will review research grants and research proposals, and monitor RCS activities in each region. They will help to coordinate the regional entities working on similar issues in the region. There are currently four separate committees, one each for the Region of the Americas, the African and Eastern Mediterranean Regions combined, the South-East Asia and Western Pacific Regions combined, and the European Region. They will meet once a year and the chairs of each committee will be members of the Steering Committee.

The main difference between these committees and the previous Regional Advisory Panels (RAPs) is that they will bring together the HRP Alliance partners within the regions and will have a clear networking objective. This will facilitate mentorship arrangements and take advantage of local and regional individual training programmes.
5.2.6 Planned activities for the HRP Alliance

- Most of the HRP Alliance structures and activities will be consolidated in 2015.
- All four Regional Research Committees will meet in 2015.
- The HRP Alliance e platform will be launched on 17 February 2015. It is anticipated that the electronic research-networking tool will be finalized in 2015.
- “Strategies to improve quality of care in SRHR” is the theme for a competitive intra-regional grant that will be implemented in all WHO regions in 2015. This will aim to increase partnerships, including mentoring activities, within the regions. It is anticipated that one research proposal/institution in each of the regions will be supported.
- Proposal development workshops will be organized to strengthen skills in the recipient centres. If possible, the mature partner institution will facilitate these workshops. Successful proposals will be funded. HRP will provide technical support, including ensuring approval by the RHR Department’s Research Project Review Panel (RP2) and the WHO Ethical Review committee (WHO-ERC).

5.3 Regional activities

5.3.1 WHO African Region

Progress

5.3.1.1 Institutional capacity-strengthening

During 2014, LID grants were disbursed in five countries: Burkina Faso (Institut de Recherche en Sciences de la Santé, Ouagadougou); Côte d’Ivoire (Cellule de Recherche en Santé de la Reproduction, Abidjan); the Democratic Republic of the Congo (Université de Kinshasa, Faculté de Medecine Département de Gyneco-Obstetrique, Kinshasa); Guinea (Cellule de Recherche en Santé de la Reproduction, Conakry); and the United Republic of Tanzania (Kilimanjaro Christian Medical Centre, Moshi). Supported centres continued to fulfil their annual workplans, including conducting RCS exercises at their institutes and designing research projects, thus building research capacity in their countries. HRP supported the institutions to develop research proposals related to country needs. It is expected that these research proposals will be submitted for approval and funding in 2015.

The University of Addis Ababa, Ethiopia, and the University of Malawi were not awarded LID grants in 2014, as the grant applications were either not submitted or not focused on RCS respectively. HRP staff will continue to support these institutions in preparing grant applications for 2015.

5.3.1.2 Research training grants

Two researchers from the Institut de Recherche en Sciences de la Santé in Burkina Faso received research-training grants for Master’s programmes. A grant was also awarded to the Witwatersrand Reproductive Health and HIV Research Unit in Johannesburg, South Africa, to fund four participants (from the Democratic Republic of the Congo, Kenya, Nigeria and Zimbabwe) to attend its “Research methodology course in sexual and reproductive health and gender-based violence”, held from 17–28 November 2014. The course has been held annually since 1997, and in 2014 was attended by 20 participants, from Nigeria, South
Africa, Swaziland, Uganda, United Republic of Tanzania and Zambia. In addition, the Effective Care Research Unit in East London, South Africa, organized a research methods course on systematic reviews and intervention studies, attended by 35 students from 10 African countries.

It should be noted that all research-training grants were used for activities within the region.

5.3.1.3 Regional network of research institutions

The RHR Department continued to support ReproNet-Africa, which works on for region-specific networking, partnership and advocacy for reproductive health issues. Support included the publication of a newsletter and management of a website for information dissemination.

Planned activities

- A meeting to set the regional research priority is being organized with the regional office. This will be an opportunity for the African Regional Research Committee to meet as well.

- There are currently sufficient numbers of LID grantee institutions in Africa. However, there is currently only one active WHOCC – the Effective Care Research Unit in South Africa. Nominating one or two new WHOCCs will be a priority for 2015.

5.3.2 WHO Region of the Americas

Progress

5.3.2.1 Institutional capacity strengthening

The Centre for Research in Development Sciences of San Andrés University (CIDES-UMSA) in La Paz, Bolivia, and the Centre for Population Studies (CEPEP) in Asunción, Paraguay, continued to receive LID grants. Both centres have completed their programmes of work for the first five-year cycle of the LID grant, and have started the next round.

CIDES-UMSA conducted a graduate certificate course on “Use of census information for local municipal planning”. This 300-hours training course was the first to be offered in Bolivia, and has the distinctive characteristic of including a module on “Human rights, gender: towards equity in development”. The Centre also held a national workshop on perinatal information systems for representatives of tertiary level hospitals from different cities in Bolivia, opening the door to future joint research projects with these hospitals. These could be an effective way to generate local knowledge for immediate use by health institutions, aimed at improving service quality within the framework of universal coverage and quality of care. The Centre became the first institution in Bolivia to receive academic accreditation for its Doctoral programme on development studies.

An important outcome of the LID grant support to CEPEP was the reorganization and enlargement of its library, which benefits both CEPEP staff and neighbouring institutions. Over the years, LID support has paid for approximately 104 books on social science, research methodology, sexual and reproductive health, psychology and epidemiology have been bought, as well as subscriptions to local journals. The LID grant supported a subscription for CEPEP to WHO’s HINARI “Access to Research in Health Programme” (2).

5.3.2.2 Research project support

CEPEP completed a study on “Intimate partner violence and reproductive coercion against women”. This reported that intimate partner violence is a complex phenomenon, with unique features in each case. The results were presented at the 8th Chilean Sociology Congress and Pre-ALAS Congress, and will be submitted for publication (4). A new research project on “Intimate partner violence from the perspective of men in Paraguay” is under review, and should be funded and implemented in 2015.

CIDES-UMSA completed a study on “Qualitative diagnosis about access to sexual and reproductive health services of pregnant adolescents in public health networks”. The study, carried out in El Alto and La Paz, found that adolescents delay informing their parents about pregnancy and seeking health services. When it becomes known that they are pregnant, they are stigmatized and meet with a range of negative sanctions. Those who do seek health services often find that these services are not prepared to attend to pregnant adolescents.

5.3.2.3 Research training grants

Research training grants were awarded through the Latin-American Program of Research in Sexual and Reproductive Health (PLISSER), administered by the Biomedical Institute of Experimental Medicine in Buenos Aires, Argentina. This Institute coordinates individual research training activities in the WHO Region of the Americas. In total, 13 Fellows were awarded grants to attend courses or practical training of six months or less. Of these, three grants were awarded to students to take an online course on research methods in sexual and reproductive health, held by the Geneva Foundation of Medical Education and Research (5).

5.3.2.4 Dissemination of research findings

One of CIDES-UMSA’s major achievements was publishing and disseminating the research results from its study of “Maternal health in intercultural context: Study of Aymara, Ayoreode, Chiquitano, Guarani, Quechua and Yuqui people” as a book (6). The results were presented at the XXIII Biannual ALIRH conference in Mexico in November 2013, and subsequently at four regional workshops in different ethnic communities in Camiri, Chimore and Santa Cruz in March and April 2014 (7).

As in previous years, the Department continued to support 10 institutions in the Region of the Americas for subscriptions to the HINARI Programme, in order to gain access to more than 15,000 information resources.

Planned activities

• During 2015, efforts in the Americas will focus on increasing the use of analyses from the SIP/CLAP database as a means for research training.

• In addition, the Programme will support ALIRH meetings and convene the Americas Regional Research Committee at the same time as a meeting in Bolivia to identify potential new LID institutions.

• Research projects from LID grantees will be supported.
5.3.3 WHO Eastern Mediterranean Region

Progress

5.3.3.1 Institutional capacity-strengthening

During 2014, LID grants were disbursed to the Afghan Public Health Institute in Kabul, Afghanistan, for the fourth year. The Institute held research methodology training courses to enlarge the pool of researchers in reproductive health.

Following the review of institutional profiles, one institution from each of Pakistan and Palestine were invited to apply for an LID grant. It is expected that these will be awarded in early 2015.

5.3.3.2 Research project support

The Department continued to support the Afghan Public Health Institute with elaborating a research proposal. It is planned to twin this Institute with a more experienced institute in Pakistan that is being considered for LID grant in 2015.

5.3.3.3 Research training grants

No individual training grants were awarded in 2014. Instead, support was provided to a research methodology workshop in Afghanistan. This involved 28 participants from tertiary care hospitals, the majority of whom were from the maternity and obstetrics and gynaecology department of Kabul Medical University and the Ministry of Public Health.

5.3.3.4 Dissemination of research findings

An introductory workshop on networking for strengthening maternal and neonatal health surveillance was held in Manama, Bahrain, on 21–22 September 2013. Thirty-one participants attended the workshop, coming from Bahrain, Iraq, Jordan, Oman, Palestine, Qatar, Saudi Arabia, United Arab Emirates and Yemen. Other attendees came from the executive board of the Health Ministers’ Council for Cooperation Council States and a training faculty from the American University of Beirut. The objectives of the workshop were to: review opportunities and prerequisites for establishing a regional collaborative partnership network of national maternal and neonatal health surveillance systems; implement evidence-based interventions; conduct relevant research activities; and utilize results in decision-making in the Eastern Mediterranean Region.

Planned activities

• The Eastern Mediterranean Region lacks both LID grantees and WHOCCs. Potential LID institutions in Pakistan and Palestine will be visited and evaluated in 2015.

5.3.4 WHO European Region

Progress

5.3.4.1 Institutional capacity-strengthening

An LID grant continued to the Tajik Scientific Research Institute of Obstetrics, Gynaecology and Perinatology (SRIOGP) of the Ministry of Health of Tajikistan.
5.3.4.2 Research project support
Tajik SRIOGP submitted the research proposal “An assessment of the capacity and quality of maternal and neonatal health care at the clinical units of the Scientific Research Institute of Obstetrics, Gynaecology and Perinatology (SRIOGP) in Dushanbe, Tajikistan”. This received scientific and ethical clearance from WHO and is now being implemented. It is expected to be completed in 2015.

5.3.4.3 Research training grants
In 2014, 239 health professionals from 60 countries – mostly developing countries – participated in the online training course “From research to practice training course in sexual and reproductive health”. The course was facilitated by Geneva Foundation for Medical Education and Research (GFMER) country coordinators in 22 countries. A total of 36 teachers from WHO, GFMER and other national and international institutions are involved in teaching and tutorship the course. Teaching methods consist of online lectures (recorded, didactic presentations), key readings, reading materials, additional references and referrals to related websites.

Furthermore, 13 participants representing different Tajik SRIOGP departments attended a four-day training workshop in Dushanbe, Tajikistan, from 20–25 January 2014. This covered the principles, methods, case studies and design methodologies for operations and the implementation of research in the Europe Region.

Planned activities
• There is a need for research mentoring in the European region, especially for institutions in Central Asia. The Programme will award one centre in Kyrgyzstan an LID grant, focusing on abortion research, and provide one Lithuanian institute with a Research Mentoring Grant (RMG) to support it in its role as a mentor institute for Russian-speaking countries.

5.3.5 WHO South-East Asia and Western Pacific Regions

Progress
5.3.5.1 Institutional capacity-strengthening
LID grants were continued to three institutions: the Health Research Epidemiology Unit, Ministry of Health, Bhutan; the National Institute of Public Health, Cambodia; and the Department of Medical Research, Myanmar. Institutions in Nepal and Sri Lanka were approved for LID grants. These grants will be awarded in early 2015.

5.3.5.2 Research project support
The Health Research Epidemiology Unit, Bhutan, completed the study on “Factors contributing to low institutional delivery in Chukha district”. The findings suggest that the place of delivery (childbirth) is determined by a combination of factors, relating to individual women, the community and to services.

The National Institute of Public Health, Cambodia, has submitted to HRP a research project “Empowering adolescents towards better reproductive health”. This was approved by the RP2, and it is anticipated that the study will start in the first quarter of 2015.
The Department of Medical Research, Myanmar, completed a study on “Male involvement in reproductive health issues of women in rural settings of Upper Myanmar”. The findings suggest that male involvement in women’s reproductive health services in rural communities is associated with increased use of reproductive health services. The research findings were presented at Myanmar Health Research Congress in 2013. The Department also submitted a research project on “Sexual behaviour and contraceptive practices among adolescent university students in Mandalay District”. This has been approved and will start in 2015.

5.3.5.3 Research training grants

Two individual RTGs were awarded to students from the Department of Medical Research in Myanmar. One candidate was supported for a PhD programme at the International Programme in Epidemiology at the Faculty of Medicine, Prince of Songkla University Hat Yai, Thailand. The other was supported for post-doctoral research/visiting Fellow at the University of Stanford, USA.

In addition, HRP supported the following group training activities.

i. The Health Research Epidemiology Unit, Bhutan, organized two workshops on research methodology, one each focusing on quantitative and qualitative methods respectively. Thirty-five participants who attended the workshops were trained in research methodology and developing research proposals. Draft research proposals prepared during the workshops will be finalized and submitted for funding from HRP and other organizations.

ii. Myanmar conducted two workshops in 2014: (a) The “Responsible conduct of research and preparing a scientifically strong research proposal” workshop aimed to increase participants’ skills in developing and implementing research projects (two research proposals were prepared and submitted to HRP for funding); and (b) Evidence-informed policy-making in the health sector” workshop, attended by 37 participants, aimed to enhance participants’ skills in acquiring, assessing, adapting and applying research evidence and learning the fundamentals of how to prepare policy briefs and organize policy dialogues.

Planned activities

• Identified institutions in, Nepal and Sri Lanka will be visited and supported as LID grantees.

• WHOCCs in the region will be evaluated for ongoing collaboration.

• A meeting of the Regional Research Committee will be organized with the specific objective of discussing regional SRHR and RCS priorities.

• Research projects from LID grantees (Cambodia and Myanmar) will be supported.
5.4 References


Key objectives in human reproduction
The activities of the Human Reproduction team of the RHR Department focus upon the following thematic areas within a consolidated and comprehensive approach to sexual and reproductive health: (i) family planning/contraception; (ii) sexually transmitted infections (STIs), including HIV/AIDS; (iii) women’s health, including cancers of the reproductive tract; and (iv) infertility/subfertility. The workplan in the area of human reproduction is progressively expanding its focus on implementation into the areas of: research and development; guidelines; and dissemination, advocacy 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 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.

<table>
<thead>
<tr>
<th>HRP output</th>
<th>2014–2015 budget (US$)</th>
<th>2014 expenditure (US$)</th>
<th>Financial implementation rate (%)</th>
<th>Key results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total human reproduction</td>
<td>15 900 000</td>
<td>6 005 637</td>
<td>38%</td>
<td>A multicentre randomized clinical trial of two hormonal implant contraceptives – Jadelle® (75 mg levonorgestrel) and Implanon® (68 mg etonogestrel) – in seven countries involving 2963 women showed similar efficacy and safety for both devices.</td>
</tr>
<tr>
<td>Research and development</td>
<td>13 128 315</td>
<td>5 233 866</td>
<td>40%</td>
<td>A feasibility study of a new indicator for assessment of unmet need for family planning was completed. The indicator was “percentage of women of reproductive age attending HIV care and treatment services with unmet need for family planning”. The study led to the development of a screening tool (by WHO in collaboration with partners) for measurement of the indicator.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The largest global community survey of the sexual and reproductive health and human rights of women living with HIV was conducted to inform the WHO normative guidance.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The Department prioritized implementation research on topical pre-exposure prophylaxis as a woman-controlled HIV-prevention method.</td>
</tr>
<tr>
<td>HRP output</td>
<td>2014–2015 budget (US$)</td>
<td>2014 expenditure (US$)</td>
<td>Financial implementation rate (%)</td>
<td>Key results</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>------------------------</td>
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<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Norms, standards and guidelines | 1 061 012              | 264 912                | 25%                              | • The Department contributed to the development of the Target Product Profiles (TPPs) for point-of-care tests (POCTs) to detect *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, human papillomavirus and syphilis, as well as a comprehensive set of research questions for further validation/development of POCTs for STIs.  
• Laboratory evaluation of the performance of a dual HIV/syphilis POCT was completed in two countries.  
• The Department launched guidelines on human rights and contraceptive services as well as information on and analysis of existing quantitative indicators in relation to contraceptive services based on human rights. The Department also developed a framework on ensuring human rights in contraceptive services and information.  
• The RHR and HIV Departments jointly launched *Global guidance on criteria and processes for validation: elimination of mother-to-child transmission (EMTCT) of HIV and syphilis*.  
• *SRH and HIV linkages compendium: indicators and tools* were finalized and disseminated.  
• The Departments of RHR, IVB and NVI jointly launched the new WHO guidelines *Comprehensive cervical cancer control: a guide to essential practice* in December. It has been welcomed by countries, partners and a wide range of stakeholders.  
• An important HRP–IARC research collaboration was established on the validation of new HPV rapid tests, new screening strategies for cervical cancer prevention and control, and operations research to strengthen cervical cancer prevention and control programmes in countries with the introduction of new tools. |
<table>
<thead>
<tr>
<th>HRP output</th>
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<th>Financial implementation rate (%)</th>
<th>Key results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring and evaluation</td>
<td>461 442</td>
<td>150 400</td>
<td>33%</td>
<td>• The current basic Consolidated Standards of Reporting Trials (CONSORT) guidelines for clinical trials have been identified for modification when reporting studies with interventions to resolve infertility. In 2014, as a founding member of the Infertility Harbin Consensus Group, the Department provided technical support in the generation of the SHORT and LONG versions and adaptations of the basic CONSORT guidelines for clinical trials, defined as “Improving the reporting of clinical trials of infertility treatments” (IMPRINT). These IMPRINT CONSORT guidelines are being endorsed by journals that publish reproductive medicine studies.</td>
</tr>
<tr>
<td>Partnerships, dissemination,</td>
<td>1 249 232</td>
<td>356 458</td>
<td>29%</td>
<td>• Brief sexuality-related communication: recommendations for a public health approach – this long-expected guideline was completed.</td>
</tr>
<tr>
<td>communication, information and advocacy</td>
<td></td>
<td></td>
<td></td>
<td>• The Implementing Best Practices (IBP) initiative worked with WHO regional and country offices to document best practices and introduce tools for scaling them up, supporting activities in over 25 countries.</td>
</tr>
<tr>
<td>advocacy</td>
<td></td>
<td></td>
<td></td>
<td>• The first peer-reviewed supplement on multipurpose prevention technologies was published and widely disseminated.</td>
</tr>
</tbody>
</table>
Key objectives in improving maternal and perinatal health

The primary objectives of HRP’s work in maternal and perinatal health are to generate new knowledge and synthesize existing knowledge to develop international norms and standards, in order to improve maternal and perinatal health. The group engages actively in knowledge translation, by developing and strengthening knowledge networks and disseminating evidence-based information in low- and middle-income countries. Essential components of the team’s work include improving research and research methods, and strengthening research capacity within its collaborative network. The team tracks and supports innovations that have the potential to improve health outcomes for mothers and infants.

The work undertaken in this area draws upon a wide range of disciplines, with the aim of coordinating research and normative efforts from the laboratory to the health systems, and from public health to politics, society and culture. It also aims to increase the awareness of the general public about issues related to maternal and neonatal health.

<table>
<thead>
<tr>
<th>HRP output</th>
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<th>2014 expenditure (US$)</th>
<th>Financial implementation rate (%)</th>
<th>Key results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total maternal and perinatal health</td>
<td>9 863 000</td>
<td>6 810 369</td>
<td>69%</td>
<td>In fistula care, short-term catheter stay after surgery was found to be non-inferior to the more conventional two-week catheter stay in the largest fistula care trial to date (publication forthcoming).</td>
</tr>
<tr>
<td>Research and development</td>
<td>8 658 248</td>
<td>6 222 086</td>
<td>72%</td>
<td>• The WHO Fetal Growth Study recruitment was completed, with data gathered from 1440 women in 10 countries.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Systematic analysis of causes of maternal deaths published in 2014 indicated that indirect causes and obstetric haemorrhage were the leading causes.</td>
</tr>
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<td></td>
<td>• Secondary analyses of data from the WHO Multicountry Survey on Maternal Near-Miss Mortality were published as a special supplement of the BJOG: An International Journal of Obstetrics and Gynaecology, and in articles published in other journals. An important finding was the significant under-utilization of antenatal corticosteroids in women delivering preterm babies.</td>
</tr>
<tr>
<td>HRP output</td>
<td>2014-2015 budget (US$)</td>
<td>2014 expenditure (US$)</td>
<td>Financial implementation rate (%)</td>
<td>Key results</td>
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</table>
| **Norms, standards and guidelines**      | 653 179                | 315 845                | 48%                               | • The WHO recommendations for augmentation of labour were published.  
• In May 2014, estimates of maternal mortality, including trends from 1990 to 2013, were published. Globally, there were an estimated 289 000 maternal deaths in 2013, a decline of 45% from 1990. |
| **Monitoring and evaluation**            | 0                      | 0                      | 0                                 |                                                                                                                                              |
| **Partnerships, dissemination, communication, information and advocacy** | 551 573                | 272 438                | 49%                               | • The WHO statement on the prevention and elimination of disrespect and abuse during facility-based childbirth has been endorsed by more than 70 organizations. |
### Key objectives in preventing unsafe abortion

Nearly half of all abortions in the world are unsafe (49%). Every year, 21.6 million unsafe abortions take place and nearly 1 in 10 pregnancies ends in an unsafe abortion. Better access to and use of contraception, sexuality education, and provision of care for complications are all essential to reducing unsafe abortion, as is the availability of safe, legal abortion care. HRP's work on preventing unsafe abortion strives towards the goal of eliminating unsafe abortion, using a multidisciplinary approach. This includes estimating the incidence of unsafe abortion and related morbidity and mortality, and conducting clinical, operations and social science research. HRP also works to translate the available research evidence into norms, tools and guidelines, and provides technical support to countries to prevent unwanted pregnancies and implement safe, legal abortion care. This work forms an integral part of WHO's efforts to improve reproductive health and to reduce maternal morbidity and mortality.

<table>
<thead>
<tr>
<th>HRP output</th>
<th>2014–2015 budget (US$)</th>
<th>2014 expenditure (US$)</th>
<th>Financial implementation rate (%)</th>
<th>Key results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total preventing unsafe abortion</td>
<td>6 974 000</td>
<td>1 640 072</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>4 945 411</td>
<td>770 299</td>
<td>16%</td>
<td>• A special supplement issue on “Expanding access to medical abortion” was published by Reproductive Health Matters, with articles highlighting the findings of work supported by HRP.</td>
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<tr>
<td></td>
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<td>• A study in Ethiopia, India and South Africa on the capability of community health workers to assess eligibility for medical abortion yielded mixed results, suggesting that they were more successful in ruling out ineligible cases.</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>• The study on abortion complications in Ghana, Lao People's Democratic Republic, Myanmar, Nigeria and Sri Lanka generally showed low levels of severe morbidity.</td>
</tr>
<tr>
<td>Norms, standards and guidelines</td>
<td>869 395</td>
<td>267 903</td>
<td>31%</td>
<td>• The Clinical practice handbook for safe abortion was launched to facilitate the implementation of the 2012 WHO Safe abortion guidelines.</td>
</tr>
<tr>
<td>Monitoring and evaluation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Partnerships, dissemination, communication, information and advocacy</td>
<td>1 159 194</td>
<td>601 871</td>
<td>52%</td>
<td>• A series of briefings and workshops were conducted on the WHO Safe abortion guidance for a broad range of UN treaty monitoring bodies.</td>
</tr>
</tbody>
</table>
**Key objectives in adolescents and at-risk populations**
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 improving the 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.

<table>
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<tr>
<th>HRP output</th>
<th>2014–2015 budget (US$)</th>
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</thead>
<tbody>
<tr>
<td>Total adolescents and at-risk populations</td>
<td>12 634 000</td>
<td>7 414 818</td>
<td>59%</td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>7 100 032</td>
<td>4 283 205</td>
<td>60%</td>
<td>• Two research protocols for developing and testing interventions to reduce unintended pregnancy in adolescents were developed and fieldwork was initiated.</td>
</tr>
<tr>
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<td>• Three scientific papers were published on: (i) research gaps in the care of women with female genital mutilation (FGM); (ii) a systematic review of the evidence on clitoral reconstruction after FGM/cutting, and (iii) case studies on clitoral reconstruction after FGM/cutting.</td>
</tr>
<tr>
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<td>• The Department developed a research protocol to evaluate the safety and efficacy of clitoral reconstruction following FGM, and the impact of comprehensive psychosexual care on health outcomes.</td>
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<td>• In order to foster the respect, protection and fulfilment of human rights related to SRH, the Department has developed tools that can assist stakeholders to integrate human rights and gender equality into SRH law, policy and programme development, and implementation.</td>
</tr>
<tr>
<td>HRP output</td>
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</table>
| Norms, standards and guidelines | 2,231,439              | 1,605,582              | 72%                                 | • The Department has contributed to normative development at the international and regional levels on SRH, human rights and gender equality, and remains a significant actor in strengthening the content and meaning of sexual and reproductive health and rights.  
• The Department published an evidence brief on Ebola virus disease (EVD) and seminal fluids, collating the current scientific knowledge surrounding the length of time EVD can be traced in seminal fluid, the infectiousness of such fluid, and any documentation of secondary infection cases.  
• A clinical handbook, *Health care for women subjected to intimate partner violence or sexual violence* (a derivative of the 2013 WHO clinical and policy guidelines, *Responding to intimate partner violence and sexual violence against women*) was published in November 2014 and has been disseminated in several countries.  
• A toolkit to strengthen medico-legal evidence for conflict-related sexual violence – with job aides for practitioners on the collection and use of forensic data and for coordinating engagement of other stakeholders in medico-legal response – was finalized.  
• A WHO guideline was developed: *Brief sexuality-related communication: recommendations for a public health approach*. |
| Monitoring and evaluation       | 1,014,290              | 252,764                | 25%                                 | • The Global Early Adolescent Study (GEAS), exploring gender norms and healthy sexuality among early adolescents, was extended to 10 countries where data collection efforts were initiated in 2014.  
• Case studies documenting the scale-up of programmes providing ASRH services in 13 countries were carried out and published. |
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<tr>
<th>HRP output</th>
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</table>
| Partnerships, dissemination, communication, information and advocacy | 2 288 239               | 1 273 267              | 56%                               | • A special supplement of the *Journal of Adolescent Health*, reviewing the progress made in various aspects of adolescent sexual and reproductive health and rights in the 20 years since the International Conference on Population and Development (ICPD) was published and launched at multiple high-level organizations.  
• A *Lancet* Series on violence against women and girls was coordinated by the Department and the London School of Hygiene and Tropical Medicine’s Centre for Gender, Violence and Health, and was launched on 21 November 2014 to mark the “International Day for the Elimination of Violence Against Women”.  
• The Department supported the development and adoption of a Member-State-led World Health Assembly Resolution 67.15 on “Strengthening the role of health systems in addressing violence, in particular against women and girls and against children”.  
• The Department has been assisting UN human rights bodies to ensure that their interpretations of international human rights standards are evidence-based and thereby contribute to the improvement of SRH worldwide.  
• The Department has played a leadership role by underscoring the need to achieve and exceed all health-related MDGs, which include ending preventable maternal deaths and improving SRH, and to ensure that the new development framework, including the Sustainable Development Goals, highlights these priorities as part of completing the unfinished work of the health-related Millennium Development Goals. |
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|            |                        |                        |                                  | • The Department, including HRP, is a key actor on human rights and SRH among development partners, including international and regional nongovernmental organizations and academic institutions, and has built partnerships with these actors at the international, regional and national levels.  
• The Department collaborated with UNICEF and Save the Children in publishing a guidance document for safe delivery and newborn care in regions affected by Ebola virus disease (EVD), and this was disseminated widely. |
Key objectives in research capacity-strengthening
The work of the RHR Department in the area of research capacity-strengthening aims to strengthen research capacity in countries, enhance research in sexual and reproductive health that is 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.

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</table>
| Strengthening of research and technical capacity | 4 000 000               | 835 668                 | 21%                              | • In 2014, HRP awarded Long-term Institutional Development (LID) grants to 12 institutions. Four of these completed their research projects and disseminated results as publications and at regional seminars and conferences.  
• HRP awarded 21 individual research training grants. Most of these were within the regions, ensuring cost-effective participation at the country level and south–south collaboration.  
• HRP established new partnerships to strengthen research capacity by joining ESENSE on Health Research (Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts). This network of funding agencies aims to improve the coordination and harmonization of research capacity strengthening investments and the Implementation Research Platform. |
Key objectives in general technical, advocacy and communications, and research project review and ethics

Through its advocacy and communications work, the RHR Department 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, WHO and other agencies, on issues associated with debates on ethical, legal and social implications.

The Research Project Review Panel (RP2) has a mandate from HRP to cover the scientific, technical, financial and ethical review of all new proposals and annual review for all multi-year projects. Through RP2, the ethics focal point: oversees 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, neonatal and child health, at regional and international conferences; and addresses issues associated with debates on ethical, legal and social implications.

The biostatistics and data management team provides support for statistical and data management for HRP research projects and supports research capacity-strengthening in biostatistics and data management.

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<tr>
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<tbody>
<tr>
<td>General technical, advocacy and communications, and research project review and ethics</td>
<td>5,588,000</td>
<td>2,519,028</td>
<td>45%</td>
<td>• The Research Project Review Panel (RP2) conducted 43 successful, cost-effective and efficient project reviews during 2014, as either a first submission, a resubmission or for continuing review.</td>
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<td>• Fourteen new projects were submitted to the RP2, and an additional six projects were resubmitted, following a first review by the RP2 in 2013. Of these new projects, 10 were initially reviewed electronically (a technical and budgetary/financial review) when first submitted, and then forwarded to the WHO-ERC for ethical review.</td>
</tr>
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<td>• Twenty-nine RP2 members were involved in committee review meetings (face-to-face, video or teleconferencing). For continuous and repeated assessments, the RP2 ensured that the same members were involved in subsequent committee reviews of a project.</td>
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<td>• In March, five RP2 members attended a face-to-face meeting for the scientific, technical, budgetary and ethics review of 10 projects. A further seven members contributed simultaneously via teleconference.</td>
</tr>
<tr>
<td>HRP output</td>
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<td>Financial implementation rate (%)</td>
<td>Key results</td>
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- A new communications strategy for the Department, including HRP, was developed in 2014, with the participation of partners, funders and staff, and with the support and guidance of a leading global communications firm. The new strategy is focusing our communications work on a smaller number of key events, but with much more intensive communications for each, including social media.

- The Department produced and distributed 41 translations of existing RHR Department publications (see Annex B).

- Research results and knowledge synthesis were published in the scientific press, in 123 peer-reviewed articles (see Annex B). There was a sharp increase in the number of times these articles were cited by others, indicating increased relevance and impact.

- There were 2 million page views of the Department’s “Reproductive health” webpage, 2.8 million of the WHO Reproductive Health Library (RHL) website and 239,000 video views on the HRP YouTube channel.

- The RHR Department and HRP outputs were widely disseminated, and high-level advocacy for sexual and reproductive health was carried out, at 28 different conferences, symposia and international meetings (see Annex B).

- A number of international days were marked by the Department, including International Day of Zero Tolerance to Female Genital Mutilation; Obstetric Fistula Day; World Contraception Day; International Day of the Girl Child; International Day for the Elimination of Violence against Women; World AIDS Day; Human Rights Day and World Prematurity Day. Web features were prepared for these days which were well supported by the WHO central web services. The WHO home page also regularly highlighted aspects of the Department’s work throughout 2014.
<table>
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<tr>
<th>HRP output</th>
<th>2014–2015 budget (US$)</th>
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- A new Twitter channel was opened for HRP in mid-September, with the @HRPresearch handle. The number of followers had reached 310 by the end of 2014 and is growing steadily.

- During 2014, 10 issues of the Department’s electronic newsletter were sent out.

- The Reproductive Health Update newsletter was redesigned and re-launched in December 2014 as HRP News: Sexual and Reproductive Health. The number of subscribers, who have all “opted in” to this newsletter, now stands at over 3000.

- The second FP2020 progress report was finalized with the leadership of the FP2020 Performance, Monitoring and Evidence (PME) working group, co-chaired by the Director of the RHR Department.

- The WHO Technical Guidance Note: Strengthening the inclusion of reproductive, maternal, newborn and child (RMNCH) health in concept notes to the Global Fund was completed for the Global Fund to Fight AIDS, Tuberculosis and Malaria.

- In support of the 20th anniversary of the ICPD Programme of Action (ICPD Beyond 2014), the Department has produced nine fact sheets on key sexual and reproductive health and rights (SRHR) aspects of the ICPD Programme of Action and has disseminated these at many events, including at a high-level meeting co-organized at the time of the UN Commission on Population and Development in New York.

- The Pan-African resolution on gender-based violence was developed with technical support from the Department, and was approved by the Pan-African Parliament.
<table>
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<tr>
<th>HRP output</th>
<th>2014–2015 budget (US$)</th>
<th>2014 expenditure (US$)</th>
<th>Financial implementation rate (%)</th>
<th>Key results</th>
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</table>
|            |                        |                        |                                  | • Reports on child, early and forced marriage legislation in Africa and the Asia-Pacific region were developed in collaboration with the Inter-Parliamentary Union and the Pan-African Parliament.  
• A paper, Women and health: 20 years of the Beijing Declaration and Platform for Action, was prepared in collaboration with other WHO departments and has been submitted for discussion at the WHO Executive Board in 2015. |
## Annex B. Indicator report

### Summary of indicators for 2014–2015 and interim achievement values as of 31 December 2014

<table>
<thead>
<tr>
<th>Output</th>
<th>Output Indicator</th>
<th>Target for 31 December 2015</th>
<th>Interim achievement value as of 31 December 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. New knowledge generated</td>
<td>HRP Output 1.1 Implementation research and clinical trials on SRH published</td>
<td>(180) scientific articles published</td>
<td>123</td>
</tr>
<tr>
<td></td>
<td>HRP Output 1.2 Global and regional estimates of reproductive, maternal and perinatal conditions published</td>
<td>(4) global/regional estimates published</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>HRP Output 1.3 Interventions developed, tested and implemented to address unmet needs in sexual and reproductive health (e.g. adolescent interventions)</td>
<td>(3) new interventions developed, tested and disseminated</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>HRP Output 1.4 New or ongoing research projects funded</td>
<td>(30) research projects approved by HRP Research Project Review Panel (RP2)</td>
<td>17</td>
</tr>
<tr>
<td>2. Research evidence synthesized</td>
<td>HRP Output 2.1 Systematic reviews of key questions in sexual and reproductive health published</td>
<td>(30) systematic reviews published</td>
<td>32</td>
</tr>
<tr>
<td>3. Strengthened research and technical capacity</td>
<td>HRP Output 3.1 National research capacity strengthened</td>
<td>(50) research centres strengthened through HRP grants</td>
<td>26</td>
</tr>
<tr>
<td>4. Guidelines, tools, policy statements and other developed, based on a robust assessment of the available evidence</td>
<td>HRP Output 4.1 Technical, clinical and policy guidelines and other issued on sexual and reproductive health (e.g. family planning, maternal and perinatal health)</td>
<td>(6) new or updated guidelines issued</td>
<td>6</td>
</tr>
<tr>
<td>5. Strengthened research/policy dialogue</td>
<td>HRP Output 5.1 Policy options analysed and synthesized, derived from technical and clinical guides</td>
<td>(20) policy briefs/guideline derivatives issued</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>HRP Output 5.2 National capacity to support and develop evidence-based policies strengthened</td>
<td>(8) regional or international consultations convened or supported for systematic introduction of policy options</td>
<td>25</td>
</tr>
</tbody>
</table>
Output 1.1 Scientific articles published.

HRP 2014 publications list


Output 1.2 Global and regional estimates of reproductive, maternal and perinatal conditions published.


Output 1.3 Interventions developed, tested and implemented to address unmet needs in sexual and reproductive health.

1. **Short-term catheter stay after simple fistula repair**
   HRP jointly with EngenderHealth ran a research study that looked at the duration of catheterization after fistula repair surgery. Results of the study showed that seven-day bladder catheterization is safe and effective for managing women following repair of simple fistula with no evidence of a significant increased risk of repair breakdown, urinary retention or residual incontinence through three months after surgery. Implementation of the findings will contribute to reducing hospital stays for women, decreasing post-surgery complications, freeing up bed space at facilities, and lower costs, potentially allowing more women to receive clinical care.

2. **Dual HIV and syphilis testing**
   The Department supported the improvement of dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis screening programmes over the past year in several countries to estimate the burden of maternal and congenital syphilis at a subnational level, and then worked with all of the countries on strategies for scaling up syphilis testing within prevention of mother-to-child transmission (PMTCT) of HIV programmes. Independent laboratory evaluation in two countries of three commercially available dual HIV/syphilis rapid diagnostic tests found that all three demonstrated excellent performance and operational characteristics.

3. **Framework for ensuring human rights in contraception information and services**
   See: *Ensuring human rights in the provision of contraceptive information and services, Guidance and recommendations*, WHO, 2014).

Output 1.4 List of research projects funded.

1. A65878 – “Formative research and development of innovative tools for better outcomes in labour difficulty (BOLD).”

2. A65879 – “Research and development of innovative tools for better outcomes in labour difficulty (BOLD-SELMA): a cohort study.”


5. A65870 – “Carbetocin RTS (room temperature stable) for preventing postpartum haemorrhage: a randomized non-inferiority controlled trial (CORE).”

6. A65867 – “Effectiveness and acceptability of availing skilled birth attendant (SBA) services through community reproductive health nurses (CORN) to a household level in rural communities of Ethiopia.”
8. A65892 – “Adolescent/youth reproductive mobile access and delivery initiative for love and life outcomes (ARMADILLO) – formative protocol for adaptation, development and pilot-testing research for preparation of ARMADILLO platform for multi-site research trial.”
9. A65880 – “How women are treated during facility-based childbirth: development and validation of measurement tools in Nigeria, Mozambique and India.”
10. A65882 – “A survey of hospital and clinic pharmacies on the patterns of services provided on emergency levonorgestrel (LNG) contraception in Malawi.”
11. A65897 – “A multi-centred, open-label, randomized clinical trial comparing HIV incidence and contraceptive benefits in women using depot medroxyprogesterone acetate (DMPA), levonorgestrel (LNG) implant, and copper intrauterine devices (IUDs).”
13. A65000 – “Sexual behaviour and contraceptive practices among adolescent university students (Upper Myanmar).”
15. A65886 – “Phase one protocol for formative, adaptation and field assessment research for preparation of Smart Registry Platform for THRIVE reproductive, maternal, newborn and child health (RMNCH) multi-site research trial.”
16. A65861 – “Training midwives in Kyrgyzstan to provide safe abortion care with mifepristone and misoprostol.”

Output 2.1 Systematic reviews published.


Output 3.1. Research centres strengthened through issuance of HRP long-term institutional development or other research capacity strengthening grants.

Region of the Americas
1. Instituto de Biología y Medicina Experimental, University of Buenos Aires, Argentina.
2. Hospicio Gineco Obstétrico Dr Jaime Sanchez Porcel, Sucre, Bolivia.
3. Centre for Research in Development Sciences, San Andrés University, La Paz Bolivia.
4. Centro de Investigación, Educación y Servicios (salud sexual y reproductive), Bolivia.
5. Faculty of Health Sciences, Autonomous University, Santo Domingo, Dominican Republic.
6. Universidad de Cuneca, Cuneca, Ecuador.
8. Hospital Nacional Especializado de Maternidad, El Salvador.
10. Hospital General Pediatrico Niños de Acosta Ñu, Paraguay.
11. Peruvian University Cayetano Heredia, Lima, Peru.

African Region
12. Institut de Recherche en Sciences de la Santé, Ouagadougou, Burkina Faso.
13. Université de Kinshasa, Faculté de Médecine Département de Gyneco-Obstétrique, Kinshasa, Democratic Republic of the Congo.
15. Addis Ababa University, Ethiopia.
17. University of Malawi, Malawi.
18. Kilimanjaro Christian Medical Centre, Moshi, United Republic of Tanzania.
19. Effective Care Research Unit – University of Witwatersrand and University of Fort Hare East London, South Africa.
20. Reproductive Health and HIV Research Institute of the University of Witwatersrand, South Africa.

European Region
22. Geneva Foundation for Medical Education and Research, Switzerland.

Eastern Mediterranean Region
23. Kabul Medical University/Afghan Public Health Institute, Afghanistan.
South-East Asia and Western Pacific Regions

24. Health Research Epidemiology Unit, Ministry of Health, Bhutan.
26. Department of Medical Research, Upper Myanmar.

Output 4.1 Technical, clinical and policy guidelines issued on sexual and reproductive health.

Guidelines
3. Decision-making tool for family planning clients and providers. Module on provider-initiated HIV testing and counselling.
4. WHO recommendations for augmentation of labour.
5. Health care for women subjected to intimate partner violence or sexual violence. A clinical handbook. Field testing version.

Language translations [not included in indicators]
1. Active management of the third stage of labour. New WHO recommendations help to focus implementation. FRENCH, PORTUGUESE, SPANISH.
2. The prevention and elimination of disrespect and abuse during facility-based childbirth. AMHARIC, FRENCH, PORTUGUESE, SPANISH, SWAHILI.
3. Clinical practice handbook for safe abortion. SPANISH.
4. Delayed clamping of the umbilical cord to reduce infant anaemia. FRENCH, PORTUGUESE, SPANISH.
5. Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Global guidance on criteria and processes for validation. RUSSIAN.
6. Ensuring human rights in the provision of contraceptive information and services. Guidance and recommendations. FRENCH, SPANISH.
7. Ensuring human rights in the provision of contraceptive information and services. Guidance and recommendations. Executive summary. FRENCH, SPANISH.
8. Guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. FRENCH, SPANISH.
9. Monitoring national cervical cancer prevention and control programmes. Quality control and quality assurance for visual inspection with acetic acid (VIA)-based programmes. FRENCH.
10. Preventing early pregnancy and poor reproductive outcomes among adolescents in developing countries: what the evidence says. RUSSIAN.
11. Programming strategies for postpartum family planning. FRENCH, SPANISH.
12. Safe abortion technical and policy guidance for health systems. UKRAINIAN.
13. Strategies and laboratory methods for strengthening surveillance of sexually transmitted infections. RUSSIAN, SPANISH.

14. Targets and strategies for ending preventable maternal mortality. Consensus statement. FRENCH, RUSSIAN.

15. The WHO application of ICD-10 to deaths during pregnancy, childbirth and the puerperium: ICD-MM. RUSSIAN.

16. Using lay health workers to improve access to key maternal and newborn health interventions in sexual and reproductive health. Summary information. RUSSIAN.

17. WHO Guidelines for treatment of cervical intraepithelial neoplasia 2–3 and adenocarcinoma in situ. FRENCH.

18. WHO recommendations for prevention and treatment of pre-eclampsia and eclampsia. FRENCH, PORTUGUESE, SPANISH.

19. WHO recommendations for the prevention and treatment of postpartum haemorrhage. FRENCH, PORTUGUESE, SPANISH.

20. WHO recommendations on prevention and treatment of postpartum haemorrhage. Highlights and key messages from new 2012 global recommendations. FRENCH, PORTUGUESE, SPANISH.

21. WHO recommendations. Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. RUSSIAN.

**Total 41 language translations.**

**Programme Reports [not included in indicators]**


2. Highlights of 2013


**Output 5.1 Policy briefs and guideline derivatives issued.**

1. Conducting and evaluating national civil society advocacy for reproductive, maternal and child health. Strategies, tactics and approaches.

2. Eliminating forced, coercive and otherwise involuntary sterilization. An interagency statement. OHCHR, UN Women, UNAIDS, UNDP, UNFPA, UNICEF and WHO.


4. Ensuring human rights in the provision of contraceptive information and services. Guidance and recommendations. Executive Summary.


6. Framework for ensuring human rights in the provision of contraceptive information and services.

10. Strategies, tactics and approaches. Conducting and evaluating national civil society advocacy for reproductive, maternal and child health.
11. WHO Technical Guidance Note: strengthening the inclusion of reproductive, maternal, newborn and child (RMNCH) health in concept notes to the Global Fund.
13. 7 Fact sheets on: Adolescent pregnancy; Contraception; Female genital mutilation; Maternal mortality; Preventing unsafe abortion; Sexually transmitted infections; Violence against women (Intimate partner and sexual violence against women).
14. 10 mHealth Briefs: JSI’s C-Stock; Pathfinders m4change2; FHI 360’s m4RH; WAHA International’s mHealth programme; Wired Mothers; PATH’s Digital Immunization Registry; KEMRI’s TextIT; Sesame Workshops Galli Galli Sim Sim; IRH’s Cyclelet; UNICEF’s mTRAC and U-Report.
16. The prevention and elimination of disrespect and abuse during facility-based childbirth.
18. Using auxiliary nurse midwives to improve access to key maternal and newborn health interventions. Summary information.
20. Active management of the third stage of labour. New WHO recommendations help to focus implementation.
21. Delayed clamping of the umbilical cord to reduce infant anaemia.
22. WHO recommendations on prevention and treatment of postpartum haemorrhage. Highlights and key messages from new 2012 global recommendations.
23. A guide to the provision of safe delivery and immediate newborn care in the context of an Ebola outbreak.

Output 5.2 Regional/international consultations convened or supported for systematic introduction of policy options.
1. National Adolescent Health Programme and the National Adolescent Health Consultation, 7–9 January, New Delhi, India.


4. UNESCO launch of document on good practices on menstrual education, 13 March, New York, USA.

5. Interagency meeting on current evidence, lessons learned and best practices on preventing pregnancy in adolescents in Latin America and the Caribbean, 17–19 March, Managua, Nicaragua.

6. International seminar on adolescent health in Portuguese-speaking countries, 31 March, São Paulo, Brazil.

7. Country consultation on targets and strategies for ending preventable maternal mortality, 14–16 April, Bangkok, Thailand.

8. WHO Regional Office for South-East Asia meeting: 2015 and beyond – the unfinished agenda of MDGs 4 and 5 in South-East Asia, 28 April–4 May, Kathmandu, Nepal.

9. Pan American Health Organization/Latin American Center for Perinatology capacity development workshop on strengthening family planning services, 22–23 May 2014, St George’s, Grenada.

10. H4+ SIDA inter-country annual review and planning meeting, 26–28 May, Victoria Falls, Zimbabwe.


12. WHO/UNFPA meeting on strengthening capacity for a public health approach to prevention and response to violence against women, 16–20 June, Entebbe, Uganda.

13. mPossible: e/mHealth for universal coverage of maternal and child health services regional conference, 23–24 June, Dhaka, Bangladesh.


19. WHO/UNFPA meeting on strengthening capacity for a public health approach to prevention and response to violence against women, 8–12 September, Johannesburg, South Africa.
20. Regional seminar for Asia-Pacific parliaments on “Ending the cycle of violence against girls in Asia-Pacific”, organized by the Inter-Parliamentary Union, 23–25 September, Dhaka, Bangladesh.

21. Lessons learned and tools developed for Innovations Working Group (IWG) for Implementing Best Practices (IBP), 29 September, Cape Town, South Africa.


23. Regional programme managers’ meeting on adolescent health, international inter-ministerial meeting on the demographic dividend, 27–28 November, New Delhi, India.

24. mHealth Summit: “Ebola and mHealth – from tragedy to strategy,” organized by UNICEF and the United States Agency for International Development (USAID)/Intrahealth, 9–11 December, Washington, DC, USA.

25. Sexual and reproductive health and rights: today and tomorrow, organized by the International Centre for Reproductive Health (ICRH), 4–5 December, Ghent, Belgium.

**2014 HRP donors**
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