Annual technical report 2015

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

2015

human reproduction programme hrp
research for impact
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World Health Organization

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)

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WHO/RHR/HRP/16.08

UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP). Annual Technical Report 2015

Editing: Green Ink (www.greenink.co.uk)
Layout: Oceans Translations (www.oceanstranslations.com)
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Printed by the WHO Document Production Services, Geneva, Switzerland

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Acronyms and abbreviations

ACS	antenatal corticosteroids
AGH	Adolescents and at-Risk Populations (team within RHR/HRP)
AHEAD	Adolescent Health Experience after Abortion or Delivery (trial)
ALIRH	Latin American Association of Researchers in Human Reproduction
AMR	antimicrobial resistance
ANC	antenatal care
ARMADILLO	Adolescent/Youth Reproductive Mobile Access and Delivery Initiative for Love and Life Outcomes
ARV	antiretroviral
ASRH	adolescent sexual and reproductive health
ASRM	American Society for Reproductive Medicine
AST	antimicrobial susceptibility testing
BOLD	*Better Outcomes in Labour Difficulty (project)*
BSC	brief sexuality-related communication
CDC	United States Centers for Disease Control and Prevention
CEFM	child, early and forced marriage
CEPEP	The Centre for Population Studies, Asunción, Paraguay
CERCA	Community-embedded reproductive health care for adolescents (project)
CERQual	Confidence in the Evidence from Reviews of Qualitative research tool
CESCR	Committee on Economic, Social and Cultural Rights
CIDES-UMSA	The Centre for Research in Development Sciences of San Andrés University, La Paz, Bolivia
CIRE	Continuous Identification of Research Evidence
CoIA	Commission on Information and Accountability for Women's and Children's Health
CONSORT	Consolidated Standards of Reporting Trials
CRVS	civil registration and vital statistics
DECIDE	Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence framework
DHS	Demographic and Health Survey
DMPA	depot medroxyprogesterone acetate
DSMB	Data Safety and Monitoring Board
EBOV	Ebola virus
EC	emergency contraception
ECOWAS	Economic Community of West African States
EMTCT	elimination of mother-to-child transmission
EPMM	Ending Preventable Maternal Mortality (strategy)
ERC	see WHO-ERC

EtD	Evidence to Decision (framework)
EVD	Ebola virus disease
FGM	female genital mutilation
FIGO	International Federation of Gynecology and Obstetrics
FP2020	Family Planning 2020 (an outcome of the 2012 London Summit on Family Planning)
GAP	gentle assisted pushing
GAPP	Global Abortion Policies Project
GARPR	Global AIDS Response Progress Reporting System
GASP	Gonococcal Antimicrobial Surveillance Programme
Gavi	Gavi – The Vaccine Alliance (formerly the Global Alliance for Vaccines and Immunization)
GBV	gender-based violence
GDG	Guideline Development Group
GEAS	Global Early Adolescent Study
GFF	Global Financing Facility
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
GLASS	Global AMR Surveillance System
GRADE	Grading Recommendations, Assessment, Development and Evaluation
GREAT Network	Guideline-driven, Research priorities, Evidence synthesis, Application of evidence, and Transfer of knowledge
GRC	Guidelines Review Committee
GVAC	Global Validation Advisory Committee
H4+	UNFPA, UNICEF, WHO, The World Bank, UNAIDS, UN Women
HPV	human papillomavirus
HRP	UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction; also: Human Reproduction Programme
HSV	herpes simplex virus
IAEA	International Atomic Energy Agency
IARC	International Agency for Research on Cancer
IAS	International AIDS Society
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)
ICD-PM	WHO Application of ICD-10 to perinatal deaths (ICD-Perinatal Mortality)
ICFP	International Conference on Family Planning
ICPD	International Conference on Population and Development
ICT	information and communication technology
IEC	information, education and communication
iEtD	interactive Evidence-to-Decision (tool)

IFFS	International Federation of Fertility Societies
IMPT	Initiative for Multipurpose Prevention Technologies
INGO	international nongovernmental organization
IPPF	*International Planned Parenthood Federation*
IPU	*Inter-Parliamentary Union*
IRB	Institutional Review Board
IRP	Implementation Research Platform
IUD	intrauterine device
IVB	Immunization, Vaccines and Biologicals (WHO Department)
IWG	Innovation Working Group
KG	Knowledge Gateway
LBC	liquid-based cytology
LID	Long-term Institutional Development (grant)
LMIC	low- and middle-income countries
LNG	levonorgestrel
M&E	monitoring and evaluation
MAPS	mHealth for Assessment and Planning for Scale (toolkit)
MCA	Maternal, Newborn, Child and Adolescent Health (WHO Department)
MCS	multicountry survey
MDG	Millennium Development Goal
MEC	Medical eligibility criteria for contraceptive use
MHTF	Maternal Health Task Force
MISP	Minimum Initial Service Package
MMEIG	Maternal Mortality Estimation Interagency Group
MMWG	Maternal Morbidity Working Group
MOH	ministry of health
MPA	medroxyprogesterone acetate
MPT	multipurpose prevention technology
MSI	Marie Stopes International
MSM	men who have sex with men
mTERG	Technical and Evidence Review Group on mHealth for RMNCH
NET-EN	norethisterone enanthate
NGO	nongovernmental organization
NIH	United States National Institutes of Health
NVI	Noncommunicable Diseases, Disability, Violence and Injury Prevention (WHO Department)
OCHA	United Nations Office for the Coordination of Humanitarian Affairs
OpenSRP	Open Smart Register Platform
PAC	Project Advisory Committee
PAHO	Pan American Health Organization
PCC	Policy and Coordination Committee

PICO	population, intervention, comparator and outcome
PLISSER	Latin American Program of Research in Sexual and Reproductive Health
PMTCT	prevention of mother-to-child transmission
POCT	point-of-care test
PPFP	postpartum family planning
PrEP	pre-exposure prophylaxis
PRS	Programme Reporting Standards
PSI	Population Services International
RCS	research capacity-strengthening
RCT	randomized controlled trial
RDT	rapid diagnostic test
RHL	Reproductive Health Library
RHR	Reproductive Health and Research (WHO Department)
RMNCAH	reproductive, maternal, newborn, child and adolescent health
RMNCH	reproductive, maternal, newborn and child health
RP2	Research Project Review Panel
RRC	Regional Research Committee
RT-PCR	reverse transcription polymerase chain reaction
RTS	room temperature stable
SAWG	Scientific Advisory Working Group
SBA	skilled birth attendance/attendant
SDG	Sustainable Development Goal
SELMA	Simplified, Effective, Labour Monitoring-to-Action tool
SRH	sexual and reproductive health
SRHR	sexual and reproductive health and rights
SPR	Selected practice recommendations for contraceptive use
STAG	Scientific and Technical Advisory Group
STI	sexually transmitted infection
SVRI	Sexual Violence Research Initiative
TAG	Technical Advisory Group
TAG	Topic Advisory Group
TDR	Special Programme for Research and Training in Tropical Diseases (hosted at WHO)
TMB	treaty monitoring body
TRP	Training Resource Package for Family Planning
TU	testosterone undecanoate
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFPA	United Nations Population Fund
UNHCR	United Nations High Commissioner for Human Rights
UNICEF	United Nations Children's Programme

UNODC	United Nations Office on Drugs and Crime
UNPD	United Nations Population Division
USAID	United States Agency for International Development
VIA	visual inspection of the cervix with acetic acid
VSU	victim support unit
WAHO	*West African Health Organisation*
WFP	World Food Programme
WHO	World Health Organization
WHO-ERC	WHO Ethics Review Committee
TAG	Technical Advisory Group
TAG	Topic Advisory Group
TDR	Special Programme for Research and Training in Tropical Diseases (hosted at WHO)
TMB	treaty monitoring body
TPP	Target Product Profiles
TRP	Technical Review Panel
TRP	Training Resource Package for Family Planning
TRT	Technical Resource Team
TT	tetanus toxoid
TU	testosterone undecanoate
UHC	universal health coverage
UICC	Union Internationale Contre le Cancer
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Programme
UNODC	United Nations Office on Drugs and Crime
UNPD	United Nations Population Division
USAID	United States Agency for International Development
VIA	visual inspection of the cervix with acetic acid
WAHO	West African Health Organisation
WHA	World Health Assembly
WHO	World Health Organization
WHOCC	WHO Collaborating Centre
WHO-ERC	WHO-Ethics Review Committee

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 (UN) 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, the WHO Department of Reproductive Health and Research (RHR).

Universal access to sexual and reproductive health and rights is now globally recognized as crucial for improving the health and well-being of populations as well as making progress towards the achievement of worldwide aims and targets.These include the new Sustainable Development Goals (SDGs; 2016–2030), launched in 2015, the preceding Millennium Development Goals (MDGs; 2000–2015), the aims of the Programme of Action of the International Conference on Population and Development (ICPD, 1994) as well as the UN Secretary-General's Every Woman Every Child (EWEC) movement, in particular the new Global Strategy for Women's, Children's and Adolescents' Health, whichwas also launched in 2015.

The collective vision represented by these global goals and strategies, which has been formed by agreement within and across countries and regions including by the world's leading institutions dedicated to sustainable development, underlines the critical importance of the work of the Department, which aims to promote universal access to sexual and reproductive health.

HRP was established in 1972, and continues to support and coordinate research on a global scale; to synthesize research through systematic reviews of literature; to build research capacity in low-income countries; and to develop dissemination tools to make efficient use of an ever-increasing body of research and information. By virtue of its unique co-sponsoring arrangement, the work of HRP is coordinated with, and contributes to, the work of its co-sponsors and partners including the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), WHO, The World Bank, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the International Planned Parenthood Federation (IPPF).

The year 2015 has been an important year for the Department to further build upon the strength of its work, including on priorities such as family planning, maternal health and adolescent sexual and reproductive health. The Department continues also to strengthen its commitment to a human-rights-based approach, as well as taking a global lead on critical issues.

The achievements made by the Department across its thematic areas are here united in this report. This document also underlines the urgency of work to be done collaboratively, to make crucial progress towards improving sexual and reproductive health and rights for people worldwide.

2. High-level advocacy and input to global initiatives for sexual and reproductive health

2.1 Introduction

The WHO Department of Reproductive Health and Research, including HRP, has engaged in a range of global advocacy activities to promote sexual and reproductive health (SRH) in the context of regional and global initiatives. This includes the development of the renewed Global Strategy for Women's, Children's and Adolescents' Health launched alongside the new SDG agenda. The Department has led the development of a global plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children, and also of the Global Health Sector Strategies for HIV, viral hepatitis and sexually transmitted infections, 2016–2021. These initiatives will be elaborated under the thematic sections of this report (see section 3.7.5.1 and section 3.5.3.5, respectively). The Department has also continued its engagement with other initiatives including Family Planning 2020 (FP2020), the Sexual Violence Research Initiative (SVRI), Ending Preventable Maternal Mortality (EPMM), the International Conference on Population and Development (ICPD)Geneva Network of Member States, and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Work completed during 2015 has also been instrumental in consolidating the Department's efforts to engage with political stakeholders, including parliaments and parliamentarians, on issues related to sexual and reproductive health and rights.

The Department engaged in global and regional processes for the advancement of sexual and reproductive health and rights (SRHR) and for strengthening of normative standards in this regard. In particular, the Department led the technical work-stream on human rights and the Global Strategy for Women's and Children's Health; released a ground-breaking report on Sexual health, human rights and the law; led the publication of a special supplementto The BMJentitled "Towards a new Global Strategy for Women's, Children's and Adolescents' Health", and a special supplement tothe Journal of the International AIDS Societyentitled"Sexual and reproductive health and human rights of women living with HIV". Furthermore, the Department published several papers on different dimensions of human rights as they relate to SRH. The Department continued to develop new tools and guidance on human rights in relation to family planning, safe abortion, mistreatment and abuse, and female genital mutilation (FGM).

Major achievements

- The Global Strategy for Women's, Children's and Adolescents' Health was launched at theUN General Assembly, 26 September 2015, in New York.
- A draft was developed of the global plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children.
- The draft Global Health Sector Strategy on sexually transmitted infections, 2016–2021, was completed.
- A special supplement to The *BMJ* was issued, entitled "Towards a new Global Strategy for Women's, Children's and Adolescents'Health".

- A report of a study on child, early and forced marriage (CEFM) legislation in the Asia-Pacific region was developed in collaboration with the Inter-Parliamentary Union (IPU).
- The *WHO Statement on caesarean section rates* was published, superseding the earlier 1985 statement, which is widely quoted. The new Statement emphasized that while there seem to be mortality benefits up to national population level rates of 10%, much of the association can be explained by the development status of the country.
- Estimates of maternal mortality 1990–2015 were published, both as a paper in *The Lancet* and as a full interagency report.It is estimated that 303 000 maternal deaths will occur in 2015 and there has been a 44% decline in the maternal mortality ratio since 1990; falling short of the MDG goal.
- The Department published the WHO framework on quality of care for pregnant women and newborns around the time of childbirth *(Quality of care for pregnant women and newborns – the WHO vision, published in BJOG)*. The quality statements and indicators for the eight domains focusing on both provision and experience of care were finalized.

2.2 Contribution to global initiatives and follow up of the commitments

2.2.1 The Global Strategy for Women's, Children's and Adolescents' Health –the Every Woman Every Child movement and the accountability framework

Progress

Within the context of the Every Woman Every Child (EWEC) globalmovement and the new sustainable development agenda, the Department has played a key role in the process of development of the renewed Global Strategy for Women's, Children's and Adolescents' Health*(1)*. The EWEC is an unprecedented global movement that continuously mobilizes international and national action by governments, the UN, multilaterals, the private sector and civil society to address the major health challenges facing women, children and adolescents; this year EWEC has put the new Global Strategy into action. The new Global Strategy (2016–2030) is a roadmap to achieve the highest attainable standard of health for all women, children and adolescents –to transform the future and ensure that every newborn, mother and child not only survives, but thrives. The new Global Strategy builds on the success of the previous Global Strategy launched in 2010 and its EWEC movement, a platform to accelerate the health-related Millennium Development Goals,which now puts women, children and adolescents at the heart of the new UN SDGs. The new Global Strategy was launched at the 2015 UN General Assembly where UNSecretary-GeneralBan Ki-moon announced over $25 billion in initial commitments spanning five years to help end preventable deaths of women, children and adolescents, and ensure their health and well-being. Heads of state and governments, international organizations, the private sector, foundations, civil society, research and academic institutions, and other key partners joined the event during the UN Sustainable Development Summit for the adoption of the post-2015 development agenda (convened as a high-level plenary meeting of the General Assembly) to pledge their support to the Global Strategy for Women's, Children's and Adolescents' Health.

The new Global Strategy has been developed through an extensive consultation process involving governments, civil society, the private sector, UN agencies and other constituencies. The Department played a central role in the development of the Global Strategy and was

actively engaged in the preparation of the consultations held in 2014–2015,first in Geneva, followed by New Delhi and Johannesburg. More than 7000 individuals, organizations and government representatives participated in the consultations during the World Health Assembly, through face-to-face and online consultations, as well as through the development of evidence-based background papers.

Together with the support to the process of consultations on the Global Strategy, theDepartment led the development of a special supplement to The BMJ,"Towards a new Global Strategy for Women's, Children's and Adolescents'Health"*(2)*. Launched at the 2015 UN General Assembly in New York, the special supplement consists of 15 papers that are the foundation of the Global Strategy. The papers, developed by a large and diverse range of global experts, pull together the latest evidence on"what works" to improve the health and save the lives of women, children and adolescents, particularly in low-resource settings. The 15 papers, co-authored by WHO and led by the Department, outline the current evidence and identify successes and critical gaps in progress, and also highlight key priorities to end preventable deaths and build resilient and prosperous societies. They provide evidence that has helped inform the development of the new Global Strategy. The 15 papers' findings underscore how persistent inequalities within and between countries mean that the poorest, most disadvantaged women, children and adolescents often miss out on life-saving health services and experience serious violations of their human rights.

The papers clearly highlight that "business as usual" will not work. For women, children and adolescents around the world to survive, thrive and transform, we need actions that will result in enormous social, demographic and economic benefits.

A critical part of this new Global Strategy for Women's, Children's and Adolescents' Health 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. In this context, in 2015 theDepartment supported the preparation of the Stakeholders'Meeting on Accountability for Women's, Children's and Adolescents' Health, held in Geneva on 16–17 November.The original members of the Commission on Information and Accountability (CoIA) and its independent Expert Review Group (iERG) members, and some 100 senior representatives from governments, parliaments, civil society, international organizations and the private sector met to operationalize the new accountability framework of the Global Strategy.

Planned activities

- In 2016, the Department will contribute to the operationalization of the Global Strategy for Women's, Children's and Adolescents' Health in alignment with the post-2015 sustainable development agenda.Countries will lead the implementation of the Global Strategy guided by their own country plans, with support from WHO and other partners. Significant attention will be paid (i) to building the capacities of health systems so that they are resilient, efficient and effective, and (ii) to promoting multistakeholder partnerships that go beyond the health sector.
- In 2016, the Department will contribute to the development of an accountability framework for the new Global Strategy, including the prioritization of indicators and proposed processes foraction, monitoring and review. Additionally, the department will lead on SRH related sections of an annual report of progress in implementation of the Global Strategy, analysing and reporting on the prioritized indicators.

- The Department will develop framework for its work on humanitarian settings extending over crosscutting activities addressing reproductive, maternal and perinatal health, abortion, family planning, sexual health, and gender-based violence for populations affected by humanitarian crises and fragile settings. So far we have conducted a scoping review of SRH interventions in humanitarian and fragile settings between 2005 and 2015 that has informed the development of the framework by identifying gaps and research opportunities. Priority areas for the RHR Department are currently under development.
- Building onto the operational framework of the new UN Global Strategy for Women's, Children's and Adolescents' Health, the Department is identifying priorities on monitoring and evaluation for SRH in humanitarian crises and fragile settings. This will bring together UN agencies (e.g. UNICEF, the UN Office for the Coordination of Humanitarian Affairs, and the UN High Commissioner for Refugees) and governmental bodies (e.g. the United States Centers for Disease Control and Prevention), as well as nongovernmental organizations and project implementers, designers and architects to disseminate knowledge on available and current innovations for humanitarian settings.

2.2.2 Sustainable Development Goals

Progress

At the 2015 UN General Assembly, more than 150 world leaders gathered together to adopt the ambitious new sustainable development agenda. The new agenda – *Transforming our world: the 2030 agenda for sustainable development*– was agreed by the 193 Member States of the UN and consists of a Declaration, 17 SDGs and 169 targets *(3)*.

Among the 17 SDGs, Goal 3 covers health: Ensure healthy lives and promote well-being for all at all ages. Targets related to sexual and reproductive health (SRH) include: target 3.1: "By 2030, reduce the global maternal mortality ratio to less than 70 per 100 000 live births" and target 3.7: "By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes". SDG 5 (Achieve gender equality and empower all women and girls) is also relevant to health, especially target 5.6: "Ensure universal access to sexual and reproductive health and reproductive rights as agreed in accordance with the Programme of Action of the International Conference on Population and Development and the Beijing Platform for Action and the outcome documents of their review conferences". The Department has been actively engaged in the promotion of anSRH-related SDG, acting as a prominent focal point for SRHR within the global community during the SDGs negotiations. A consultative process was conducted to devise a list of indicator recommendationsrelating specifically to SRHR; this processinvolved a wide range of stakeholders and technical experts, including experts from the Department. Additionally, SDG Goal 5 (Achieve gender equality and empower all women and girls) includes relevant SRH targets and proposed indicators on violence against women, female genital mutilation, early marriage and reproductive rights.

Although the SDGs are comprehensive, visionary and inspiring in many ways, the scope of SRHR issues they address is limited, and the SDG indicators are not likely to include certain critically important elements of SRHR.To address these potential gaps, the Guttmacher Institute and The Lancet established a commission on SRHR in the post-2015 world that will begin work in early 2016 with the aim of developing a wide-ranging and evidence-based agenda for key SRHR priorities worldwide over the next 15 years. This Commission will also make the case for adopting policies and

programmes aimedatturning that vision into reality.The coordinator of the Adolescents and at-Risk Populations team of the Department was invited to be a commissioner.

Planned activities

- The Department will be actively engaged in the process of developing and reporting on the SRHR-related SDGs indicators.
- The Department is actively engaged in the Commission on SRHR established by the Guttmacher Institute and The Lancet journal. A staff member participates as one of the 14 Commissioners, who aim to review the evidence, assess gaps, identify key priorities in SRHR for the future, and issue a concise set of recommendations. The work of the Commission will be carried out during 2016 and finalized in 2017.

2.2.3 Global Financing Facility (GFF)

Progress

The Global Financing Facility (GFF) in Support of EWEC was launched in July 2015 at the Addis Ababa Conference on Financing for Development, to contribute to smart, scaled-up and sustainable financing for women's, children's and adolescents' health. The GFF isintended to facilitate coordination of the flow of funding among key partners in support of national plans, to assist governments to increase domestic resources for health, and to reduce inefficiencies in spending. The GFF is linked to a specific GFF Trust Fund managed by The World Bank that provides an opportunity for 62 low- and lower-middle-income countries to receive grants for women's, children's and adolescents' health linked to the use of International Development Association (IDA) loans. The Department has been involved in supporting the development of the "Investment Cases" in the Democratic Republic of the Congoand Kenya in order for these countries to access the Trust Fund resources. Research conducted by the Department is already helping countries to prioritize their actions.

Planned activities

- In 2016, the Department will supportcountries on specific SRH issues based on country requests.

2.3 ICPD Beyond 2014 and Beijing +20

Progress

In 2015, the Departmentcontinued its efforts to support the ICPD Beyond 2014 review process[1] 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 (SRH). In follow-up to the production of seven fact sheets in 2014 relating to key areas of SRHR, theDepartment worked on the dissemination of this material at key conferences and forums held in 2015.[2]

The Department also worked on the dissemination of the position paper based on information available on progress and gaps in implementation of the ICPD Programme of Action *(4)*. 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.

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1 Official website available at: http://icpdbeyond2014.org/

2 The fact sheets are available at: http://www.who.int/reproductivehealth/icpd/en/

The Department has also been involved in the ICPD Geneva Network of Member States, 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 with a specific focus on the role of SRHR in that agenda.In particular, theDepartment provided regular updates on the process of development of: the Global Strategy for Women's, Children's and Adolescents' Health*(1)*; the draft global plan tostrengthen the role of the health systems to address interpersonal violence, in particular against women and girls, and against children;[3] and the three draft Global Health Sector Strategies for HIV, viral hepatitis and sexually transmitted infections 2016–2021.[4]

In 2014, 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 Fourth World Conference on Women, in Beijing, and the Beijing Declaration and Platform for Action*(5)*. With participation of all relevant WHO Departments, the paper, entitledWomen and health: 20 years of the Beijing Declaration and Platform for Action*(6)*, was completed in December 2014 and subsequently 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. In early 2015, the comments from the WHO Executive Board about the paper were incorporated to develop a new version,which was discussed at the World Health Assembly in May 2015*(7)*.

Planned activities

- 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.
- The Department will remain actively engaged in the Geneva ICPD Network.
- Theglobal plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children, and the Global Health Sector Strategy for sexually transmitted infections will be finalized in early 2016 and discussions at the World Health Assembly in May 2016 will be followed.

2.4 The H4+ mechanism

Progress

The UN H4+ mechanism, which combines the efforts of UNFPA, UNICEF, WHO, The World Bank, UNAIDS and UN Women, works with countries to support the implementation of commitments to the UN Secretary-General's Global Strategy for Women's, Children's and Adolescents' Health and the EWEC movement, to accelerate progress towards achieving MDGs 4 and 5. H4+ efforts focus on provision of joint support to countries in planning and implementing effective reproductive, maternal, newborn and child health (RMNCH) interventions, by strengthening the health systems and improving equity in access to quality services.

The Department led WHO's efforts in monitoring support of the more than 75 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: provide an

3 Available at: http://www.who.int/topics/violence/interpersonal-violence-against-women-children/en/

4 Available at: http://www.who.int/hiv/strategy2016-2021/en/

updated overview of H4+ country coordination, functionality and activities; synthesize information on H4+ efforts to accelerate implementation of the Global Strategy; and inform the post-2015 development agenda initiatives by documenting and sharing the H4+ lessons learnt on interagency collaboration and joint implementation. The resulting progress report for 2014, found that the H4+ collaboration had improved harmonization of stakeholder agendas and reduced duplication of efforts, thereby turning potentially competitive organizational relationships into partnerships*(8)*. Additionally, the H4+ mechanism was credited with being effective in generating and maintaining support and funding for RMNCH interventions by facilitating external partner alignment with national RMNCH priorities while also mobilizing increased domestic resources for RMNCH at national and subnational levels. Direct support addressing country-specific RMNCH needs 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 2016, the Department will support the development of transition plans at the country level in response to post-2015 shifts in the funding landscape,and will also explore the evidence base behind key country-driven innovative programmes, such as integrating services for men and boys into RMNCH services.
- The Department, in collaboration with all H4+ partner agencies, will contribute to development of the role for H4+ in support of the new Global Strategy for Women's, Children's and Adolescents' Health.

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

Progress

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

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 domestic 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 SRHR.

Under the leadership of the Department, the relationship between WHO and IPU has evolved over the last couple of years to become a systematic cooperation on a range of areas of work, including policy research, accountability, advocacy and technical support for development of legislation and policies as relates to SRHR, and with a focus on a variety of topics, including violence against women, family planning, maternal and child health, and traditional practices (e.g. child, early and forced marriage) as well as women's and children's health more broadly.

Within this collaboration, a highlightwas the unanimous adoption of the landmark resolution in 2012, *Access to health as a basic right: the role of parliaments in addressing key challenges to securing the health of women and children(9)*. The resolution highlighted the human rights, political and socioeconomic imperatives according to which parliamentarians can act to support women's and children's health.

As a recent follow-up to thisIPU resolution, the Department supported IPU in a study toreview progress of the implementation of the resolution,the findings of which were presented at the 132nd IPU General Assembly in Hanoi, Viet Nam, in March 2015.

In the last year, theDepartment has also formally engaged withparliamentarians and IPU in the process of developing the new Global Strategy for Women's, Children's and Adolescents' Health*(1)*. Parliamentarians have participated in the formal consultations held in Geneva, Johannesburg and New Delhi, which led to the development of the official IPU commitment to the Global Strategy, submitted on 9 September 2015. IPU committed to ensuring that national parliaments continue to play a central role in improving women's, children's and adolescents' health at national, regional and global levels, as well as improving accountability.

IPU and the Department have also collaborated in the area of child, early and forced marriage (CEFM) with a specific focus on the impact of legislation on child marriage as related to health outcomes. Results of a first study on 10 African countries were presented at the Pan African Parliament meeting in November 2013, and this was instrumental in the finalization of a Pan African Parliamentary resolution on gender-based violence.

The Department and IPU developed a second study on the impact of legislation on CEFM in 37 Asia-Pacific countries. The findings of the study were presented at the Regional Seminar for Asia-Pacific Parliaments "Ending the cycle of violence against girls in Asia-Pacific", in Dhaka, 23–25 September 2014 *(10)*and a publication synthetizing the main findings was published in the *Review of Faith and International Affairsin* 2015 (11). The final study report was prepared during 2015 and will be published in early 2016. In follow upto this work, the Parliament of Bangladesh has requested WHO and IPU to conduct a study on CEFM legislation and health in the country.

The Department has also been actively engaged in the context of the IPU Women Speakers of Parliament to support women's participation and leadership on political, economic and social issues, as well as to promote women's health as a priority in national agendas. Recently the Department's Director represented WHO at the Fourth World Conference of Speakers of Parliament, held in New York, USA,in September 2015.

Within the context of collaboration with other parliamentary forums, the Department has worked with the European Parliamentary Forum on the G7/G20 Parliamentary Meeting for Women's and Children's Health held in Berlin alongside G7 Germany (the G7 Summit 2015). The Department has provided crucial input to the final statement by G7/G20 parliamentarians to be handedover to the German G7 Sherpa. The Department is also working in collaboration with the Italian and Japanese governments in preparation for the 2016 and 2017 G7 summits to position women's, children's and adolescents' health, including sexual and reproductive health (SRH), on the agenda for both summits.

Planned activities

- In collaboration with parliamentary platforms, the Department plans to continue research on the impact of legislation onCEFM on SRH.

- The Department willcontinue to provide support for the development of SRH-related legislation upon parliaments' request.
- The Department will support IPU in its engagement within the Global Strategy operationalization framework and the accountability mechanisms.
- In collaboration with IPU, the Department will develop an online database on CEFM marriage legislation.
- The Department plans to collaborate with G7 countries, both at government and parliament level, in preparation for the 2016 and 2017 G7 Summits on issues relating toSRH.

2.6 The Global Fund to Fight AIDS, Tuberculosis and Malaria

Progress

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.

WHO signed an agreement with the Global Fund to provide country-specific technical support to increase the quality of RMNCHelements in the Concept Notes used to apply for Global Fund support. The Departmenthas contributed to providing technical support to countries in developing proposals that include sexual and reproductive health (SRH) aspects. WHO has conducted multiple capacity-building workshops for RMNCH consultants, partners, ministry of health (MOH) focal persons and WHO staff, involving 15 countries in the WHO African Region.

Furthermore, Department staff participated in technical meetings to support Ebola-affected countries in the development of recovery and resilience plans with a focus on funding from Gavi, the Global Fund and other partners, in Accra, Ghana, 9–11 June. Department staff also participated in a five-day technical consultation in Owerri, Nigeria, 15–20 June, to develop a protocol for a pilot project to integrate prevention of mother-to-child transmission (PMTCT) and reproductive, maternal, newborn, child and adolescent health(RMNCAH) as recommended by the Governmental Advisory Committee, and to obtain feedback from Nigerian stakeholders, including participants from nongovernmental organizations (NGOs), government and implementation partners from state, local and federal levels. The technical consultation in Nigeria resulted in a research protocol to conduct a study to assess the viability of integrating an expanded portfolio of services to improve PMTCT of HIV and syphilis within antenatal care (ANC) settings in selected Nigerian states.

Planned activities

- The Global Fund has identified 20 countries where the rate of implementation is lagging behind and has created an initiative to review the bottlenecks to implementation in these countries, together with a number of partners at the global level.The Department will continue to provide support on SRH aspects of proposals in these countries.

2.7 Family Planning 2020 (FP2020)

The Family Planning 2020 (FP2020) partnershipaims to support 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 in response to high levels

of unmet family planning needs, which was the focus of a global summit in London in 2012 initiated by the Government of the United Kingdom of Great Britain and Northern Ireland (United Kingdom) and the Bill & Melinda Gates Foundation. The Department has been a key partner in implementing the objectives of the Summit.

Progress

In the three 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*(12)*, across the 69 FP2020 focus countries, in 2013, 8.4 million more women and girls were 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 Department, has been on board since the inception of the initiative and has contributed actively with the Department Director beinga member of the Reference Group, representing WHO.

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 is in line with the guidelines and framework recently developed by WHO, as well as providing technical support in the area of country engagement.

Recently FP2020 has gone through a process of strategic review and reform of its structure to accelerate progress over the remaining five years of the partnership. This has led to a stronger role for the FP2020 Secretariat and the Reference Group, as well as the dissolution of theworking groups onRights and Empowerment, Market Dynamics and Country Engagement. The Performance Monitoring and Evidence (PME) Working Group will continue, and the work will be refined to ensure alignment with the new FP2020 priorities.

Planned activities

- The Department will keep contributing to the FP2020 initiatives on behalf of WHO as a member of both the Reference Group and the PME working group.
- The Department will support FP2020 in engaging withparliamentarians and parliamentary forums on issues related to contraception and family planning.

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3. Thematic areas

3.1 Family planning and contraception

3.1.1 Introduction

Unintended pregnancy, resulting from unmet need for family planning/contraception, is a problem that threatens the lives and well-being of women and girls and their families globally. Populations most impacted are sexually active adolescents, individuals with low socioeconomic status, those living in rural communities, and those coping with conflicts and disasters. Latest estimates indicate that 225 million women in developing countries have an unmet need for modern contraceptive methods *(1)*. The need is greatest within populations where risks of maternal mortality are highest.

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 mission, the Departmentis implementing a collaborative, science-driven approach. This section reports on how, in 2015, this approach has translated into concrete and coordinated activities towards strengthening and improving equitable access to quality family planning services at scale and towards maintaining family planning as a global development priority.

Major achievements

- In 2015, the Department published 25 papers on family planning and contraception.
- WHO publishedits eagerly anticipated update of the *Medical eligibility criteria for contraceptive use* (MEC) guidance and its accompanying job aid for providers of family planning services, the MEC Wheel on 1 June 2015. Through a rigorous review of the latest science addressing contraceptive safety, 14 topics (encompassing more than 575 recommendations) were reviewed as part of the revision process to develop the fifth edition of the MEC.
- The *Compendium of WHO recommendations for postpartum family planning* guidance uses a new user-friendly digital platform to enable easy access to its recommendations. It is aimed at health-care providers who counsel postpartum women on contraceptive options; it helps these providers to quickly and easily access WHO recommendations on what contraceptive options are available for these clients. This tool was completed in December 2015.
- The Department provided technical support to 10 countries in the WHO African Region to develop postpartum family planning.

3.1.2 Research and development

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 is a multicountry complex-designed intervention being implemented in Kenya, South Africa and Zambia to increase the participation of the community and health-care providers in the provision of family planning and contraceptives. The Project uses a "Theory of Change" framework to define the pathway to the desired overall

outcome, which is to address the unmet need for family planning and contraceptive services within a human rights framework.

Progress

- The 18-month formative phase was approved by the Research Project Review Panel (RP2) on 28 March 2015 and by WHO's Ethics Review Committee (WHO-ERC) on 21 May 2015. All local institutional review board (IRB) approvals have also been obtained. The site-initiation meetings were conducted from 21 July to 2 August 2015 at all three sites.
- Manuscripts of scoping reviews on approaches to community and health-care provider participation and on definitions of "quality of care" from health-care provider and community perspectives have been completed and were submitted for review in December 2015.
- For the formative phase, qualitative research training was conducted in Lusaka for the social scientists and the qualitative research teams from the three countries from 19–21 August 2015. Focus group discussions (FGDs) and in-depth interviews (IDIs) were initiated in September 2015; 14 FGDs and 10 IDIs have been conducted in each country. Legal and policy mapping was initiated in August 2015 and is completed. Mapping of facilities and services began in September 2015, and the findings are being written up.
- An investigators' update meeting took place by WebEx on 10 November 2015 to discuss preliminary results of the formative phase activities, and to plan the next steps, including initiating the development of the approach for engaging the community and health-care providers and for defining the eligibility and matching criteria for the intervention sites.

Planned activities

- By March 2016, we plan to complete the formative phase activities, disseminate the results and start developing the protocol for the implementation phase. A Working Group meeting is planned for March 2016 to discuss the results of the formative phase and develop the protocol for the implementation phase.
- We plan to obtain approvals for the implementation phase protocol from the RP2, WHO-ERC and local IRBs by June 2016. If approved, the implementation phase is expected to begin in August 2016.

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 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

Research teams are conducting systematic reviews of five 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 and (e) out-of-pocket payments and user fees. The second researchers meeting was held in June 2015 in Geneva, 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.

The reviews were finalized in November and disseminated at a large meeting of bilateral, multilateral and nongovernmental donors in the family planning community, in December 2015. The aim of this meeting was to present the results, identify gaps in the research, propose a research agenda to funders and ultimately to begin implementation of the findings.

Planned activities

- In 2016, the systematic reviews and consolidated findings will be published in a special issue of a leading peer-reviewed journal.

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 services and commodities affordably for the poor and underserved 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

Two quasi-interventional studies testing two different demand-side financing approaches with voucher schemes (multipurpose versus single vouchers) in Pakistan's Punjab province were completed, in collaboration with Population Services International (PSI) and Marie Stopes International (MSI).

Final reports on the end-line survey findings are currently being prepared. A series of dissemination meetings with the Ministry of Health, the Packard Foundation (donor) and other donors were conducted in 2015 in Pakistan.

Planned activities

- A series of peer-reviewed papers on the end-line evaluation will be submitted in early 2016 (2–4).

3.1.2.4 Operations research on postpartum family planning in the Democratic Republic of the Congo and Burkina Faso

This operations research RCT aims to identify and test the effectiveness of a package of PPFP interventions that reinforce existing pre- and postnatal services. The package of interventions (as conceived in the formative phase) will be delivered at primary health care centres. To assess impact, use of family planning methods immediately

postpartum, six days, six weeks, 5–6 months and 8–9 months after delivery will be compared with the usual PPFP services provided at control health centres.

Progress

The PPFP protocol, guides and tools were approved by RP2 in May 2015 and by WHO-ERC in August 2015 (with conditional approval in July 2015). The pre-formative phase, including identifying and mapping health centres and a review of relevant documents in each country, was completed in July 2015. Three sites were identified in each country for use in the formative phase and the remainder of the sites will be randomly selected as control or experimental sites for the intervention phase.

A training workshop on the use of the counselling guide and focus group discussion tools was held in Ouagadougou on 29–31 July 2015 with the principal investigators and data analysts from the two research sites (Burkina Faso and the Democratic Republic of the Congo). Burkina Faso then started the formative phase in August followed by the Democratic Republic of the Congo in October. Formative data collection, for identifying barriers and catalysts as well as for feedback on the counselling tool, was completed in November 2015. On 14–18 December 2015, WHO headquarters organized a workshop for the two country teams and other stakeholders to discuss the final results of the formative phase and the finalization of the PPFP package to be ready for the intervention phase.

Planned activities

- Based on the results from the formative phase, the PPFP package will be amended for the intervention phase that will start in the first quarter of 2016. The protocol and instruments will be resubmitted to WHO-ERC in early January 2016.

3.1.2.5 Preclinical development of simple and inexpensive depot injectable formulations for combination contraception and HIV prevention

The Department has undertaken to develop and test the preclinical feasibility of injectable-type multipurpose prevention technology (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

An RP2 proposal has been approved and initiated in collaboration with Queen's University Belfast, Northern Ireland, United Kingdom in 2015. Two different injectable formulation strategies will be investigated, the first based on a reformulation of the injectable contraceptive Depo-Provera®, and the second on in situ forming implants. Both strategies will make use of medroxyprogesterone acetate (MPA) as a hormonal contraceptive and one or more of the antiretroviral (ARV) drugs MC1220, rilpivirine (RPV) and cabotegravir (GSK744).

Preliminary characterization studies were conducted to evaluate the physico-chemical properties of MPA and the ARV drugs. The studies performed to date demonstrate that MPA, MC1220 and RPV are suitable candidates for the development of MPT injectable formulation products if MC1220 polymorphism is controlled.

The characterization studies of the commercial contraceptive Depo-Provera® represent a good basis for further development of depot suspension combinative drug products associating the contraceptive MPA with an ARV candidate.

Planned activities

- More work will be done to pursue the development of these MPT injectable formulations as depot suspensions and in situ forming implants.

3.1.2.6 Study of the factors affecting access to emergency contraception using levonorgestrel 1.5 mg in Malawi

Emergency contraception (EC), as part of a wide range of options, especially for cases of unprotected sex, including cases of sexual assault, or perceived contraceptive failure, has the potential to significantly reduce the incidence of unintended pregnancy and the consequent need for abortion.

Progress

Results of the study show that essentially all facility-level respondents had heard of EC compared to 78.9% of police officers at victim support units (VSUs), where victims of sexual assault are taken care of. Progestin ECs (especially levonorgestrel) are the most widely available. The most common indication for EC was unprotected sex, burst condom. EC stock-outs in the preceding 12 months were only experienced in 12% of the service-delivery points surveyed. Respondents identified cultural and religious beliefs along with misconceptions related to the view of ECs as "abortion pills" as the main barriers to utilization.

Despite wide and consistent availability of ECs, utilization remains low. Police officers working at VSUs are particularly lacking in knowledge on EC. There is a need to address cultural and religious beliefs and common misconceptions within a comprehensive advocacy programme to promote EC utilization.

Planned activities

- The full study report will be completed for publication in 2016.
- More discussions on the roles of the officers at VSUs will be held, with a view to planning more in-depth training.

3.1.2.7 ECHO (the Evidence for Contraceptive options and HIV Outcomes) Trial

ECHO is a multicentre, open-label, randomized clinical trial comparing HIV incidence and contraceptive benefits in women using depot medroxyprogesterone acetate (DMPA), levonorgestrel (LNG) implants and copper-bearing intrauterine devices (Cu-IUDs) for contraception. The ECHO Trial will provide the most definitive information concerning the comparative risk of HIV acquisition and other risks and benefits resulting from the use of DMPA or LNG implants, with Cu-IUDs as the control group. The ECHO Trial will be conducted at 12 clinics in southern and eastern Africa.

To implement this study, the Department set up the ECHO Consortium, comprising major organizations; it will be jointly led by FHI 360 and WHO.

Progress

The protocol has been approved by RP2 and the WHO-ERC. Funding has been provided for the East London site in South Africa, which is supported by WHO. The Department participates and provides input during regular management committee and all-site conference calls.

On 8–10 December 2015, the Department hosted an annual meeting of researchers, policy-makers, implementers, civil society and other stakeholders engaged in research,

programmes or policy on hormonal contraception and HIV. The meeting identified research, policy and programme gaps in the field.

Planned activities

- Enrolment of study participants started in December 2015 as most of the site activation visits had been done and the study products had been procured. Study enrolment will continue in 2016.
- The next meeting is scheduled for November 2016.

3.1.2.8 Effect of combined contraceptive pills on exclusive breastfeeding and infant weight gain; a double-blind randomized clinical trial of combined and progestogen-only pills with an observational control group of IUD users

The uncertainty and controversy about the safety of combined oral contraceptives (COCs) during breastfeeding can only be resolved through attaining high-quality data from a double-blinded RCT on the effect of COCs on breastfeeding, adding an observational control group of women using IUDs during breastfeeding. This will be an international, multicentre trial in which healthy, exclusively breastfeeding women with singleton healthy infants born after full-term pregnancies will be enrolled after consenting to be randomized either to COCs (30 µg ethinylestradiol, 150 µg LNG) or to progestogen-only pills (POPs; 30 µg LNG), starting the pills after six completed weeks postpartum. Additionally, exclusively breastfeeding women choosing Cu-IUD for contraception will, after consent, be enrolled and frequency-matched by parity (nulliparity, parity 1+) and age (5-year age bands) to every second woman randomized to COCs or POPs.

Progress

The project protocol is under review by RP2.

Planned activities

- An expert working group meeting will be held in January 2016, followed by initiation meetings and local IRB approvals in four countries.

3.1.2.9 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 worldwide. Implanon® is a single-rod, implant that contains the progestin etonogestrel, providing contraceptive protection for up to three years. Jadelle® has two LNG rods and provides protection for up to five years. The safety and efficacy of single-rod versus two-rod contraceptive implants were investigated in a multicentre clinical trial. 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 Cu-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 *(5)*.

Progress

Results of the study indicating that both contraceptive implants are safe and highly effective for up to three years of use, and that their effects are rapidly reversible upon removal, have been published and are available online in the journal, *Human Reproduction(6)*. Abstracts

reporting on five years of follow-up assessments were presented at the International Federation of Gynecology and Obstetrics (FIGO) World Congress in Vancouver, 2015, and at the Reproductive Health Supplies Congress in Oslo, 2015.

Planned activities

- A manuscript reporting on the five-year follow-up of clients in the implant study will be submitted to a peer-reviewed journal in the first quarter of 2016.

3.1.2.10 A prospective, open-label, single arm, multicentre study to evaluate efficacy, safety and acceptability of the peri-coital oral contraception using levonorgestrel 1.5 mg

Levonoregestrel (LNG) 1.5 mg is an effective emergency contraceptive that can be taken following unprotected intercourse. Some users take it repeatedly, as their means of regular contraception. This has raised the question of whether the use of LNG 1.5 mg on each day of coitus by women who have relatively infrequent sex may be an efficacious, safe and acceptable contraceptive method. A study on this topic was conducted in four countries: Brazil, Hungary, Singapore and Thailand.

There were 321 women who were included in the evaluable population, with 141.9 woman-years of observation and with a rate of 7.1 (95% confidence interval [CI]: 3.8–13.1) pregnancies per 100 woman-years of typical use, and 7.5 (4.0–13.9) pregnancies per 100 woman-years of sole use. In the primary evaluable population (women under 35 years old), the rate was 10.3 (5.4–19.9) pregnancies per 100 woman-years of typical use, and 11.0 (5.7–13.1) pregnancies per 100 woman-years of sole use. There were three reported severe adverse events and 102 other mild adverse events, with high recovery rate. The most common adverse events were headache, nausea and abdominal and pelvic pain. Vaginal bleeding patterns showed a slight decrease in volume of bleeding and the number of bleeding-free days increased over time. The method was considered acceptable, as over 90% of participants would choose to use it in the future or would recommend it to others.

Progress

This paper was presented at the FIGO World Congress in Vancouver (October 2015). The paper has also been accepted for publication in Human Reproduction in early 2016 (7).

Planned activities

- The paper will be presented at the International Conference on Family Planning (ICFP) in Bali, Indonesia, in January 2016.
- The next steps for further research on peri-coital contraception are being discussed with partners and donor agencies.
- The further research ideas will be presented at the European Society of Contraception and Reproductive Health Congress in Basel, Switzerland, in May 2016.

3.1.3 Norms, standards and tools

3.1.3.1Medical eligibility criteria for contraceptive use, fifth edition

Over the past 40 years, there have been significant advances in the development of new contraceptive technologies, including changes in formulations and dosing, schedules for administration and novel delivery systems. However, current policies and health-care practices in some countries are based on scientific studies of

contraceptive products that are no longer in wide use, on long-standing theoretical concerns that have never been substantiated or on the personal preference or bias of service providers. These outdated policies or practices often result in limitations to both the quality of and the access to family planning services for clients. The goal of the document, *Medical eligibility criteria for contraceptive use,* is to improve access to and quality of family planning services, by providing policy-makers, decision-makers and the scientific community with recommendations that can be used for developing or revising national guidelines on medical eligibility criteria used in the provision of all hormonal contraceptives, IUDs, barrier methods, fertility awareness-based (FAB) methods, coitus interruptus, lactational amenorrhoea method (LAM), male and female sterilization, and emergency contraception.

Progress

On 1 June 2015, WHO issued its eagerly anticipated update of the Medical eligibility criteria for contraceptive use (MEC) guidance *(8)* and its accompanying job aid for health-care providers of family planning services, the MEC Wheel *(9)*.

Through a rigorous review of the latest science addressing contraceptive safety, 14 topics (encompassing more than 575 recommendations) were reviewed as part of the process to develop the fifth edition of the MEC. Key highlights of the revision are as follows:

- inclusion of four additional methods in the guidance;
- relaxed restrictions on several contraceptive methods for breastfeeding women in the postpartum period;
- more contraceptive options for women taking antiretroviral medications;
- reiteration of eligibility for all contraceptive methods for adolescents; and
- clearer guidance for women at high risk of sexually transmitted infections (STIs) and women at high risk of HIV infection.

To ensure that this updated guidance reaches front-line health-care providers as quickly as possible, a 2015 edition of the MEC Wheel was prepared *(9)*. The 2015 MEC Wheel features the latest recommendations, additional contraceptive methods, a layout that is more in line with clinical decision-making and more guidance for breastfeeding and postpartum women.

Following the release of the updated guidance, key recommendations within the MEC fifth edition were presented during numerous international meetings, including the International Council of Nurses (June 2015), the Asia-Pacific Regional Meeting of the International Confederation of Midwives (July 2015), and the FIGO World Congress (October 2015). Further, the guidance was presented during principle regional events, notably in the WHO Region of the Americas and the WHO African Region. Lastly, a half-day session, which included a panel and small-group discussions, was organized during the Implementing Best Practices (IBP) semi-annual meeting of partners to maximize the implementation of the latest MEC recommendations (June 2015).

Publication of the scientific foundation of WHO's recommendations on contraceptive safety continues to be a high priority. As such, since August 2014 more than eight systematic reviews have been published in open-access format in the journal *Contraception (10–17)*. Moreover, a paper identifying the principle remaining research gaps has been published to help identify priorities and stimulate further research *(18)*. In addition, a commentary summarizing the development of the MEC over the past 20 years and future directions was published in a special issue of *Current Clinical Opinion for Obstetrics and Gynecology (19)*.

Translations of the MEC guideline and the MEC Wheel into French and Spanish were initiated. The Government of Brazil will support and undertake the Portuguese translation of the two resources.

Planned activities

- During 2016, systematic reviews summarizing the body of evidence addressing (i) hormonal contraception and HIV acquisition risk and (ii) hormonal contraception and drug interactions with ARV medications will be updated and published in peer-reviewed journals. These reviews will be sent through WHO's Continuous Identification of Research Evidence (CIRE) system for assessment by experts on contraceptive safety.
- French and Spanish translations of the 2015 MEC guidance and MEC Wheel will be finalized, published and widely distributed.
- Anticipated conferences for further dissemination of the MEC and MEC Wheel include the 2016 European Society for Contraception and the 2016 Societé de Contraception Francophone meetings.
- Responding to WHO's commitment to the Family Planning 2020 (FP2020) initiative, the Department will provide targeted technical assistance to Member States to implement the latest MEC recommendations.

3.1.3.2 Selected practice recommendations for contraceptive use, third edition

Since 2001, WHO has issued the guideline, *Selected practice recommendations for contraceptive use* (SPR), with the goal of providing guidance to policy-makers, programme managers and the scientific community in the form of a set of evidence-based recommendations on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate. The document aims to provide guidance to national family planning/reproductive health programmes in the preparation of national guidelines for contraceptive service delivery. Moreover, the SPR addresses ongoing controversies and inconsistencies regarding how to maximize the effectiveness of contraceptive methods and how to manage their side-effects or other problems during use *(20)*.

Progress

A draft of the third edition of the SPR guideline was prepared and sent for external review in December 2015. The third edition of the SPR includes service delivery recommendations for five additional contraceptive methods (the combined contraceptive patch, the combined contraceptive vaginal ring, subcutaneously administered DMPA, ulipristal acetate for emergency contraception and Sino-implant (II)) and new guidance on how to initiate regular contraception after taking emergency contraception.

Planned activities

- Following external peer review, the draft third edition of the SPR will be submitted to WHO's Guidelines Review Committee in January 2016. It is envisioned that the finalized guidance will be published in early 2016.
- Efforts to publicize the release of the new guidance through the Department's partners and networks, including social media, will be employed. Additionally, opportunities for dissemination of the updated guidance during upcoming professional conferences will be sought.

- Translation of the guidance into French and Spanish will be undertaken as soon as possible.

3.1.3.3 Compendium of WHO recommendations for postpartum family planning

Progress

In response to the growing global recognition of the very high unmet need for family planning among women during the immediate and extended postpartum period, and confusion among providers and policy-makers as to how to interpret and apply the complex recommendations, WHO has developed a new user-friendly digital platform to enable easy access to its recommendations. Aimed at health-care providers who counsel postpartum womenon contraceptive options, the *Compendium of WHO recommendations for postpartum family planning* helps these providers quickly and easily access WHO recommendations on what contraceptive options are available for postpartum women *(21)*.

Planned activities

- Launch of the Compendium will take place on 26 January 2016 at the ICFP, in Bali, Indonesia.
- During 2016, the Compendium will be demonstrated and presented during numerous professional meetings (e.g. the 11th Biennial Conference of the Global Network of WHO Collaborating Centres for Nursing and Midwifery, July 2016), as well as regional technical meetings involving WHO regional offices and IBP partners. A commentary that announces the availability of the Compendium and summarizes its key features will be published in a peer-reviewed journal to ensure the professional community is aware of the new resource. Moreover, WHO will respond to requests for technical assistance from Member States to implement the digital resource.

3.1.3.4 Family planning global handbook

WHO's publication, *Family planning: a global handbook for providers*, offers evidence-based information for contraceptive service delivery for front-line health-care providers offering services to clients *(22)*. This resource incorporates recommendations from the *Medical eligibility criteria for contraceptive use* (MEC) and the *Selected practice recommendations for contraceptive use* (SPR) guidelines *(8, 20)*. It also includes many other useful pieces of information that health-care providers need to know when counselling clients on contraceptive safety and efficacy, as well as instructing clients on how to use methods and address problems and/or concerns they may have.

Progress

Updating of *Family planning: a global handbook for providers* was initiated in November 2015. While the bulk of the revised edition will focus on ensuring that the recommendations in the fifth edition of the MEC and the soon-to-be released third edition of the SPR are incorporated into the manual, additional WHO guidance on other relevant sexual and reproductive health topics will also be addressed in the revision.

Planned activities

- The 2016 edition of Family planning: a global handbook for providers will be finalized in early 2016 and sent for peer review prior to publication of this popular health-care provider reference, which is anticipated for mid-2016. Through collaboration with the Johns Hopkins Center for Communication Programs, translations of the handbook into numerous languages will be initiated.

3.1.3.5 Medical eligibility criteria for contraceptive use (MEC) and Selected practice recommendations for contraceptive use (SPR) implementation guide

Responding to requests from Member States over the years for further clarifications on how programmes can implement recommendations within the MEC and SPR guidelines effectively, the Department will develop a MEC and SPR implementation guide. This document will address issues such as how to differentiate recommendations classified as a MEC category 2 and 3, and how to address issues related to follow-up, exams, tests and other concerns that programmes confront when implementing the guidance in these documents.

Progress

The Department established an Implementation Guide Working Group to undertake the development of the MEC and SPR implementation guide, which will serve as a resource to accompany these two guidelines. The bulk of the multidisciplinary Working Group's work will be undertaken during 2016.

Planned activities

- Through an evidence-informed and consultative process, the Implementation Guide Working Group will advise the Department on the development of the implementation guide during 2016. Two technical stakeholder consultations are envisioned to ensure that the resource is accurate and informed and that it responds to the realities facing national programmes and implementing agencies and partners.
- The Department plans to finalize the guide by the end of 2016.

3.1.3.6 Family Planning Training Resource Package

The Family Planning Training Resource Package (TRP) is a comprehensive set of instructional materials and curricular components to design, implement and evaluate training. It provides organizations with essential resources for trainers and programme managers, for pre-service and in-service training, for both the public and private sectors *(23)*. The TRP is used by instructors and curriculum developers for high-quality training and customized to meet the needs of specific audiences. Regular updates will incorporate new materials and comply with the latest technical changes in content.

Each module includes: session plans and training schedules; facilitator's guide; presentation slides; interactive group and self-study activities, and case studies; job aids, learning guides, knowledge and skills evaluations; and references.

Progress

Thirteen modules are in English, with new modules on emergency contraception (for family planning providers and pharmacists) and the Standard Days Method. Many additional key documents have been translated into French, with Spanish translations planned. A workshop was conducted in 2015 during the FIGO World Congress in Vancouver, and in countries (Tanzania, Malawi and the Philippines, etc.). In addition, technical assistance was offered to Timor Leste to revise their training curriculum.

Planned activities

- A project to assess the impact of using the TRP in countries will be conducted in 2016.
- A workshop will be conducted at the ICFP in Bali, Indonesia, in January 2016.

- New modules on female sterilization and vasectomy are being developed.
- Translations of the remaining key documents into French and Spanish are being pursued.
- Country and regional workshops are being planned.

3.1.4. Monitoring and evaluation

3.1.4.2 Human rights and family planning indicators and quality assessment tool for contraceptive programmes

This work focuses on strengthening the capacity of health systems to monitor human rights dimensions in contraceptive programmes. The objective of this work is to develop a global approach to support regions and countries in ensuring accountability by strengthening the monitoring and evaluation (M&E) capacity of human rights dimensions in contraceptive programmes.

WHO has developed a process for identifying existing quantitative health indicators that can be used in a rights-based analysis to provide a baseline assessment *(24)*. This process has been applied to existing quantitative health indicators, and 12 indicators have been prioritized. A method for systematically analysing these indicators has been developed.

Progress

Building on this previous work, a new draft report is under preparation, which acknowledges the limitations of only using quantitative indicators to monitor rights, and identifies areas where additional measures are needed (novel quantitative, qualitative or policy indicators).

This work will contribute towards development of a tool that can be used globally in contraceptive programmes to monitor human rights dimensions. The tool is being developed as an extension of the Department's work on contraception and human rights, and will be refined through regional consultations for input and reviews. Key partners and stakeholders have been engaged in the process from inception to ensure ownership in the development of the tool, and its broad adoption globally.

An expert group meeting was held in December 2015 with the main purpose of providing input to the work done on tools for M&E. The expert group reviewed and identified technical gaps and priorities, made recommendations on technical and operational methods, and reviewed activities and outputs as necessary.

Planned activities

- The draft document will be revised, and input and feedback received will be incorporated in January 2016.
- The tool will be completed in late 2016.
- Pilot testing of the tool in three proposed countries – Kenya, Nigeria and the United Republic of Tanzania – will take place in mid-2016.
- Translation of the tool into French from the English version will be undertaken in late 2016.
- Results will be reviewed at the second meeting of the expert group in July 2016 followed by implementation/dissemination in the field in late 2016/early 2017.

3.1.4.3 Strengthening family planning and contraceptive services using WHO contraception guidelines

This work focuses on strengthening the capacity of health systems in assessment of quality of care in contraceptive programmes.

The main areas of work on strengthening quality of care in contraceptive programmes at the Department include (i) primary research and research synthesis, (ii) development and dissemination, via efficient mechanisms, of international clinical standards and guidelines based on research evidence and (iii) M&E of the capacity for informed decision-making within family planning programmes at country and regional levels.

Progress

An expert group meeting was held in October 2015 with the main purpose of providing input to the draft document on quality assessment of contraceptive programmes. The expert group reviewed and identified technical gaps and priorities, made recommendations on technical and operational methods, and reviewed activities and outputs as necessary.

The end output – an updated tool for assessing quality from a human rights perspective in contraceptive programmes – will be tool that will facilitate implementation of the principles and recommendations provided in the recently developed WHO guidelines on *Ensuring human rights in the provision of contraceptive information and services(25)*.

Planned activities

- The draft document will be revised and input received during the October 2015 consultation will be incorporated; the revised document will be available in early 2016.
- Translation of the tool into French from the English version will be done in mid-2016.
- Pilot testing of the tool in three proposed countries – Kenya, Nigeria and the United Republic of Tanzania – will take place in January–April 2016.
- The results will be reviewed at the second meeting of the expert group in June 2016, followed by revision and finalization of the tool in mid-2016 and implementation/dissemination in the field in late 2016.

3.1.5 Disseminations and partnerships

The work included under dissemination and partnerships is intended to support utilization of evidence in countries through the systematic introduction of science-driven solutions and a systematic approach to scaling up those solutions.

3.1.5.1 Activities of the Implementing Best Practices (IBP) initiative

In 1999, the Department, the United States Agency for International Development (USAID), the UNFPA and nine other agencies created the IBP initiative to work at the global, regional and country levels to foster collaboration, reduce duplication of efforts 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 Department, the partnership has now grown to 45 organizations, allowing for close collaboration between the Department and the IBP partners.

The IBP initiative is finalizing a new strategic plan that will guide the project during the period 2016–2020. An assessment of the 2011–2016 strategy was conducted between

June and August 2015 to lay the foundation for the new strategic plan. The objectives of the IBP initiative are reached through a combination of activities, some of which are highlighted below.

Progress

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

The IBP Secretariat at WHO worked closely with the West African Health Organisation (WAHO) and IBP partners to provide technical and financial support to organize the WAHO Good Practices Forum in Health. The IBP Secretariat also co-facilitated two planning meetings with WAHO (in January and April 2015) to prepare for the Good Practices Forum. The first focused on developing a guide for documenting the implementation of good practices in nine of the WAHO countries and the second helped to prepare for workshops in each of these countries prior to the Forum.

Together with USAID, Evidence to Action (E2A) and other partners, the IBP Secretariat organized a pre-forum workshop entitled "Fostering change for scale-up of good practices in the WAHO Region". More than 100 ministry of health focal points, officials and nongovernmental organization (NGO) partners from across West Africa attended. This workshop was meant as an introduction regarding the need to plan for systematic scale-up of practices. Participants were expected to take the lessons learnt as discussed at the workshop and keep them in mind throughout the Good Practices Forum.

The first Economic Community of West Africa States (ECOWAS) Good Practices Forum in Health, held in Ouagadougou, Burkina Faso, 29–31 July 2015, was a great success with more than 300 participants from the 15 ECOWAS countries. The level of enthusiasm and participation was impressive.

The June 2015 semi-annual IBP meeting took place in Addis Ababa; it was the first to take place in Africa. Over 220 people attended the meeting, including IBP partners' colleagues from East Africa, with the goal of deepening their involvement in IBP.

(ii) Partnership and knowledge management

In June 2015, IBP started to update and reshape the IBP Strategic Framework for 2016–2020. The new strategy will better reflect changes in the family planning landscape and strengthen the ability and commitment of IBP member organizations to actively engage in the work of the IBP Consortium.

A final draft of the new IBP strategy was presented to the IBP Consortium members and steering committee at the semi-annual meeting in Washington, DC, 10–11 December 2015. An opportunity for comments was given at both of these meetings with relevant suggestions being incorporated into the final version.

With partners, the IBP Secretariat organized several webinars in 2015 including: An introduction to the high impact practices (HIPs) for family planning; Standards for identifying evidence-based practices in reproductive health; Overview of the fostering change framework; and Learning through implementation: reaching first-time parents and young married women in Burkina Faso.

Over the last year, the IBP Knowledge Gateway (KG) has grown steadily with an average of 750 new members per month. After our semi-annual meetings in June and December, new membership peaked. The total membership now stands at over 66 000 and 48 new communities of practice were created in 2015. There are now over 900 communities

of practice; 143 were active over the last year and 73 within the last month. The KG averages over 1200 contributions per month, which is on par with the past few years.

Planned activities

- Five interactive sessions are planned for the ICFP in Bali, Indonesia (January 2016), which will focus on key issues in family planning today, especially scaling up and using partnerships to be successful. In addition, 10 ICFP workshops will focus on IBP tools, approaches and key issues with a view to improving family planning programmes worldwide.
- A two-page infographic has been developed to depict IBP's involvement since the first ICFP in 2009. It also provides additional information on the 2013 ICFP in Addis Ababa. This will be distributed at the ICFP.[5]
- The Department will follow up with WAHO on the next steps after the 2015 Forum on Good Practices. Activities to develop more widespread capacity to document the implementation of good practices and develop capacity to plan for the scale-up of good practices will be the focus of IBP partner interventions in 2016.
- The Department will continue to support partners to use the IBP Knowledge Gateway and conduct webinars on key issues in reproductive health.
- The new IBP strategy will be disseminated widely to members at all levels of their organizations.
- Due to the great success of the Addis Ababa IBP semi-annual meeting in June 2015, it is envisioned that one of the two 2016 semi-annual meetings will take place in Latin America.
- Virtual discussion forums will be organized in French on the MEC and MEC wheel *(8, 9)*, the *Compendium of WHO recommendations for postpartum family planning (21)*, and on task shifting implementation and scale-up issues.

3.1.5.2 Strengthening family planning services in the WHO African Region through increased utilization of WHO tools and guidelines

The Department is advocating for and promoting the use of its contraception guidelines, facilitating regional and national adaptations of WHO recommendations, and providing technical assistance to Member States through regional and sub-regional mechanisms.

Specifically, in 2015 the Department supported:

(a) development of a comprehensive package of resources for countries to implement a coordinated effort for the introduction, adaptation, implementation and scale-up of new contraceptive tools and WHO-endorsed practices; and

(b) regional capacity-building to work with countries to document successes, challenges and ways of overcoming challenges during implementation of evidence-based interventions, including those endorsed in WHO guidelines – this improved capacity is intended to provide a basis for improving successful family planning services.

5 The infographic is available at: http://www.ibpinitiative.org/images/ICFP2016IBPPoster.pdf

Progress

(i) Participation in Chiang Mai meeting on postpartum family planning (PPFP)

WHO staff participated in a meeting organized by FP2020 and Jhpiego in June 2015 in Chiang Mai, Thailand, on "Accelerating access to postpartum family planning in sub-Saharan Africa and Asia". WHO focused on implementation of PPFP programmes in the 10 countries in the WHO African Region that were targeted for the Chiang Mai meeting. In order to ensure WHO's involvement from the beginning, the Department invited colleagues from the WHO Regional Office for Africa, three staff from the Intercountry Support Teams (ISTs) and national professional officers from the 10 selected WHO country offices to participate in the meeting.

(ii) Brazzaville meeting to actively involve WHO's Regional Office and follow-up to the Chiang Mai meeting

The Department and the WHO Regional Office for Africa organized a regional consultation in Brazzaville, Congo, in September 2015, to discuss progress on the 10 countries' PPFP workplans, which will receive support from the Department. The meeting was also an opportunity to understand the entire project and to have the Regional Office's full engagement. Next steps were developed to ensure good coordination and communication between WHO headquarters, the WHO Regional Office for Africa and the countries. The need for an explicit plan for monitoring the grant and reporting on implementation, as well as a plan for funding levels for each activity was identified and these plans are being developed.

(iii) Product development: implementation package

After the IBP Addis Ababa semi-annual meeting in June 2015, a consultation of partners and WHO National Professional Officers (NPOs) was held to discuss the implementation package being put together under the WHO Umbrella project. Participants agreed there was a need for a "how-to" guide to help in the use of the existing tools.

In addition, it was felt that an update of the FP advocacy toolkit for inclusion in the package would be very valuable. The update is under way.

(iv) Finalizing a guide for documentation with WHO's Regional Office for Africa and WAHO

WHO headquarters and the WHO Regional Office for Africa have undertaken work to update and merge the WAHO documentation tool and the Regional Office's tool to document best practices. Planning has begun and a consultation is planned for early 2016 to guide the development of the tool.

Planned activities

- The Department will continue to follow up and support WHO regional and country offices and partners from the 10 country teams working on PPFP action plans (generated at the Chiang Mai meeting). Countries will focus on coordination and M&E of the PPFP action plans as well as ensuring that the updated MEC and related tools are used to strengthen programmes.
- A follow-up meeting will be convened by FP2020 and Jhpiego at the ICFP conference in Bali, Indonesia, in January 2016. WHO headquarters invited the same colleagues from WHO country and regional offices to accompany country teams and discuss the current status of the workplans.

- The implementation package and the documentation tool will be finalized and tested, followed by training of ISTs and partners in their use.
- A subregional consultation will be held on task sharing, with the Ouagadougou Partnership (OP). The OP has nine priority countries that will develop country action plans, which WHO country offices will support along with partners.
- Through the IBP Knowledge Gateway, virtual communities of practice will be created for WHO colleagues and partners involved in the WHO Umbrella project to allow continued interactions, sharing of lessons learnt and dissemination of new tools on a regular basis.

3.1.5.3 FIGO workshops on MEC and other WHO family planning guidelines

Progress

The two one-day workshops covered recent WHO guidelines and dissemination tools on contraception and maternal and perinatal health. The workshops were attended by representatives of national member associations, members of the FIGO Safe Motherhood Committee, FIGO senior executives and staff from the Department and the WHO Department of Maternal, Newborn, Child and Adolescent Health.

Planned activities

- It was agreed that a coordination mechanism between WHO and health-care professional associations (i.e. FIGO, International Confederation of Midwives [ICM], International Paediatric Association [IPA]) should be developed to streamline the production of evidence-based guidelines. To facilitate this process, a WHO–FIGO working group will be established to develop and follow up concrete proposals.

3.1.5.4 Classification of contraception methods: meeting and decisions

There remain inconsistencies in the definition and criteria for classifying contraceptive methods as "modern" contraceptives. The Department and USAID therefore convened a technical consultation in January 2015 to address issues related to classifying contraceptives.

Progress

The consultation agreed that, as a basic premise, reporting systems need to be consistent in having clear and well defined criteria when classifying contraceptives as "modern" and "traditional". Methods that are actively included in country programming, including FAB methods – such as the Standard Days Method, the Billings (Cervical Mucus) Method, the Sympto-thermal Method and the Two-Day Method – should be considered as modern methods. Data on their use should be collected and reported separately in countries where these methods are promoted in family planning programmes. In regions where LAM is promoted, taught and used, it should be reported as a modern method. Withdrawal should continue to be classified as a traditional method as it is not included among methods actively promoted in programmes and contributes significantly to overall contraceptive use. Herbs, charms, folk methods and vaginal douching should not be classified as contraceptive methods as they have no scientific basis for being effective in preventing pregnancy and they are not being promoted in any family planning programmes. Further work, especially on training and programming, is needed to define and measure use of emergency contraception to reflect its contribution to reducing unmet need for family planning.

It is important that WHO identifies a classification system that is evidence-based and guided by the goal of improving access to a wide range of methods of assured quality that are effective, acceptable and affordable for women and men. Measurement challenges will need to be addressed, but they should not be the driving force to determine which methods are counted as modern and which are not. The ideal contraceptive classification system should be simple, should lead to greater clarity, consistency and parsimony, and should be easy to use and understand by a broad set of stakeholders, including researchers, programme managers, policy-makers, and other potential users. However, any changes should not be overly disruptive to present systems of data reporting or jeopardise the ability to evaluate trends. A paper was prepared based on the technical consultation, including a table of contraceptives and classification systems.

Planned activities

- The paper from the meeting has been submitted for peer review and publication is expected in 2016.

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3.2 Adolescent sexual and reproductive health

3.2.1 Introduction

One of the key priorities for the work of the WHO Department of Reproductive Health and Research including HRP is adolescent sexual and reproductive health (ASRH). The range of related activities includes research (such as primary data collection, systematic reviews and secondary analyses), country-level support of monitoring and evaluation, and promoting implementation of evidence-based interventions. Ultimately this work contributes to improving access to sexuality education and sexual and reproductive health (SRH) services, including contraception, to promote healthy sexual development in adolescents and prevent SRH problems, such as early and unintended pregnancies.

Major achievements

- The Department's three flagship adolescent research studies – ARMADILLO (providing ASRH messages through mobile phones), AHEAD (preventing rapid repeat pregnancy) and GEAS (understanding factors in early adolescence, including gender norms which are precursors to ASRH behaviours) – have completed their formative phases in multiple countries.
  - — ARMADILLO: Activities for message development have been completed, and the messages are now being pilot-tested in Kenya. Formative activities for message development are under way in Peru.
  - — AHEAD: Formative data collection has been completed to inform an intervention strategy in Ghana, and formative activities are under way in Malawi.
  - — GEAS: Formative research has been completed at all 15 study sites and the toolkit face-validity and pilot-testing process has begun.
- Country case studies of the policy and programmatic environment have been prepared in 10 countries and six of these were published as peer-reviewed journal articles.

3.2.2 Research and development

3.2.2.1 Intervention research

(i) The AHEAD trial (Adolescent Health Experience after Abortion or Delivery): preventing rapid repeat pregnancy

Progress

The study protocol was published in *Reproductive Health* in November 2015 *(1)*. Phase 1 has been completed in Ghana. During 2015, qualitative data were collected on adolescents, health-care providers and government officials relating to adolescents' experiences of unplanned pregnancy and abortion in Ghana. The data collection took place in all three ecological zones throughout the country. A data analysis and project planning workshop was held in August 2015. Based on the results of this formative work, the team in Ghana believe that a renewed curriculum is needed for abortion providers in government health-care facilities – a curriculum that highlights the importance of giving post-abortion adolescents access to all contraceptive methods, including long-acting reversible contraceptives (LARCs), and the importance of ensuring that health-care facilities have these methods; a curriculum that will develop a cadre of trained health-care providers that will provide these services to adolescents. This intervention will be pilot-tested in phase 2 of the project.

Planned activities

- Malawi has drafted their protocol and data collection will occur at three health-care facilities in the country for phase 1 in early 2016.

(ii) The ARMADILLO study (Adolescent/Youth Reproductive Mobile Access and Delivery Initiative for Love and Life Outcomes)

Progress

The study protocol was published in *Reproductive Health* in August 2015 *(2)*. Phase 1 data collection has been completed in Kenya. During 2015, draft messages were developed that were tested with young people and caregivers using focus group discussions. The data collection took place in and around Mtwapa, Kenya. The data are informing current work to finalize the messages. Additionally, Peru was identified as a second ARMADILLO country site. The protocol was adapted and received clearance from the Research Project Review Panel (RP2), WHO's Ethics Review Committee (WHO-ERC) and the local Institutional Review Board (IRB). The formative work at three study sites across Peru was initiated at the end of 2015.

Planned activities

- In Kenya in 2016, the protocol will be developed for a randomized controlled trial (RCT) design to measure the impact of the messages developed for ARMADILLO. Outcomes will include knowledge, norms, self-efficacy and behavioural outcomes.
- In Peru in 2016, the ARMADILLO messages will be developed and finalized based on the formative research.
- Following the RCT, the Department will conduct a coverage study to assess the reach of ARMADILLO in both countries.

(iii) GEAS (Global Early Adolescent Study)

The Department is working with the Johns Hopkins School of Public Health to carry out a multinational longitudinal study of the social processes shaping young people's

health, with particular attention to the ways gender norms inform adolescent sexual health and behaviours in different contexts. The study is planned for implementation in two phases, taking place in sites in Belgium, Bolivia, Burkina Faso, China, the Democratic Republic of the Congo, Ecuador, Egypt, India, Kenya, Malawi, Nigeria, Scotland, South Africa, the United States of America (USA) and Viet Nam.

Phase 1 of the study employs a mixed-methods approach for the creation of a toolkit that includes four new instruments assessing gender norms and sexuality, specifically for use among early adolescents worldwide.

Progress

In 2015, the formative component of phase 1 was completed at most sites, informing the development of a practical toolkit to be pilot-tested and validated in the latter half of phase 1 and used in a five-year longitudinal study in phase 2. The toolkit consists of:

- The Gender Norms Scales – to assess beliefs about normative expressions of what it means to be a young adolescent boy or girl.
- The Gender Equitability in Relationships Instrument – to assess gender biases in relationships.
- The Health Instrument (10 modules) – to assess physical and mental health, healthy sexuality and sexual health, empowerment and related factors.
- The Context Measure – to measure social cohesion, safety and security, risk and protective factors in the neighbourhood, from the perspective of the adolescent.

Also in 2015, a systematic review to understand the factors that shape gender norms among young adolescents was finalized and submitted to a peer-reviewed journal. This systematic review is part of the efforts to understand how gender norms are shaped during the early adolescent period. It is a mixed-methods review of both quantitative and qualitative studies. The review highlights that norms related to sexuality are intensified when boys and girls attain puberty. These norms are shaped by peers, parents and schools. They vary for boys and girls as well as by their ethnicity, race and class.

Planned activities

- A special supplement of the *Journal of Adolescent Health* will be published in the second half of 2016 summarizing key findings from the over 900 narrative interviews that have been translated, transcribed, coded, analysed and synthesized into eight core themes and manuscripts.
- In 2016, phase 1 will be completed and preparations for phase 2 will begin in earnest. Using the globally validated toolkit, a five-year longitudinal study of 1400 10- to 14-year-olds in each site will aim to generate empirical evidence linking gender norms to ASRH outcomes, explore the relationships between gender norms and social contexts, and contribute to evaluation of long-term consequences of programmatic efforts to change gender norms in early adolescence.
- In 2016, it is expected that the systematic review on factors that shape gender norms among young adolescents will be published.

3.2.2.2 Systematic reviews and secondary data analyses

As part of the work to strengthen the evidence base on the SRH of adolescents and diverse populations, several systematic reviews were carried out focusing on a range of outcomes.

(i) Systematic review on adolescent access to SRH commodities through pharmacies

Progress

A systematic review of the literature on adolescent access to SRH commodities through pharmacies found that limited evidence exists in the current literature. The majority of the available evidence focuses on adolescents' experiences obtaining emergency contraception from pharmacies. Much of the evidence also focuses on misconceptions among both pharmacists and clients that better access to emergency contraception could result in increases in sexually risky behaviours and decreases in the use of other contraceptives. Overwhelmingly, the existing evidence does not support either of these views. Further, access for adolescents still remains a problem, largely because pharmacists act as gatekeepers, hindering adolescents' ability to obtain SRH commodities even when policies or law are in place to promote access through pharmacies.

Planned activities

- A manuscript is currently under peer review for publication in 2016.

(ii) Systematic review of provider-side barriers to access to contraception for adolescents

Progress

A systematic review of the literature on provider-side barriers to access to contraception among adolescents in low- and middle-income countries (LMICs) is under way. Following systematic searches of relevant databases, the search strategy identified 20 articles for inclusion, representing geographically diverse settings.

Planned activities

- The evidence from these 20 articles will be abstracted and analysed.
- A manuscript will be written and submitted for publication to disseminate the findings.

(iii) Systematic review of sexually transmitted infection (STI) services for adolescents and youth in low- and middle-income countries: perceived and experienced barriers to accessing care

Progress

The Department carried out this piece of work with the United States Centers for Diseases Control and Prevention (CDC). We conducted a qualitative systematic review of mixed-methods studies to assess views of adolescents and service providers on barriers that prevent adolescents from seeking appropriate STI services. We searched the peer-reviewed literature for studies published between 2001 and 2014 with a study population of young people (aged 10–24 years) and/or health-care providers. Nineteen studies from 15 countries met the inclusion criteria. We employed thematic analyses to identify key themes across the studies.

Findings suggest that young people lacked knowledge about STIs and services. They experienced barriers related to service availability and accessibility because of a lack of integration of services. However, the most commonly reported barriers related to the acceptability of services. Young people reported avoiding services or having confidentiality concerns based on provider demographics and behaviours, such as rude or unfriendly treatment, blaming, lecturing or scolding. Further, experiences

of shame and stigma were common barriers to seeking care. Adolescents in LMICs experienced significant barriers in obtaining STI services. Improving service uptake will require efforts to address clinic systems and provider attitudes, including confidentiality issues. Moreover, addressing barriers to STI services will require addressing cultural norms related to adolescent sexuality.

Planned activities

- A manuscript has been submitted to the Journal of Adolescent Health and is under review. This will be published in 2016 and then disseminated

(iv) Community-based reproductive health interventions for young married couples in resource-constrained settings: a systematic review

Progress

The Department carried out a systematic review of community-based approaches used to deliver reproductive health interventions to young married couples in resource-constrained settings; this work was done in conjunction with the Health Institute for Mother and Child (MAMTA), and Indian nongovernmental organization (NGO).

The systematic review included research studies and evaluation reports of different community-level initiatives to improve access to contraception, pregnancy care and safe abortion services for young married couples in which the women were in the age-group of 15–24 years. Of the 14 projects that met the inclusion criteria, eight also met the quality criteria and were thus included in the review: five from India, two from Nepal and one from Malawi.

The analysis showed that community-based interventions consisting of counselling for young married women and their husbands, family and community members, as well as capacity-building of health workers, were effective in increasing contraceptive use, delaying pregnancy and improving pregnancy care. Stratifying young women in line with their specific reproductive health needs (i.e. newly married women, pregnant women, mothers of one or more children) and addressing their differing needs is a successful strategy. Notably, none of these projects explicitly addressed improving access to safe abortion care.

The review, which was published in *BMC Public Health in 2015*, suggests that multi-layered community-based interventions, targeting young married women, their families and the health system can improve the utilization of reproductive health services among young couples in resource-constrained settings. The review also identified the need for further research to fill the knowledge gaps that exist about improving the utilization of reproductive health-care services, especially safe abortion care, among young married women in LMICs *(3)*.

Planned activities

- This paper is feeding into our advocacy and support to countries, on employing evidence-based interventions to reach young married couples, which will continue during 2016.

(v) Secondary data analysis of contraceptive use patterns among adolescents

Progress

Meta-regression analysis focusing on patterns of contraceptive use among adolescents is ongoing. This analysis uses Demographic and Health Survey (DHS) data from more

than 40 LMICs to explore proportions of adolescents in each country that (a) have never used a method of family planning, (b) have used a method but are not currently using one, (c) are currently using a method considered to be a least effective method (traditional methods), (d) are currently using a method considered to be effective (modern contraceptive methods excluding LARCs), and (e) are currently using a method considered to be the most effective (LARCs). These patterns of contraceptive use show a great range of experiences among adolescents across the many countries while also helping to illuminate potential points of intervention to determine reasons for non-use and for discontinuation and to encourage movement towards use of very effective methods.

Planned activities

- This analysis will be presented at the International Conference on Family Planning in Bali, Indonesia, in January 2016.
- A manuscript will be submitted for publication in 2016.

(vi) Meta-regression analysis of reasons for non-use of contraception among adolescents

Progress

An ongoing analysis using DHS data from more than 40 LMICs explores the reasons adolescents give for not currently using a method of contraception. These reasons include cost, barriers to access, and health concerns, including side-effects. Preliminary analysis suggests that there is a large degree of heterogeneity across countries among adolescents but that cost and barriers to access tend not to be highly prevalent reasons while health concerns and opposition to family planning, either on the part of the respondent or the respondent's partner, are commonly cited reasons for non-use and for not intending to use a method in the future.

Planned activities

- A manuscript will be submitted for publication in 2016.

(vii) Meta-regression analysis of adolescent access to contraception through pharmacies

Progress

To complement the above-mentioned systematic review on pharmacy provision of SRH commodities to adolescents (see item [i] in this sub-section), secondary data analyses using DHS data are under way focusing on pharmacy use by adolescents in a broad range of LMICs. Preliminary results suggest that there is wide variety in the proportion of adolescents obtaining contraceptive methods from pharmacies.

Planned activities

- A manuscript will be submitted for publication in 2016.

(viii) Secondary data analysis of first births in very young adolescents in three East African countries

The Department carried out this piece of work in collaboration with the University of Southampton, United Kingdom. Beginning in 2014, we analysed adolescent first births using disaggregated DHS data for three East African countries: Kenya, Uganda and the United Republic of Tanzania. We produced cross-sectional descriptive data on adolescent

motherhood by age-group (under 16, 16–17 and 18–19 years), marital status, wealth, education, state or region, urban/rural residence and religion. We then analysed trends for two or more DHS surveys conducted within the same country over a period of 18–23 years, and again disaggregated the data by age, wealth, urban/rural residence and marital status to ascertain which groups within the population have benefited most from reductions in adolescent first births. In order to adjust for confounding factors, we used multinomial logistic regression to analyse the social and economic determinants of adolescent first births, with outcomes again stratified by age.

Progress

Our analysis showed that in the three countries, a significant proportion of women gave birth before age 16 (7%–12%). Both the bivariate analysis and logistic regression showed that adolescent motherhood is strongly associated with poverty and lack of education/illiteracy, and this relationship is strongest among births within the youngest age group (< 16 years). There were also marked differences by region, religion and urban/rural residence. Trends over time showed that there has been limited progress in reducing adolescent first births overall, with no reductions among the poorest. Adolescent first births, particularly at the youngest ages, are most common among the poorest and least educated, and no progress has been made in reducing rates within this group over the last few decades. The report on this analysis was published in 2015 in *Reproductive Health(4)*.

The Department has used the report to advocate for segmenting adolescent populations and disaggregating adolescent data to better inform policies and programmes. In order to facilitate the use of these data by policy-makers and programme managers at both national and subnational levels, the Department continued to work with the University of Southampton, United Kingdom, to explore ways of presenting information on first births in young adolescents and the contexts in which these births occur, using geospatial methods. A paper describing this is being prepared.

The Department–Southampton University team has now started analysing levels and trends of first births in adolescents, in selected Latin American countries.

Planned activities

- The paper on first births in young adolescents, presented using geospatial methods, will be submitted for publication in 2016.
- Building on the work done on Africa, the Department–Southampton University team intends to analyse levels and trends of first births in adolescents, in selected South-East Asian and Latin American countries.

(ix) Adolescent-friendly health services in low- and middle-income countries: a scoping review

Progress

In 2015, the Department published a review of the effectiveness of approaches to improve the provision and utilization of health services in LMICs. Only a small number of study reports and evaluation reports met the review's inclusion criteria. Hence, the review did not fully represent the nature and scope of the work that has been and is being carried out in LMICs. To fill this gap, we have carried out a complementary systematic review of adolescent-friendly health services in LMICs. Our review seeks to answer three questions:

- How have initiatives in LMICs defined making health services friendly for adolescents?

- What activities have been carried out by these countries to make health services adolescent-friendly?
- How have these initiatives monitored and evaluated their work?

Planned activities

- In 2016 the Department will finalize the review and submit it for publication.
- The findings will be used in the Department's advocacy and country support work.

(x) Approaches used to improve and maintain improvements in the performance of health workers: a systematic review

Previous reviews, including one published by the Department in 2015, have shown that a competent and friendly health worker is critical to an adolescent-friendly health service. Given this, building the capacity and the attitudes of health workers to respond to adolescents effectively and with sensitivity is a key component of almost all efforts to make health services adolescent friendly.

Progress

In order to determine whether evidence-based approaches are being used to achieve this, we are carrying out a systematic review of approaches used in LMICs to improve and maintain improvements in the capacity of health workers to respond effectively and with sensitivity to adolescents.

Planned activities

- In 2016 the Department will finalize the review and submit it for publication.
- The findings will be used in the Department's advocacy and country support work.

3.2.3 Monitoring and evaluation

3.2.3.1 Analysing the adolescent content of national contraceptive policies, strategies and guidelines using the Department's guidelines on ensuring human rights in the provision of contraceptive information and services

In 2014, the Department initiated an exercise to examine whether national contraceptive policies, strategies and guidelines:

- require health workers to provide contraceptive information and services to adolescents; and
- require the relevant authorities to build health workers' competencies and attitudes, provide them with ongoing support, assess their performance and hold them accountable.

Progress

The Department's work began with South Africa. The team set out to evaluate whether the updated South African national contraception policy and guidelines adequately address the needs of adolescents. Specific guidance for adolescents was found relating to six of the nine WHO summary recommendations and 11 of the 24 sub-recommendations. Adolescents are highlighted throughout the policy as being at risk for discrimination or coercion, and laws protecting the rights of adolescents are cited. Confidentiality of services for young people is emphasized, and youth-friendly services are described as a key element of service delivery. Areas to strengthen include the need for normative guidance

ensuring both availability of contraceptive information and services for young people and adolescent participation in development of community programmes and services.
A paper on this analysis has been published in 2015 in the *Journal of Adolescent Health(5)*.

Planned activities

- Similar analyses have been initiated in the Philippines and Paraguay.
- We intended to use these analyses to advocate for the removal of policy-level barriers on contraceptive provision to adolescents.

3.2.3.2 Quality assessment guidebook digitalization and implementation in Brazil

In December 2013, the Department supported the creation of a prototype online/electronic version of WHO's *Quality assessment guidebook(6)* that would allow for digital collection of data to assess the quality and friendliness of health services for adolescents. Starting in May 2014, in close collaboration with the Ministry of Health (MOH) in Brazil and Kenya-based developers Ona, the Department supported a Brazilian adaptation of the prototype website. This involved developing a Portuguese version of the existing online assessment tool, incorporating feedback from pilot-testing of the website and its user interface in Brazil, and developing various user profiles to reflect the different levels of the Brazilian health system (federal, state, municipality, etc.).

Progress

The Department organized a training session in April 2015 for implementers of the tool, after which phased roll-out commenced in five states of Brazil on a small scale.

An integrated year-long research component was initiated, which will identify the optimal frequency with which the quality assessment tool should be implemented (including feedback from the tool to the facility) in states already selected for the phased roll-out.

The roll-out was timed to coincide with the launch of the Agenda for the Protection and Care of Adolescents, a strategy to expand access to and quality of comprehensive care for adolescents nationwide. [6] The tool was implemented at the municipality level, with municipal teams responsible for periodically assessing clinics in their domains. Data were viewable at the facility level, to allow managers to see the teams' progress. Data were also aggregated and viewable at the municipality, state and federal levels.

Planned activities

- Data collection will be completed by the end of the third quarter of 2016. Through this process, the Department will support the MOH in Brazil to analyse incoming data in order to monitor progress across and within the five states, and to identify the optimal monitoring period to implement in the context of the nationwide roll-out.
- At the same time, the Department will work with the MOH and technology partners to plan and implement a controlled scale-up across Brazil.

6 Further information is available at: http://ehnunes.com/adolescentes/abertura.html

3.2.3.3 Post-hoc evaluation of the CERCA Project, a multicomponent intervention to promote ASRH in three Latin American countries: a qualitative post-hoc evaluation

From 2011 to 2014, with funding from the European Union, the International Centre for Reproductive Health (ICRH) at the University of Ghent, Belgium, carried out an intervention study entitled "Community-embedded reproductive health care for adolescents" (CERCA) in Bolivia, Ecuador and Nicaragua, to test the effectiveness of a combination of interventions preventing teenage pregnancies. The outcome evaluation showed limited impact. In this context, ICRH and the Department agreed to carry out a post-hoc process evaluation to determine if and how CERCA's design, implementation, monitoring and evaluation contributed to the disappointing results.

Progress

Findings from the post-hoc evaluation resulted in the following lessons learnt for future projects:

- Projects like CERCA should begin with a preparatory phase in which a thorough analysis of the situation is carried out, which feeds into intervention design. A targeted and context-specific theory of change should be developed before the start of an intervention study. Such a theory should set out the individual and environmental determinants to be targeted, the interventions to be employed and the inputs, processes, outputs and outcomes to be measured, when and how they are to be measured and how the gathered data are to be used.
- If the intervention design is modified in any way, there should be corresponding changes in the measurement framework, and all changes should be meticulously documented.
- Accepting teenage pregnancies as a complex issue means that not only must the interventions be tailored to this complexity, but so must the evaluation design. In the case of multicomponent projects like CERCA, a specific evaluation approach should be developed for each activity (e.g. workshops, mobile consultancies, helpline), and data should be collected on their effectiveness, as well as on feasibility and acceptability, and on factors that help and hinder *(7)*.

A manuscript has been submitted for publication.

Planned activities

- In 2016, the Department will continue to build a portfolio of evaluations of programmes and projects that are being implemented in LMICs to complement the lessons being learnt from prospective studies.

3.2.3.4 Strengthening the collective response of the government to end child marriage through a district-level convergence approach in Jamui, Bihar and Sawai Madhopur, Rajasthan, India

The Health Institute for Mother and Child (MAMTA) is an Indian NGO active in the ASRH field since 1990. Between 2011 and 2015, MAMTA in partnership with district administrations undertook a project to support the development and testing of a government-led, cross-departmental convergence approach to ending child marriage in Sawai Madhopur District, Rajasthan, and Jamui District, Bihar. After three years of implementation, MAMTA approached the Department to evaluate the project.

The evaluation sought to answer the following questions:

1. How has the MAMTA project contributed to the establishment of concerted sectoral and intersectoral district-level efforts to prevent child marriage?
2. Did these efforts lead to more concerted actions at the block, panchayat and village levels?
3. What were the critical factors that contributed to these changes, at the individual and institutional levels?

Progress

The evaluation described how the project was designed, implemented and monitored (and how this related to the plan), and what was achieved at the state, district, block, gram panchayat and village levels. It also proposed recommendations for MAMTA to consider when undertaking efforts to expand or replicate this work *(8)*.

Planned activities

- In 2016, the Department will share the findings and recommendations of the evaluation in India and in the global child marriage prevention community.
- Additional research will also be undertaken in this area.

3.2.3.5 Drawing lessons from the first generation of the scale-up of adolescent sexual and reproductive health (ASRH) programmes

At the International Conference on Population and Development (ICPD) in Cairo in 1994, governments committed to promoting the sexual and reproductive health of adolescents through policies and programmes, with varying results to date. In many countries, these efforts do not contain all three of the following components: providing sexuality education; providing SRH services; and creating a safe and supportive environment.

There are a number of LMICs where scaled and sustainable government-led efforts are under way. Not all of these government-led programmes implement activities in all three components as noted above. Having said this, each of these "first generation" of scaled up ASRH programmes represents a success and offers important lessons on what it took to overcome the obstacles that have prevented so many other countries from achieving scale.

Progress

In 2015, the Department documented (or initiated documentation of) case studies in: Argentina, Brazil, Colombia, Estonia, India, Mongolia, Mozambique, Nigeria, Pakistan and Senegal. Papers relating to Estonia, Mozambique, Pakistan and Senegal were published during the course of the year *(9–12)*.

Planned activities

- These case studies will feed into a global meeting to be held in Geneva in April 2016, whose first objective will be to draw out the lessons learnt from the LMICs present which have scaled up ASRH programmes, highlighting both commonalities and specificities in each context, and achievements as well as challenges. The second objective will be to strategize on how the experiences gained from the first generation of scale-up could inform the second generation of programmes that are being initiated in a number of countries.

3.2.4 Dissemination and partnerships

3.2.4.1 Dissemination of research evidence

Progress

In January 2015, the Department published a special supplement to take stock of progress in adolescent health, 20 years since the ICPD. The special supplement to the *Journal of Adolescent Health* contains five papers reviewing research evidence, implementation experience and an overview *(13)*.

During the course of the year, the Department worked with USAID and UNFPA to publish a complementary paper, which conveyed the following two key messages:

- We must ensure the implementation of interventions that have been shown to be effective, with fidelity to the methods and adequate dosage.
- We must avoid implementing ineffective interventions that waste human and financial resources, and raise questions about the value of policies and programmes that do not demonstrate results *(14)*.

The Department shared the key messages emanating from the special supplement through global launch events that took place at the end of 2014 and in early 2015, as well as a sustained online and media promotion campaign, while also presenting the findings at key global conferences including the 3rd Asia Population Association Conference (Kuala Lumpur, Malaysia; July 2015) and the International Federation of Gynecology and Obstetrics (FIGO) World Congress (Vancouver, Canada; October 2015).

The Department worked with the WHO Regional Office for Africa to organize a three-day workshop on the special supplement, which brought together about 35 participants including MOH staff, staff of WHO country and regional offices, and representatives of other UN agencies. Plans are under way to organize a similar workshop in the WHO South-East Asia Region early in 2016.

At the invitation of the Swiss Agency for Development and Cooperation (SDC), a member of the Department's Adolescents and at-Risk Populations team presented a talk at a TEDx event held in Chisinau, Moldova, in May 2015, on the subject of "Why we shouldn't shy away from sexuality education".[7] The video has been accessed nearly 10 000 times since it was launched in September 2015.

Planned activities

- In 2016, the Department will continue to communicate the lessons learnt from our review of research evidence and programmatic experience to help ensure that ASRH programmes are informed by this evidence and experience.

3.2.4.2 Feeding into the work of others

The Department's evidence synthesis on adolescent-friendly health services has fed into the development of guidelines on this subject by WHO's HIV Department and is feeding into guidelines being developed by WHO's Maternal, Newborn, Child and Adolescent Health Department.

7 Video available at: https://goo.gl/XNgKmj

Progress

Over the year, Department staff contributed to consultative processes, including the adolescent component of the revised Global Strategy for Women's, Children's and Adolescents' Health (led by UNFPA), the General Comment on adolescent development (led by UNICEF), the work of the Inter-Parliamentary Union in engaging governments to address child, early and forced marriage (CEFM), and the resolution on CEFM at the 29th Human Rights Council meeting in 2015 *(15)*.

Planned activities

- In 2016, the Department will continue to work in conjunction with other relevant departments at WHO and with partner organizations within and outside the UN system towards our shared goals.

3.2.4.3 Capacity-building

The Department contributed to strategy development and to capacity-building. For example:

- In February 2015, the Department was invited to contribute to Jhpiego's "Global summit on key insights and transformative solutions on access, uptake and quality of sexual and reproductive health care for adolescents".
- In March 2015, the Department made significant contributions to a "Day of learning" organized by the David and Lucile Packard Foundation for its global staff team.

As in previous years, the Department coordinated a module on ASRH in the Geneva Foundation of Medical Education and Research's e-course, "Research capacity-strengthening in sexual and reproductive health"; the Department also worked with the Foundation's staff to evaluate the effects of the course on the participants.

Planned activities

- In 2016, the Department will continue to use a variety of means to build country capacity in planning and implementing ASRH programmes.

3.2.4.4 Country support

Progress

During the course of the year, Department staff provided support to:

- Myanmar, for the development of an updated national strategy on adolescent health;
- India, for a national technical working group to guide the implementation and monitoring of its National Adolescent Health Programme;
- Bangladesh, to strengthen political leadership in child marriage prevention.

Planned activities

The Department also worked with the Bill & Melinda Gates Foundation to secure funding to strengthen the provision of contraceptive information and services to adolescents. This work will be initiated in 2016 in 10 African countries in five areas:

i. Prepare country-specific policy briefs to advocate for action based on secondary analyses of:

   — data on demand and met/unmet need for contraception;

- data on barriers to access and uptake of contraception by different groups of adolescents;
- national contraceptive policies, strategies and guidelines.

ii. Build capacity in service provision using a variety of WHO tools.

iii. Build capacity in monitoring and using monitoring data.

iv. Advocate for attention to adolescents in proposals and plans.

v. Provide support for documentation.

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3.3 Maternal and perinatal health

3.3.1 Introduction

The maternal and perinatal health programme of work follows carefully selected priorities that are based on global priorities, as well as the strengths and capacity of the team and its networks. The Sustainable Development Goals (SDGs) launched in 2015 prioritized maternal and newborn targets for the next 15 years. These targets and the priority themes of "Survive-Thrive-Transform" will guide our work in the coming years. The programme's focus in recent years puts it in a strong position to address the new challenges.

Following the conclusion of the WHO Multi-Country Survey on Maternal Severe Morbidity and several secondary analyses in 2014–2015, the programme prioritized the areas of intrapartum care and caesarean section. These two priorities were addressed through the ongoing Better Outcomes in Labour Difficulty (BOLD) project and a number of systematic reviews and analyses on the rates of caesarean section. The *WHO Statement on caesarean section rates* published in April 2015 addressed this global challenge *(1)*.

The work on mistreatment of women during childbirth and maternal severe morbidity formed the basis for the development of the new WHO framework on quality of care for pregnant women and newborn babies around the time of childbirth, which was endorsed by the Scientific and Technical Advisory Group (STAG) in 2015 as a priority *(2)*. With increased collaboration between the WHO Department of Reproductive Health and Research (RHR), including HRP, and the WHO Department of Maternal, Newborn, Child and Adolescent Health (MCA) in this area, the work gained significant momentum. Through this collaboration, WHO has taken a leading position globally in improving quality of care for women specifically around the time of childbirth, and for newborn babies.

In addition to the quality-of-care work, the second priority area has been on preterm birth. The RHR Department has developed a significant portfolio of work on preterm birth in 2015 including a new grant from the Bill & Melinda Gates Foundation to

evaluate the efficacy of antenatal corticosteroids for women at risk of preterm birth in a multicountry randomized controlled trial (RCT).

The global epidemiology work played an important role in the launching of the Global Strategy for Women's, Children's and Adolescents' Health in September 2015 *(3)* and the subsequent publications of the global maternal mortality estimates in November *(4, 5)*. The programme is developing global preterm birth estimates to be published in 2016. The programme finalized the perinatal death classification and this will be published as *The WHO application of International Classification of Diseases 10th revision (ICD-10) to perinatal deaths: ICD-PM* (or "ICD-Perinatal Mortality"), a sister document to the *ICD-MM* (ICD-Maternal Mortality) *(6)*; the *ICD-PM* also complements the *Maternal death surveillance and response* (MDSR) *(7)* and the perinatal death audit project, both of which are led by the MCA Department.

In 2016–2017, the Department will develop key activities around maternal and early newborn sepsis and also on implementing the 2015 quality-of-care framework for pregnancy and childbirth. This framework conceptualizes quality of care for maternal and newborn health by identifying domains which should be targeted to assess, monitor and improve care within the context of the health system *(2)*. It forms the basis for the development of quality standards and measures that will guide quality improvement for mothers and newborns within the context of the SDGs.

Major achievements

- The WHO framework on quality of care for pregnant women and newborns around the time of childbirth was published in *BJOG*. The quality statements and indicators for the eight domains focusing on both provision and experience of care were finalized.
- The Department released the *WHO statement on caesarean section rates*, including information on optimal rates and monitoring of caesarean sections at facilities. This eagerly awaited statement superseded the earlier 1985 statement, which has been widely quoted. The new Statement emphasizes that while there seem to be mortality benefits up to national population level rates of 10%, much of the association can be explained by development status of the country. WHO recommends the 10-group Robson classification to monitor caesarean section rates.
- An analysis of changes in caesarean section usage in 21 countries was published in *Lancet Global Health*. By combining data from the WHO Global Survey on Maternal and Perinatal Health and the WHO Multi-Country Survey on Maternal and Newborn Health, the paper demonstrated that the Robson classification can be applied to facility-level data in low- and middle-income countries (LMICs) for standardized comparisons of caesarean section data across countries and time points, and to identify subpopulations driving changes in caesarean section rates.
- *WHO recommendations on interventions to improve preterm birth outcomes* (for mothers and newborns) were published. This brought much-needed international guidance following the publication of the large multicountry trial that cast doubt on the safety and efficacy of antenatal corticosteroids for women at risk of preterm birth in LMICs. In addition, the Department secured a grant from the Bill & Melinda Gates Foundation to conduct a randomized clinical trial in sub-Saharan Africa and South Asia to address an important research gap on this topic.
- *WHO recommendations for prevention and treatment of maternal peripartum infections* were launched during the International Federation of Gynecology and Obstetrics (FIGO)

World Congress in Vancouver, Canada. The recommendations mainly address preventive interventions and can be seen as a springboard for the maternal and early newborn sepsis initiative that will be launched in 2016.

- *The mistreatment of women during childbirth in health facilities globally: a mixed-methods systematic review* was published in the journal PLoS Medicine, with extensive international media coverage. The review, which was based on data from 34 countries, suggested that mistreatment of women during childbirth is widespread globally.
- Estimates of maternal mortality for the period 1990–2015 were published as a peer-reviewed paper in The Lancet and as a full Interagency report. It is estimated that 303 000 maternal deaths occurred during 2015 and that there has been a 44% decline in the maternal mortality ratio (MMR) since 1990, falling short of the Millennium Development Goal (MDG) to reduce it by three quarters. These estimates will serve as the baseline for SDG target 3.1: by 2030 reduce the global MMR to less than 70 per 100 000 live births.

3.3.2 Research and development

3.3.2.1 Improving quality of care for mothers and newborns

(i) Implementation of evidence-based antenatal care in Mozambique: a cluster randomized controlled trial

Antenatal care (ANC) 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 RCT with a "stepped wedge" design in Mozambique by implementing an intervention targeted at increasing the delivery of evidence-based practices included in the ANC package delivered by midwives and promoting the integration of key interventions into routine ANC. The ultimate goal is to improve maternal and newborn outcomes as well as the detection, treatment and prevention of major health-related conditions in pregnant women.

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 successfully launched the intervention in the first health-care facility. Since then and during 2015, the intervention has been rolled out in a new facility every two months in accordance with the study design. The 10th facility entered the intervention in December 2015 and data collection is scheduled to end on 31 January 2016 including more than 230 000 ANC visits. The results of the formative research were published in September 2015 in *BMC Pregnancy and Childbirth (8)*. The 2014 Annual Steering Committee meeting recommended introducing a women's satisfaction survey and this was conducted in July 2015.

Planned activities

- In 2016, upon finalizing data collection, the database will be prepared for the analysis and subsequently analysed according to the planned data analysis protocol. Preparation of manuscripts reporting the results of the RCT will follow.

- The Department plans to continue engaging with stakeholders and other institutions that are playing a role in advancing maternal and infant health in Mozambique, to discuss the implications of this project should the results prove that the intervention is effective. In particular, the necessary next steps should be discussed, including plans of the Ministry of Health (MOH) to potentially scale up the use of the intervention in the country, if deemed appropriate.
- The Department envisions maintaining and strengthening the research capacity built in Mozambique to contribute to future research in the country and other African countries.

(ii) Multicountry study to develop fetal growth standards

The Department completed a multicountry study to develop fetal growth standards for international application, by assessing fetal growth under nutritionally unrestricted conditions in populations of different ethnic and geographic backgrounds. The study included 1439 pregnant women from 10 countries with different ethnic and geographic backgrounds. Results of this study will have important clinical and research implications for the prenatal and postnatal periods, as well as for maternal health.

Progress

During 2015, the study's dataset was analysed and growth curves were fitted to the data to develop fetal growth standards, taking into account ethnic and geographic differences.

Planned activities

- The manuscript will be submitted for publication in February 2016.

(iii) Better Outcomes in Labour Difficulty (BOLD)

Complications arising during labour and childbirth account for a significant proportion of the global burden of maternal and newborn mortality and morbidity, particularly in LMICs. Yet, the quality of intrapartum care for women who access care in many health-care facilities in low-resource settings remains suboptimal. The Department initiated the 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-care facilities and the communities in low-resource settings. The project aims to achieve this goal through a two-pronged approach: (a) by developing a "Simplified, Effective, Labour Monitoring-to-Action" tool (SELMA) that will assist health-care providers to monitor labour and decide on appropriate actions more efficiently; and (b) by developing innovative tools and service prototypes (termed "Passport to Safer Birth"), co-designed by women, community groups and health-care providers, to enhance access to respectful, quality care for pregnant women at the time of birth. The goal of the project is to integrate these tools (SELMA and Passport to Safer Birth) into a quality improvement approach that can be tested in a multicountry intervention research project.

Progress

The project started with a technical consultation of the Steering Committee and the Technical Advisory Group in February 2014. Following ethics and administrative approval of the study protocols by WHO and the participating hospitals, data collection for the clinical cohort for the development of SELMA was conducted in 13 hospitals in Nigeria and Uganda between December 2014 and November 2015. Data collection for the qualitative and service design research for development of Passport to Safer Birth

began in December 2014 and was completed in June 2015. Two study protocols (cohort and formative research) and a commentary were published in BMC Reproductive Health in May 2015 *(9, 10, 11)*. Since January 2014, a bi-monthly project newsletter has been published and disseminated to the project partners and researchers.[8]

A critical aspect of BOLD formative research is the identification of childbirth practices that are evidence-based, feasible to deliver by the health system and yet align with the values and preferences of pregnant women and their families. These practices, termed the "negotiated standards of care", are intended to underscore the importance of providing humane and respectful care while maintaining high ethical and safety standards in clinical practice, and are an integral component of the Passport to Safer Birth. The Department participated in a series of workshops in Nigeria and Uganda in October and November 2015 to mediate the development of these standards by health-care facility administrators, health-care providers, women and community members. The development of these standards was guided by the WHO quality of care framework for maternal and newborn health and informed by the findings of qualitative data from the study populations, as well as internationally accepted best practices.

The third technical consultation of the Steering Committee took place in December 2015 to discuss the preliminary results of the cohort, qualitative and service design research, and to initiate plans for the next phase of the project.

Planned activities

- Analysis of the qualitative and service design components of the research is ongoing and the development of service prototypes and tools for the Passport to Safer Birth is expected to be completed by the first quarter of 2016. Manuscripts reporting on the qualitative and service-design components of the project will be prepared and submitted for journal publication by the end of the second quarter of 2016.
- Statistical and computational analysis for the development of early prototypes of SELMA will start in mid-January 2016 and are expected to be complete by the end of the second quarter of 2016. A preliminary review of the outputs of these activities will be conducted at a technical consultation of computational statisticians and artificial intelligence experts that will be held at WHO by the end of the second quarter of 2016.
- Subject to expected outputs from phase I of the BOLD project, the Department will work with partners to conceptualize and develop the BOLD quality improvement (QI) strategy that integrates SELMA and Passport to Safer Birth. In consultation with the Bill & Melinda Gates Foundation, this activity will be followed by the development and finalization of a research proposal to test the effectiveness of the BOLD QI strategy through a multicountry intervention research project in the last quarter of 2016.

(iv) How women are treated during facility-based childbirth: development and validation of measurement tools in four countries

Every woman has the right to dignified treatment and 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 *(12)*. Disrespectful and abusive treatment during childbirth may also result

8 Available at: www.boldinnovation.org

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 *(13)*, no effort has been made at the global level to define and measure its prevalence. This mixed-methods, two-phased study in four countries aims to develop and validate evidence-based tools so mistreatment can be accurately identified and measured.

The primary objectives of this study are:

- To develop an evidence-based definition of and identification criteria for mistreatment of women during childbirth in facilities, which can be used globally;
- To develop and validate tools for measuring mistreatment of women during childbirth in facilities;
- To explore individual, provider, institutional and health systems factors that either promote or prevent mistreatment of women during childbirth in facilities.

Progress

Phase 1 (formative phase) includes a mixed-methods systematic review on the mistreatment of women during childbirth in health-care facilities, which was published in the journal *PLoS Medicine(14),* with extensive international media coverage. Phase 1 data collection (four countries) is nearly completed and data analysis will be completed in early 2016. The study protocol (phase 1) was published in *Reproductive Health* in July 2015 *(15)*. A commentary entitled "Promoting respect and preventing mistreatment during childbirth" was also published in BJOG in 2015 *(16)*.

Phase 2 (measurement phase) will be conducted in early 2016 in four countries. A review of related measurement tools has been completed to identify existing items. The measurement tools are currently being constructed, based on the mixed-methods systematic review, findings from phase 1 and the review of existing measures.

Planned activities

- Mistreatment of women during childbirth can also constitute a violation of women's human rights. Work commenced in 2015 and will be completed in 2016, including an analysis of international human rights standards and agreements, to determine how the mistreatment of women in obstetric settings relates to (and violates) these.
- To complement the mixed-methods review of mistreatment, and related to the team's work on quality of care, a qualitative evidence synthesis of respectful maternity care was initiated in 2015 and will be completed in 2016. Definitions and behaviours identified in the course of this review will also be incorporated into the measurement phase of the research study.
- Phase 2 will commence in February 2016 and be completed by August 2016.

(v) Companion of choice around the time of childbirth

Women have traditionally been attended by a companion during labour but the move to increasing institutional childbirth has not necessarily facilitated the continuation of this tradition. Having a companion of choice has been shown in a systematic review to improve outcomes for women in labour *(17),* yet this basic, well proven intervention is far from universal. There is also a global mandate to improve the quality of maternal and newborn care and a programme that increases the use of a companion of choice

during labour is a clear response to WHO's call to "initiate, support and sustain programs designed to improve the quality of maternal health care, with a strong focus on respectful care as an essential component of quality of care" *(13)*.

Progress

To address this gap, WHO convened a technical consultation on "Companion of choice around the time of childbirth" on 11–12 August 2015. The aims of this meeting were:

- to explore measures related to a companion of choice as part of a quality-of-care framework;
- to discuss a generic protocol for implementation research (IR) to develop a model for implementation in LMICs and plans for scaling up;
- to discuss activities at the regional and global levels to support and monitor implementation at the national level.

Planned activities

- The Department will develop a generic protocol to address context-specific and relevant design and evaluation of interventions and implementation strategies for companion of care around the time of childbirth.
- The Department will undertake a synthesis of qualitative evidence entitled "Perceptions and experiences of labour companionship: a qualitative evidence synthesis".
- The Department will undertake an update of the Cochrane effectiveness review entitled "Continuous support for women during childbirth".
- The Department will develop evidence and policy briefs on labour companionship.

(vi) WHO near-miss approach for improving quality of care for severe maternal complications

The concept of "maternal near-miss", indicating very severe maternal morbidity, has evolved over the past two decades. In 2009, a WHO Working Group defined maternal near-miss morbidity as "a woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy" *(18)*. This definition has been used to develop an instrument for assisting health-care facilities specifically, and health systems more broadly, to evaluate and improve quality of care using a criterion-based clinical audit approach; this instrument has been used in a number of countries *(18)*.

Progress

(a) WHO Multicountry Survey on Maternal and Newborn Health

The WHO Multicountry Survey on Maternal and Newborn Health was a cross-sectional, facility-based survey conducted from May 2010 to December 2011. The multicountry survey (MCS) 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 at 359 facilities across 29 countries in five WHO regions *(19)*.

The MCS is the largest study of its kind to show that high coverage of effective evidence-based interventions in health-care facilities does 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.

We have continued to develop and publish new secondary analyses related to data from the MCS, as well as combining the dataset with data from the earlier, similar WHO Global Survey on Maternal and Perinatal Health to conduct more sophisticated longitudinal analyses. Since the completion of the study, 22 papers have been published in peer-reviewed journals, with an additional six papers currently under peer review. Five of those papers were published during 2015 *(20–24)*.

(b) Nigeria Near-miss and Maternal Death Survey

In addition to the MCS, the Department also supported the Nigeria Near-miss and Maternal Death Survey, which was conducted in 2012–2013. This survey was a large, cross-sectional study that investigated the incidence of severe maternal complications in a nationwide surveillance network of tertiary health-care facilities in Nigeria. The objectives were to create a data system that networks all Nigerian tertiary institutions to periodically conduct a review of the magnitude of maternal near-miss and maternal death; the nature of events responsible for near-misses and maternal deaths; the indices for the quality of care for severe obstetric complications; and the health service events surrounding these complications. It is hoped that this will assist in collectively defining and monitoring the standard of emergency obstetric care at this level of health-care delivery in a country with high maternal mortality. The study prospectively collected information on all women admitted for delivery or within 42 days after delivery or termination of pregnancy who experienced life-threatening complications in 42 tertiary health-care facilities across all geopolitical zones in Nigeria for one year. Each study facility completed a 12-month surveillance between 1 June 2012 and 14 August 2013. The study represented the first opportunity to initiate a sound and reliable quantitative system for gathering data on severe maternal morbidities and maternal deaths in Nigeria.

During the year-long study, there were 91 724 live births, 5910 stillbirths, 998 maternal deaths (excluding 136 mothers who died before arriving at the hospital), and 1451 maternal near-misses (based on WHO near-miss criteria) in the participating health-care facilities. The study highlighted several bottlenecks in the provision of care where improvement could make a difference to maternal survival. The main results of the study have been published in *BJOG* in May 2015 *(25)*. The publication was well disseminated to the relevant stakeholders in Nigeria, and globally to over 10 000 maternal, newborn and child health experts.

(c) Implementing the WHO near-miss approach

A technical consultation was held in Istanbul, Turkey, on 22–23 January 2015, titled "WHO maternal near-miss approach and quality of care: research and implementation". The objectives were to examine the evidence regarding the effectiveness, applicability and acceptability of the WHO maternal near-miss approach for all of the major causes of severe maternal morbidity and mortality, and to identify strategies to implement the maternal near-miss approach on a large scale. Meeting attendees included experts from 16 countries and WHO colleagues from different regions and departments. In discussing WHO's past, current and future work in shifting focus to maternal morbidity, the meeting highlighted the intersection between implementing the maternal near-miss approach on a large scale, including near-miss monitoring at national levels, and WHO's evolving framework on quality of care for maternal and newborn health. Examining the evidence and experience from the field, this meeting also helped to inform WHO's developing quality of care agenda as the Department works to formulate an updated version of the maternal near-miss approach.

Planned activities

- Several more secondary analyses of the MCS data are currently under review by journals or are ongoing.
- The manuscripts based on six secondary analyses of the Nigeria Near-miss and Maternal Death Survey dataset will be submitted for publication as a journal supplement.
- Based on the evidence synthesis and technical consultation, the near-miss approach guide *(18)* will be updated in alignment with WHO's work on improving quality of care for women and newborns.
- A systematic review on "Applicability of the WHO maternal near-miss approach in low- and middle-income countries" will be published.

(vii) Maternal morbidity measurement

To fulfil the need to measure and respond to the full burden of maternal morbidity, WHO initiated a four-year project, funded by the Bill & Melinda Gates Foundation, to improve the scientific basis for defining, measuring and monitoring maternal morbidity. This project aims to construct a definition and develop identification criteria for maternal morbidity, estimate the burden of individual causes or determining factors of maternal morbidity based on existing evidence, develop and test an assessment tool for measuring maternal morbidity in LMICs, and develop indicators for maternal morbidity.

On the basis of the background scoping exercise *(26)* and building upon the WHO definitions of health *(27)* and maternal mortality *(28)*, the Maternal Morbidity Working Group (MMWG), by consensus, agreed on the definition for maternal morbidity and associated disability as "any health condition attributed to and/or complicating pregnancy and childbirth that has a negative impact on the woman's wellbeing and/or functioning" *(29)*. This broad definition recognizes the impact that morbidity may have on different dimensions of health, beyond physical health, and seeks to encompass the totality of a woman's sense of well-being. Based on this definition, the MMWG developed identification criteria that served as the basis for the development of a maternal morbidity measurement tool.

Progress

(a) Estimate the burden of individual causes

The lead authors of six systematic reviews related to the maternal morbidity project were invited to Geneva to give presentations on the progress of their reviews. The reviews address a wide range of topics pertaining to maternal morbidity and health, including:

- noncommunicable diseases
- psychosis
- sepsis
- health functioning
- sexual health
- qualitative studies of maternal morbidity.

Participants held discussions on the reviews and described plans for future publications. Additionally, the group addressed plans for future work and systematic reviews needed on maternal morbidity, including on haemoglobinopathies (e.g. malaria, sickle cell) and mental health conditions. In December 2015, a manuscript on sexual health and maternal morbidity was published in *BMC Pregnancy and Childbirth(30)*.

(b) Developing and testing a morbidity assessment tool: implementation of a pilot study to test a set of maternal morbidity measurement tools in three pilot sites

This pilot study, which was completed at the end of December 2015, was implemented in Jamaica, Kenya and Malawi. The goal was to compare the types of morbidities women experienced between and across settings, and to determine the feasibility, acceptability and utility of using a modified, streamlined tool for routine measurement and summary estimates of morbidity to inform resource allocation and service provision. In each setting, approximately 250 women receiving ANC (at least 28 weeks pregnant) and 250 women receiving postpartum care (at least 6 weeks postpartum) were interviewed using the tool. In 2015, a manuscript outlining the methodology for the maternal morbidity classification criteria, upon which the measurement tool is based was accepted for publication in *BMC Pregnancy and Childbirth (31)*.

Planned activities

- Data cleaning and analysis began in 2015 and will continue in early 2016. The data from the pilot sites are being uploaded, checked and cleaned in Geneva in real time. Preliminary analyses are currently being run to determine the tool's utility.
- At a principal investigators (PIs) meeting in Geneva on 19–20 January 2016, PIs and their co-PIs will gather to review preliminary pilot results by country and discuss implications. Participants will also prepare for dissemination of the results to the MMWG and stakeholders later in 2016. Additionally, PIs will discuss possible maternal morbidity indicators based on data and brainstorming for future work on a maternal morbidity measurement tool kit.
- The pilot study protocol will be submitted to a peer-reviewed journal for wider dissemination in the maternal health community and to other relevant stakeholders.
- A meeting of MMWG will be held in the second quarter of 2016. Participants will meet to address pending project deliverables, especially maternal morbidity indicators, and to set the future work agenda for maternal morbidity measurement.

3.3.2.2 Second stage of labour

(i) The Gentle Assisted Pushing Study: a multicentre RCT of gentle assisted pushing (GAP) in the upright posture to reduce prolonged second stage of labour

Fundal pressure (pushing on the upper part of the uterus in the direction of the birth canal) is often applied in routine practice. However, the benefits of and indications for its use are unclear and vigorous pressure is potentially harmful. There is some evidence that it may be applied routinely or to expedite delivery in some situations (e.g. fetal distress or maternal exhaustion), particularly in settings where other methods of achieving delivery (i.e. forceps, vacuum) are not available. Gentle assisted pushing (GAP) is an innovative method of applying gentle but steady pressure to the uterine fundus with the woman in an upright posture. This multicentre, unblinded RCT with three parallel arms (1:1:1) will randomize 1145 women at three hospitals in South Africa. The trial will evaluate the effects of GAP in an upright posture, or upright posture alone compared with routine (supine) posture (control), on reducing the mean time of delivery and the associated maternal and neonatal complications in women not having delivered within 15–30 minutes of entering the second stage of labour.

Progress

The study protocol was given final approval by the Research Project Review Panel (RP2) and WHO's Ethics Review Committee (WHO-ERC) in late 2014, with data collection commencing in March 2015. Recruitment was initially slow but has improved substantially, with 20% of the sample size achieved.

Planned activities

- Recruitment will be concluded by end of 2016, with data analysis and submission for publication in early 2017.

(ii) Safety and feasibility study of the Odon device for assisted vaginal delivery

The aim of this study is to test the safety and feasibility of the Odon device to assist the delivery of the fetus during prolonged second stage of labour. In the context of the study with a total expected recruitment of 150 women and their babies, the device has been tested to date for safety and feasibility in 48 women undergoing normal delivery in a private hospital in Buenos Aires, Argentina. So far, two enrolment periods – between February 2011 and September 2012 with a one-year follow-up, and between February and December 2014 – have taken place. Becton, Dickinson and Company (BD) acquired the license of the Odon device in 2013 and is currently conducting preclinical and clinical studies and finalizing development of a new prototype.

Recruitment is currently paused and will resume in mid-2016 when the new BD Odon device prototype is available in sufficient numbers. It was judged of high importance to consult an external and independent group of experts about testing a new improved version of the device and how this might affect the results of the study.

Progress

Results from the first period of the study were critical in informing device development and improvements of the device prototype under development by BD. The experience also suggests that the device is easy to use and allows successful expulsion of the fetal head. The Argentinian team also gained experience in training public hospital doctors who will join the study. These training sessions included training and certification using simulators and allowed good rates of skills acquisition; this experience will be used as a basis for the training of obstetricians/gynaecologists.

The WHO RHR Department appointed a new Independent Advisory Board Committee (ISAC) and a new Data Safety and Monitoring Board (DSMB). These committees will advise WHO on decisions about the research plan and safety of the device. The first meetings of DSMB and ISAC were held in May 2015. The DSMB did not identify any serious safety issues and recommended continuation of the trial based on this interim analysis. The ISAC made recommendations to modify the trial population of women with non-emergency and normal delivery conditions to women presenting with some degree of prolonged second stage of labour, as will be defined by a new amended protocol. The Committee also agreed with the expansion of the study to public hospitals in Argentina, Kenya and South Africa.

Planned activities

- Contingent on positive results of BD's preclinical and clinical studies, the Department will resume recruitment in public hospitals in Argentina, Kenya and South Africa in mid-2016. In order to achieve a total sample of 150 women, the study will enrol an additional 102 women within six to eight months of resuming recruitment.

- Contingent on positive results on safety and feasibility, it will be appropriate to proceed with an RCT comparing the Odon device to forceps or vacuum extraction in women with prolonged second stage of labour.

3.3.2.3 Caesarean section

(i) China Labour and Delivery Survey

Acknowledging that mortality outcomes are not the only important indicators when assessing the optimal rate of caesarean section, and given the lack of a clear understanding of the complex web of causes governing the increase in caesarean section and the ecological consequences and effects of this, in 2015 the Department started working with collaborators in China on a study aiming at improving this understanding in one of the countries with the largest increase in caesarean section rates worldwide: China.

The objectives of this study are (a) to describe the contemporary caesarean delivery situation in China, and identify the main contributors to the very high caesarean section rate; and (b) to describe the current situation of obstetric complications and perinatal outcomes. This is a multicentre, large-scale, cross-sectional, observational study to collect comprehensive labour and delivery information on 200 000 births in China. This study builds on the experience, procedures and instruments used in the two WHO surveys previously conducted by the Department: the WHO Global Survey on Maternal and Perinatal Health, and the WHO Multicountry Survey on Maternal and Newborn Health, which both achieved high visibility and impact. It will also serve as a case study for the utilization of the Robson Classification, whose implementation (according to the Department's vision and strategy) is critical to understanding, monitoring and optimizing caesarean section rates at any level, but particularly at the health-care facility level.

Progress

In 2015, the study was approved by the RP2 and WHO-ERC, and the team enrolled 124 hospitals in the survey. Data collection started on 1 March 2015. By the end of August 2015, 18 000 delivery records from 78 hospitals had been submitted. The survey is expected to take two years.

Planned activities

- Data collection will continue in 2016. A Steering Committee meeting is planned for September 2016.

3.3.2.4 Obstetric fistula

The Department jointly with EngenderHealth completed a multicentre RCT that compared shorter versus longer duration of catheterization following fistula repair surgery in eight African countries.

Progress

The results of this trial were published in *The Lancet* in July 2015 *(32)*. They show that 7-day catheterization is non-inferior to 14-day catheterization in terms of incidence of fistula repair breakdown. This publication was followed by correspondence and an authors' reply published in *The Lancet* in November 2015 that emphasized the importance of the results found in the trial for women with fistula as well as for the facilities that provide fistula services *(33)*. During the World Health Assembly in May 2015, the Department participated in two fistula-related side events. The objective of these events was to advocate for ending fistula.

Planned activities

- The Department is planning to develop evidence-based guidelines on obstetric fistula using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for appraising the quality of evidence and determining the strength of recommendations. For this, the group will conduct a systematic review in 2016 on duration of catheterization after fistula surgery and include the results of the above-mentioned trial. This would be the first WHO guideline in this domain.

3.3.2.5 Hypertensive disorders of pregnancy

(i) Long-term calcium supplementation in women at high-risk of pre-eclampsia: a randomized placebo controlled trial: The Calcium and Pre-eclampsia (CAP) 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 *WHO Model List of Essential Medicines* by the 19th Expert Committee on the Selection and Use of Essential Medicines *(34)*, and current WHO guidelines issued in 2013 recommend 1.5–2.0 g daily elemental calcium supplementation in pregnant women from 20 weeks' gestation until the end of the pregnancy *(35)*.

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, in 2011 the Department engaged in a multicountry randomized, double-blind, placebo-controlled trial to assess if calcium supplementation before pregnancy and in the first half of pregnancy reduces the incidence of recurrent pre-eclampsia more effectively than supplementation starting at 20 weeks of gestation. If found effective, the groundwork will have been done for research and then implementation of food fortification programmes.

Progress

The trial started in 2011 and, as of September 2015, 2308 women have been screened; 1174 have been recruited and 422 participants have completed their pregnancies at sites in Argentina, South Africa and Zimbabwe. The sample size to be achieved is 1440 women and it is expected that the trial will successfully finish recruitment early in 2016; data collection should be complete by the end of 2016. The DSMB met in February 2015 and the fourth Steering Committee meeting was held in Johannesburg in March 2015.

Planned activities

- Recruitment will finish early in 2016, and the pool of women recruited will be followed up during 2016. Pregnancies and outcomes will be recorded until the end of 2016.

(ii) Simplified Treatment for Eclampsia Prevention using Magnesium Sulfate (STEPMAG)

Magnesium sulphate (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 relating to the use of magnesium sulphate as prophylaxis and treatment for eclampsia worldwide, a technical consultation was held in October 2013 to deliberate on how to generate an evidence base for an alternative, easier to use, but equally efficacious magnesium sulphate regimen. This consultation identified a clear need for a stepwise approach to establish the rationale and scientific basis for testing a simpler magnesium sulphate regimen. The Department has embarked on a number of converging research activities to justify the need for and the choice of a minimum dosage regimen of magnesium sulphate in preparation for a large-scale non-inferiority trial.

Progress

(a) STEPMAG preparatory systematic reviews

As part of the STEPMAG trial preparatory activities, two systematic reviews have been completed and published in 2015: "A systematic review of non-randomized studies on the use of alternative regimens of magnesium sulphate for treatment of pre-eclampsia and eclampsia" in *Acta Obstetricia et Gynecologica(36)*; and "Clinical pharmacokinetic properties of magnesium sulphate in women with pre-eclampsia and eclampsia: a systematic review" in *BJOG (37)*.

(b) Magnesium sulphate dose-finding exploratory study

In order to improve the probability of success for the proposed WHO non-inferiority trial, the Department in collaboration with Merck is conducting a pharmacokinetic–pharmacodynamics (PK/PD) modelling and simulation study to find a minimum effective and simplified dosage regimen. The goal of such a model-based approach is to systematically assess various dosing regimens in order to identify one that will achieve both equivalent (non-inferior) efficacy while at the same time being more practical to implement. Three identified datasets and sources are from Stanford University (USA), Srinagarind and Siriraj Hospitals (Thailand) and Oxford University (United Kingdom). Approvals and legal documents have been finalized and agreed with these three institutions, paving the way for Merck to be able to receive and use existing datasets for the modelling work. The modelling team at Merck has started a stepwise use of the Stanford dataset of serum magnesium levels and health outcome data in women receiving $MgSO_4$ for pre-eclampsia, to perform the population pharmacokinetic modelling.

(c) Global clinical practice patterns in the use of magnesium sulphate for the prevention and treatment of eclampsia: a multi-country survey

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

In the context of this uncertainty around the optimal magnesium sulphate regimen and the multiple barriers to its access and use, WHO is using the WHO multicountry survey network of health-care facilities to conduct a survey to characterize current clinical practices in the prevention and management of severe pre-eclampsia and eclampsia. Heads of the obstetric departments or maternity units at the participating facilities are eligible to participate. The research protocol has been approved by the RP2 in June 2015 and by the WHO-ERC in August 2015. The survey has been conducted in English, French, Japanese and Spanish.

Planned activities

- An update of the Cochrane systematic review on alternative regimens of magnesium sulphate for prevention and treatment of pre-eclampsia and eclampsia is expected to be published in early 2016.
- The PK/PD modelling and simulation study is ongoing:
  - The team in Thailand started data collection in December 2015 and will complete this in March 2016;
  - The University of Oxford, United Kingdom, has agreed in principle to share the raw data of the Magpie trial;
  - It is expected that the PK/PD modelling and simulation study will be completed in the third quarter of 2016.

A manuscript reporting the results of a multicountry survey of clinical practice patterns in the use of magnesium sulphate for prevention and treatment of eclampsia is expected to be submitted for review and publication in the second quarter of 2016.

3.3.2.6 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 100 µg 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 10 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 48 months at 30°C is feasible for the new RTS formulation of carbetocin.

Progress

During 2015, the following preparatory activities were accomplished: approvals were obtained from five countries' regulatory authorities; the research staff at the participating sites were trained on the trial's procedures; an investigators meeting was held. To date, the trial has been initiated in 5 out of 10 countries with 1370 participants.

Planned activities

- There are still five countries that have not started recruitment yet due to a delay in obtaining approval from regulatory authorities. The expected initiation date for those countries is March 2016.
- The finalization date at each participating centre will depend on the date the protocol has been approved at the country level. The first country to complete recruitment will be the United Kingdom in July 2016, and the last will be India in March 2017.
- During the recruitment period, monitoring visits will be organized to ensure protocol and good clinical practice (GCP) compliance.

(ii) Stability of oxytocin along the supply chain

The objective of this study is to evaluate how temperature variations during movement along the supply chain and during storage might affect the potency of the active ingredient of oxytocin products at health service delivery level. Several studies looked at the quality of oxytocin at the point of sale and found that in many places the active pharmaceutical ingredient did not meet the specifications. The possible causes identified were the 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.

This study has been implemented in Ghana and has been run in collaboration with Merck for Mothers, the WHO Essential Medicines and Health Products Department and UNFPA. Results show that oxytocin does not lose potency if it goes through temperature excursions during a three-month period.

Progress

Data has been analysed and the results of the study have been submitted for publication.

Planned activities

- In 2016, the study will be replicated in another tropical country with a different oxytocin manufacturer and longer durations in the distribution chain.

(iii) Systematic review on the quality of oxytocin available in low- and middle-income countries

WHO recommends oxytocin as the uterotonic drug of choice for the prevention and treatment of postpartum haemorrhage. Oxytocin is included in the WHO Model List of Essential Medicines *(34)*, as well as in the list of the UN Commission on Life-Saving Commodities for Women and Children. Oxytocin is widely available in LMICs but there are many concerns about its quality. Poor quality can be caused by low manufacturing standards or inadequate transport and storage conditions along the supply chain, or both. Oxytocin needs to be stored under refrigeration (2–8°C) as much as possible, although short periods of unrefrigerated transport not exceeding one month at 30°C or 2 weeks at 40°C, are acceptable. Oxytocin should also not to be frozen, although recent evidence suggests that multiple cycles of freezing and thawing do not significant change oxytocin content. Although several studies and reports have assessed the quality of oxytocin in LMICs, their findings have not been analysed or synthesized. The objective of this systematic review was to identify, critically appraise and synthesize the findings of studies on the quality of oxytocin commercially available in LMICs.

Progress and planned activities

- The manuscript has been submitted for publication and is currently under review for publication in 2016.

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

Progress

This project is led by the University of Birmingham, United Kingdom. The Department is participating in this analysis, which aims to look at all uterotonics and rank them in order of effectiveness. The protocol was published in Cochrane Pregnancy and Childbirth in 2015 *(38)*.

Planned activities

- The systematic review and meta-analysis will be published in 2016.

3.3.2.7 Preterm birth

(i) A two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women in preterm labour at facilities in sub-Saharan Africa and South Asia to improve newborn outcomes

Evidence from RCTs indicates that exposure of preterm infants to antenatal corticosteroids (ACS) reduces neonatal morbidity and mortality. The Cochrane review showed that use of ACS was associated with significant overall reductions in the risk of neonatal death, respiratory distress syndrome, cerebroventricular haemorrhage, necrotizing enterocolitis and systemic infections in the first 48 hours of life. Most of these trials were conducted in higher-level hospital settings in high-income countries. In these trials, the study populations were variable, including women with preterm labour, preterm pre-labour rupture of membranes, elective preterm delivery, pre-eclampsia and multiple pregnancies. The trials also employed ACS at varying gestational ages, and different regimens of two different corticosteroids (dexamethasone and betamethasone). While the coverage of ACS in high-income countries is generally high *(39)*, limited evidence from LMICs suggests that ACS use in health-care facilities in many lower-income countries is substantially lower *(40)*.

The Antenatal Corticosteroids Trial (ACT) was a community-based, cluster-randomized trial conducted in six LMICs, led by the Global Network and published in 2015 *(41)*. The trial aimed to evaluate the feasibility, effectiveness and safety of a multi-faceted intervention designed to increase the use of ACS at all levels of health care. The intervention had multiple components: training for health-care providers to assist them with recognizing and referring women at risk of preterm birth, calculating gestational age, and administering dexamethasone for eligible women (i.e. women at risk of preterm birth, 24 to < 36 weeks gestation); and supply of commodities.

While the trial successfully increased the use of ACS in the intervention arm more than four-fold compared to the control arm, the lack of evidence of benefit in newborns below the fifth percentile for weight, coupled with evidence of increased mortality in the larger newborns and infectious morbidity in mothers, is concerning. The ACT trial findings highlight that increasing ACS use alone in resource-limited settings may not provide benefit, and may cause harm. Further research is required to establish in what contexts ACS can be used safely and effectively in lower-income countries.

The Department has recently published new *WHO recommendations on interventions to improve preterm birth outcomes*, including 11 recommendations on the use of ACS *(42)*. In light of the ACT trial findings, the Guideline Development Group (GDG) recommended that ACS be used for women at risk of preterm birth between 24 weeks and 34 weeks of gestation when the following five criteria are met:

- gestational age assessment can be accurately undertaken;
- preterm birth is considered imminent;
- there is no clinical evidence of maternal infection;
- adequate childbirth care is available (including the capacity to recognize and safely manage preterm labour and birth);
- the preterm newborn can receive adequate care if needed (including resuscitation, thermal care, feeding support, infection treatment and safe oxygen use).

The sentiment of these recommendations is to minimize the risk of harm, while promoting ACS use. They are largely based on evidence from settings where the certainty of gestational age estimation was high. Therefore, accurate and standardized gestational age assessment (ideally from first trimester ultrasound scans) is considered important to ensure all eligible mothers receive ACS, while avoiding unnecessary treatment. The remarks accompanying the recommendations also specify that ACS should not be routinely administered in situations where the gestational age cannot be confirmed (particularly when gestational age is suspected to be more than 34 weeks) as the risk of harm may outweigh the benefits if matured babies are exposed to corticosteroids in-utero. The guidelines also acknowledge that the aforementioned conditions may not be operationalized in a standard and consistent manner across settings. However, the most critical and essential preconditions to achieve clinical benefits from ACS are uncertain and this is a high priority for further research *(43)*. There is a clear need for a conclusive, appropriately powered, high-quality trial in order to establish the conditions under which ACS could be used to achieve benefit and minimize harm in health-care facilities in lower-income country settings.

To address this important question, the RHR Department is working jointly with the MCA Department to conduct a two-arm, parallel, double-blind, placebo-controlled, randomized trial of ACS for women in preterm labour at facilities in sub-Saharan Africa and South Asia to improve newborn outcomes.

Progress

A draft study protocol has been developed. A technical consultation on the trial design was held in November 2015, at which the selection of the study countries and co-investigators was finalized.

Planned activities

- Data collection is planned to commence in mid-2016.

(ii) Primary and secondary prevention interventions for preterm birth

Interventions aimed at reducing the morbidity and mortality associated with preterm birth are generally classified as primary prevention (directed at all women before or during pregnancy to reduce preterm birth at the population level), secondary prevention (focused on reducing risk in women with known or identified risk factors), or tertiary prevention (initiated after the preterm labour process has begun, with a goal of preventing delivery or improving outcomes for preterm infants). The *WHO recommendations on interventions to improve preterm birth outcomes(42)* consider tertiary prevention interventions, as well as interventions for the preterm newborn (see section 3.3.3.3).

During the last decade, however, progress has also been made in identifying and evaluating promising primary and secondary prevention therapies. The aim of this activity is to systematically assess existing literature on the effectiveness and safety of interventions to prevent preterm birth, and to prioritize interventions for further research in LMIC settings. The findings of this evidence mapping and prioritization exercise will be used to inform the conduct of further systematic reviews (particularly individual patient data meta-analyses) of preterm birth prevention interventions. The results will also inform the development of a clinical trial protocol for evaluation of one or more preterm birth prevention interventions in LMIC settings.

Progress

Preliminary mapping has been completed, and the systematic review protocol developed. Evaluation and synthesis of available literature is currently in progress.

Planned activities

- The research prioritization component will commence in early 2016.

3.3.2.8 Implementation science and implementation research (IR)

(i) GREAT Network

The Department is collaborating with the University of Toronto and Knowledge Translation Canada on guideline-IR 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 LMICs, through implementation of relevant, evidence-based guidelines.

Progress

Within the GREAT Network and with support from the UN Commission on Life-Saving Commodities and the WHO Implementation Research Platform (IRP), the Department has conducted assessments of the barriers to implementation of maternal health guidelines in four countries (Ethiopia, Myanmar, Uganda, United Republic of Tanzania). The Department continues to provide technical support to these knowledge translation initiatives in these countries, as well as developing and pilot-testing an evaluation methodology in Kosovo, for future application in all participating countries.

The GREAT Network held its third international collaborators' meeting in Geneva in September 2015 to review ongoing projects and discuss new activities. Three publications are forthcoming (under review at time of writing) on GREAT Network activities relating to assessing barriers to guideline implementation in LMICs, and a follow-up evaluation of the GREAT pilot study in Kosovo *(44)*.

In 2015, The GREAT Network ran a second seed grant competition for research groups working on knowledge synthesis activities in the area of maternal and perinatal health guideline implementation; groups from China, Ethiopia and Italy were successful. A third seed grant competition for IR projects closed in December 2015. A GREAT Network website was launched in early 2015 and a quarterly newsletter on GREAT Network activities, resources and key publications was launched in June 2015.[9] An online Practicing Knowledge Translation course has been developed with a three-day in-person training component. The course is offered to four participants – two each from Ethiopia and the United Republic of Tanzania – to strengthen individual and institutional capacity in the science and practice of knowledge translation and IR.

Planned activities

- The work of the successful research groups will continue in 2016.
- The Department will provide ongoing technical support to the IR projects and collaborators within the GREAT Network.
- The Department will work on the development of new derivative tools from WHO guidelines.

9 The GREAT Network website and newsletter are available here: www.greatnetworkglobal.org

(ii) Implementation Research Platform (IRP) collaboration

The Department's Maternal and Perinatal Health and Preventing Unsafe Abortion team follows and monitors the implementation of several IR projects supported by the IRP.3.3.3 Norms, standards and tools

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

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

Progress

The study protocol was implemented in the first quarter of 2015 with an orientation meeting and workshop involving key stakeholders. The project is running smoothly and the fourth and final stage of the study was completed at the end of 2015. Preliminary results have shown positive impact of the project in terms of increased coverage of SBA, ANC, postnatal care and prevention of mother-to-child transmission of HIV. The study has been registered at the Clinical Trials Protocol Registration and Results System.

Planned activities

- As part of project implementation, a field day will be held with all the stakeholders from the Federal MOH, the Regional Health Bureau, WHO's Ethiopia Country Office and Dilla University, Gedeo, Ethiopia.
- The final study data analysis will be conducted in the first half of 2016 and the results are likely to be released by the second half of 2016.

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

Progress

The study protocol has not yet been fully approved by the RP2; it is going through revision and improvement of the study tools.

(c) Implementing a comprehensive strategy for building capacity for IR in LMICs

A number of gaps have been identified by the WHO IRP partners (WHO RHR Department, including HRP; the Special Programme for Research and Training in Tropical Diseases [TDR]; the Alliance for Health Policy and Systems Research [AHPSR]) over the past several years, including a need for effective strategies to build capacity for IR. With the calls for IR launched by IRP and by individual IRP partners, it is clear that while there is a growing interest in the field of IR, the capacity to propose and undertake well designed IR studies is still limited, especially by LMIC researchers and implementers.

Progress

A call for proposals was issued – "Strengthening Capacity for Implementation Research (SCAPIR) Training Centres". In response, two of the WHO/RHR/HRP Collaborating Centres in LMICs have been selected, as part of a group of six institutions globally, to be developed as Centres of Excellence in IR. The SCAPIR initiative will support development of the institutional capacity of training centres to implement training and manage grants for IR. The initiative will also promote IR in LMICs, ensure a high level of competency on IR at the regional and country levels, and create synergies and collaborations between programme implementers, individual researchers and public health institutions.

Planned activities

- In collaboration with the AHPSR and TDR, the Department will work on the development, adoption and institutionalization of a course on IR. The activities will take place over a period of 24 months. The anticipated start date for this work will be 1 December 2015, with completion expected by December 2017.

3.3.3 Norms, standards and tools

3.3.3.1 Optimal caesarean section rates

(i) Country-level monitoring

Since 1985, the international health care community has considered the ideal rate for caesarean sections to be between 10% and 15%. Since then, caesarean sections have become increasingly common in both developed and developing countries. In recent years, governments and clinicians have expressed concern about the rise in the numbers of caesarean section births and the potential negative consequences for maternal and infant health. Over the past three decades, as more evidence on the benefits and risks of caesarean section has accumulated, along with significant improvements in clinical obstetric care and the methodologies to assess evidence and issue recommendations, consensus has evolved that the 1985 recommendation needs to be revisited. To address these concerns, in 2014, the Department convened a technical consultation to review and update the evidence.

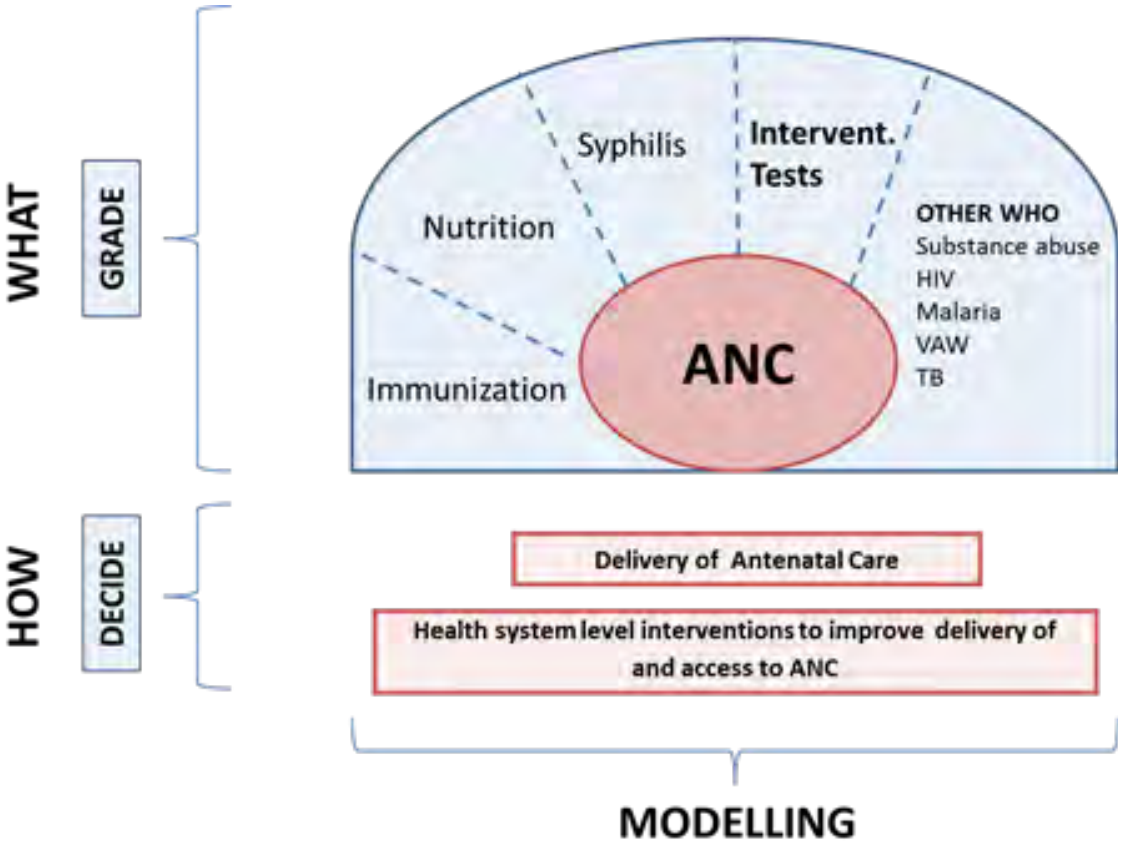
The proportion of deliveries by caesarean section at the population level is a measure of access to and use of an obstetric intervention for averting maternal and neonatal mortality and morbidity. It is useful as a reference for policy-makers and governments when assessing national and regional health 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 in order to identify gaps, support decisions and inform ongoing efforts towards improving maternal and newborn health. The Department is playing an important role in compiling and analysing rates and trends.

Progress

In April 2015, the WHO Statement on caesarean section rates was published on the basis of available data *(1)*. The Statement was translated into seven languages and was followed by an explanatory commentary in the *BJOG (45)*. The conclusions of the statement were primary based on two analyses: a systematic review of ecological studies, and a worldwide analysis of the association between caesarean section and maternal and neonatal mortality. Both were published in peer-reviewed journals in 2015 *(46, 47)*.

The alarming increases in the proportion of deliveries by caesarean section have boosted the demand and interest in global and national monitoring of caesarean section rates. In 2015, the Department conducted a systematic and comprehensive search of available nationally representative data worldwide to update global, regional and subregional rates of caesarean section and assess trends over the last decades. The manuscript has been accepted for publication in a peer-reviewed journal *(48)*. Beyond experts and governments, the concern and interest in this issue among the general public has resulted in several interviews with the media and articles in important international magazines, such as the *Economist and National Geographic*, thereby raising awareness of the increased rates.

Figure 3.3.1: Antenatal care interventions and the synthesis of evidence – GRADE and DECIDE are the frameworks for assessing the quality of evidence



(ii) Monitoring of caesarean section practices at hospital level

The lack of a standardized, internationally accepted classification system for monitoring and comparing 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. Two landmark systematic reviews conducted in the Department in 2011 and 2014 on this issue established the evidence base for the recommendation of a classification system at the international level *(49, 50)*.

Progress

The *WHO Statement on caesarean* section rates released in April 2015 proposed the Robson Classification system as the global standard for assessing, monitoring

and comparing caesarean section rates *(1)*. With the purpose of assisting facilities and countries to adopt the Robson Classification, in 2015 the Department developed a manual for its use, implementation and interpretation. In addition, the Department is providing technical assistance and guidance to enable countries to implement the classification, and generate evidence on the use of the classification and its impact.

Another important aspect of caesarean section monitoring is to assess whether a particular health-care facility's caesarean section rate is optimal or if there are unnecessary caesarean sections according to its case mix. On the basis of the data from the Multicountry Survey on Maternal and Perinatal Health, the Department and its partners published 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 *(51)*. 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 its use, an electronic calculator is available online to generate these estimates *(52)*.

Planned activities

- The Department's manual for the use, implementation and interpretation of the Robson Classification will be published in early 2016.
- It has been suggested that the mere use of the Robson Classification in a health-care facility could contribute to a decrease in the use of caesarean section just by raising awareness about its frequently unnecessary use and by providing a reliable tool to monitor practices and management. The Department will continue the work of conducting a systematic review of studies that have assessed the value of the classification as an intervention for this purpose. (The use of the Classification together with other interventions to reduce unnecessary caesarean section may be tested in a future RCT.)
- The C-Model will be further tested with interested partners and facilities.
- In order to facilitate the use of the Robson Classification, in 2016 the Department will develop a web application (app) that facilities can use to enter their data and the app will automatically produce the Robson Classification table.
- The Department will continue providing technical assistance in the implementation and training of the Robson Classification at the country and facility level and documenting the results of these efforts.

(iii) Interventions to reduce unnecessary caesarean sections

Available reviews of strategies aimed at reducing caesarean section rates have shown moderate success to date and need to be updated with the most recent evidence.

Progress

In view of the increasing priority being given to this issue in the clinical and research contexts over the last few years, in 2015 the Department engaged in updating the Cochrane systematic review published in 2011 *(50)*, which evaluated the effectiveness and safety of non-clinical interventions for reducing unnecessary caesarean sections. The Department has been working with the Cochrane Effective Practice and Organization of Care (EPOC) in this review. The data extraction was completed in December 2015, and the results and manuscript are being finalized, to be submitted for publication in early 2016.

Planned activities

- In 2016, the Department will develop WHO guidelines for interventions to reduce unnecessary caesarean sections (clinical and non-clinical). The scoping meeting is planned for 12–14 April 2016.
- For methodological reasons, Cochrane reviews exclude observational studies and individual case reports. In order to complement the core findings of the Cochrane review, the Department will document specific efforts conducted in selected countries to reduce caesarean section rates, including descriptions of the country situation, activities implemented, results and lessons learnt. Even if this documentation provides no proof of effectiveness because the interventions have not yet been tested according to current internationally accepted methodological standards, it is important to broaden the scope of the Cochrane review to gain a more comprehensive understanding of all interventions proposed and implemented to optimize the rational use of caesarean section.
- This expanded review will help to identify potential components of an intervention that can be developed, shaped and tested in future research.

3.3.3.2 Management of maternal sepsis occurring around childbirth

Maternal bacterial infection around the time of birth is among the leading causes of preventable maternal morbidity and mortality globally. Prompt identification and appropriate treatment of infection during the intrapartum and immediate postpartum periods are critical to reducing associated severe maternal, fetal and newborn complications.

Progress

The goal of the *WHO recommendations for prevention and treatment of maternal peripartum infections* is to consolidate guidance for effective interventions that are needed to reduce the global burden of maternal infections and related complications around the time of childbirth. In September 2015, the new WHO guideline containing a total of 20 recommendations relating to the prevention and treatment of maternal infections was published on the Department's website and disseminated through the Department's network of partners *(53)*. Publication of the guideline was accompanied by a commentary in *Lancet Global Health(54)* and a policy brief developed in partnership with the United States Agency for International Development (USAID): "WHO recommendations for prevention and treatment of maternal peripartum infections: highlights and key messages from the World Health Organization's 2015 global recommendations"*(55)*.

In total, 17 Cochrane reviews related to this guideline were updated and published in 2014–2015. In addition, a systematic review and meta-analysis for use of prophylactic antibiotics for manual removal of retained placenta in vaginal birth was published in *BMC Pregnancy and Childbirth* in 2015 *(56)*, and a systematic review and meta-analysis for operative vaginal deliveries was submitted to a peer-reviewed journal. Two Cochrane protocols on use of prophylactic antibiotics for women undergoing episiotomy and after normal (uncomplicated) vaginal births were submitted.

Planned activities

- Printed copies of the guideline will be made available through the Department's usual dissemination channels in 2016.

- A systematic review of observational studies and meta-analysis on use of prophylactic antibiotics for operative vaginal deliveries will be published in 2016.
- The two Cochrane reviews on use of prophylactic antibiotics for women undergoing episiotomy and after normal (uncomplicated) vaginal births will also be published.

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 and MCA Departments collaborated 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 immediately after birth.

Progress

A group of international stakeholders prioritized key questions and outcomes relating to this guideline during a technical consultation in April 2013. The RHR Department collaborated with the Cochrane Pregnancy and Childbirth Group and updated or conducted afresh a total of 23 Cochrane reviews. And with the National Center for Child Health and Development, Japan, the Department also conducted seven new (non-Cochrane) systematic reviews of non-randomized studies to further inform recommendation questions relating to the management of the mother. The Department also graded the evidence according to the GRADE methodology. The convened Guideline Development Group (GDG) held a technical consultation in May 2014 and formulated recommendations covering antenatal corticosteroids, tocolytics, antibiotics and optimal mode of preterm delivery. These recommendations were reviewed in the light of the publication of the results of the Antenatal Corticosteroids Trial (ACT) through an electronic consultation of the GDG hosted by the RHR and MCA Departments in November 2014. The final guideline document was approved by the WHO Guidelines Review Committee (GRC) in June 2015, and published on 24 August 2015 *(42)*. The guideline publication was accompanied by the publication of a WHO feature story, a web story on the RHR/HRP departmental website, a commentary highlighting the recommendations in *Lancet Global Health (43)*, and an evidence brief developed in collaboration with USAID *(57)*. In addition, the guideline has been widely disseminated through the other usual channels of the RHR and MCA Departments, including emails, social media and webinar, and through a series of presentations and a pre-congress workshop at the 2015 FIGO World Congress in Vancouver, Canada, and at the Global Maternal and Child Health Conference in Mexico City, Mexico.

Planned activities

- Dissemination activities will continue through taking opportunities to make presentations about the guideline at conferences related to maternal and child health throughout 2016.
- Knowledge translation activities relating to implementation of the recommendations at the country level will be supported by the RHR Department as requested by Member States.
- The RHR and MCA Departments will continue to monitor research activities and outputs on this topic and strategize to develop new or update the existing recommendations as needed.

3.3.3.4 Improving quality of care for mothers and newborns

With increasing global utilization of health services, higher proportions of avoidable maternal and perinatal mortality and morbidity have moved to health-care facilities. In this context, poor quality of care in many facilities becomes a roadblock in our quest to end preventable mortality and morbidity. Effective care to prevent and manage complications during childbirth and the period immediately after birth is likely to have a significant impact on reducing maternal deaths, stillbirths and early neonatal deaths. The RHR and MCA Departments developed an ambitious work plan including a quality of care framework and implementation roadmap *(2)*.

Progress

A WHO Quality of Care Working Group was established across relevant WHO departments, co-led by the RHR and MCA Departments. Building on previous work in this area, the Working Group developed a vision, definition and framework for quality of care which incorporates both the provision and experience of care, along with strategies and work areas to guide the efforts for this vision to be realized *(2)*. Furthermore, a set of standards and quality statements have been developed to aid quality improvement at the country level. These standards are based on the domains of the quality of care framework, applicable to all health-care facilities offering maternity services. They are woman-, newborn- and family-centred and supported by quality measures that can be used to assess, improve and monitor care. A technical consultation with country, regional and global experts was held in Geneva in June 2015 to build a consensus on these elements and to determine the next steps. Based on available evidence, quality measures (including input, output and outcome measures) have been developed and compiled for each statement, and a Delphi survey is currently in process with participation of 112 experts from 47 countries to prioritize and finalize these quality measures.

Furthermore, work is ongoing to synthesize evidence on quality improvement approaches and service-delivery modalities, including a synthesis of case studies that illustrate successful investments in improving the quality of maternal and newborn services. The aim of the implementation roadmap is to provide countries with highly actionable implementation guidance for improving the quality of maternal and neonatal health that supplements existing country plans and accelerates progress towards the relevant 2030 SDG targets and the goals of the Global Strategy.

Planned activities

- The Delphi survey process will be completed in 2016, leading to a working draft of quality measures to be tested and incorporated in the field.
- A technical consultation will be held in 21–22 January 2016, focusing on implementation guidance.
- A network of early-adopter countries is planned to test the implementation of the guidance, including the standards.
- The manuscripts describing the development processes and the results will be published: quality standards and statements, Delphi process and the quality measures, implementation guidance.
- The systematic reviews to synthesize evidence on implementation and quality improvement will be published: "Implementation of effective practices in health facilities: a systematic review" (currently under review); and "Care for women around the time of childbirth in onsite midwife-led birth units: a systematic review" (currently in preparation).

3.3.3.5 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 support understanding of programme impact, 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 – are 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 outcomes, and also limits replication of the programme in other contexts.

Progress

By conducting a systematic review, WHO has completed the first step towards developing Programme Reporting Standards (PRS). The systematic review provides an overview of available process reporting tools (used by researchers, organizations and donors) and reporting guidance (used by journals) for programmes in maternal, sexual and reproductive health *(58)*. Similar to the CONSORT 2010 guideline (CONsolidated Standards of Reporting Trials 2010) [10], a checklist and flowchart format can be employed for PRS, 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 comparisons between programmes. They would also facilitate the use of implementation research (IR) as part of programme implementation, since many of the processes and contextual variables documented through this process are useful sources of data for IR studies. WHO also aims to test the feasibility of using the PRS for maternal, sexual and reproductive health programmes through a variety of platforms.

Planned activities

- In 2016, the Department will finalize the Delphi survey to prioritize the items for PRS that were identified through the systematic review.
- The Department will convene a technical consultation to develop consensus and produce a PRS tool for dissemination and implementation.

3.3.3.6 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. Current WHO guidance on ANC is fragmented. While WHO provides some ANC recommendations on prevention and treatment of specific complications in pregnancy as well as other pregnancy-related recommendations in multiple separate guidelines, there is no comprehensive, up-to-date clinical guidance for ANC as a whole. The 2002 publication, *WHO antenatal care randomized trial: manual for the implementation of the new model*, is the closest to a WHO guideline document for ANC *(59)*. However, the evidence base and guidance for this document were not prepared in accordance with the current standards

10 Further information available at: http://www.consort-statement.org/consort-2010

of the WHO GRC. Emerging evidence in the period since this document was published necessitates review and update of the evidence base for ANC interventions.

Progress

As part of the Department's efforts to consolidate evidence-based guidance on the provision of quality care during the antenatal period, recommendations for the interventions needed during this period, as well as how these interventions should be delivered, are currently being developed. Following technical consultations in 2014, mapping of existing clinical practice guidelines related to ANC, and finalization of priority questions and outcomes for the recommendations, work on the recommendations for the interventions needed during the ANC period has continued during 2015 and is still ongoing. As part of this process, two systematic reviews have been published in *BJOG*: "Antenatal care for healthy pregnant women: a mapping of interventions from existing guidelines to inform the development of new WHO guidance on antenatal care"*(60)* and "What matters to women: a systematic scoping review to identify the processes and outcomes of antenatal care provision that are important to healthy pregnant women" *(61)*.

The Department is collaborating with other WHO Departments, including the Department of Maternal, Newborn, Child and Adolescent Health (MCA), the Department of Nutrition for Health and Development, and the Department of Immunization, Vaccines and Biologicals, as well as other UN partners, and initiatives such as 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)[11] framework has been used to assess the evidence and the work is being developed by a Guideline Development Group (GDG) under the following work-streams: clinical interventions, antenatal testing, barriers and facilitating factors affecting access to and provision of care, large-scale programme evaluation, health-system-level and community-level interventions, and modelling. Fifty-six Cochrane reviews have been (or are in the final stages of being) updated in preparation for these guidelines. The GDG meeting on "WHO recommendations on antenatal care" focusing on nutrition and maternal interventions and tests in pregnancy was held on 27–30 October 2015. Consensus was reached on 26 recommendations.

Planned activities

- The second GDG discussion on "How a routine ANC package should be provided" will take place in the first quarter of 2016.
- The recommendations will be finalized and published by the end of 2016 together with the publication of the Cochrane systematic review updates and other related systematic reviews.
- The GDG will explore the use of online tools for communication, including for targeting different guideline components for different audiences. Modelling will be explored as an interactive decision-making tool for policy-makers.

3.3.3.6 Antenatal care guidelines

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

11 Further information available at: http://www.decide-collaboration.eu/

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

The Department contributes to the development of "Evidence to Decision" (EtD) frameworks, in collaboration with the Norwegian Knowledge Centre for the Health Services and other DECIDE partners. This occurs particularly through the ongoing use of DECIDE frameworks in guideline development, such as the forthcoming WHO recommendations on ANC. Furthermore, the Department contributed to the development of the "interactive Evidence to Decision" (iEtD) tools that were developed to support decision-making by guideline panels, and to simplify communication and dissemination of evidence-based recommendations to health systems stakeholders *(62)*.

This project, which came to an end in 2015, has been instrumental in the Department's recent guideline development projects. The DECIDE frameworks enabled the Department to use qualitative evidence in a systematic manner in the decision-making process for the guidelines.

Planned activities

- A series of journal articles will be forthcoming on DECIDE activities and development of EtD frameworks (the journal is yet to be determined).

3.3.3.8 An approach to assess confidence in evidence from qualitative evidence syntheses (the GRADE-CERQual approach)

The Department has been actively involved in the development and application of the "Confidence in the Evidence from Reviews of Qualitative Research" (CERQual) approach, leading the use of qualitative evidence in the WHO guideline development process.[12]

Progress

This approach has been used in two current guideline processes (for the ANC guidelines and for *Health worker roles in providing safe abortion care and post-abortion contraception*), moreover it has been used in the evidence synthesis on mistreatment of women *(14)*. In October 2015, a scientific article was published describing the CERQual approach *(63)*.

Planned activities

- A set of manuscripts to describe each component of the CERQual approach and a summary of qualitative findings will be published in 2016.

3.3.4 Monitoring and evaluation

3.3.4.1 Maternal mortality estimates

In 2000 UN Member States pledged to work towards a three quarters reduction in the 1990 maternal mortality ratio (MMR) by 2015. This objective, along with achieving universal reproductive health, formed the two targets for MDG 5: "Improve maternal health". WHO leads the work of the Maternal Mortality Estimation Interagency Group (MMEIG), which periodically publishes trends and levels of maternal mortality to assess progress towards the MDG.

12 Further information available at: http://cerqual.org/

In the final years of the MDG reporting period, a number of initiatives – including the UN Secretary-General's Global Strategy for Women's and Children's Health, which mobilized countries to renew commitments to MDG 4 ("Improve child health") as well as MDG 5, and the high-level Commission on Information and Accountability (COIA), which promoted "global reporting, oversight, and accountability on women's and children's health" – were developed to accelerate progress and enable improved measurement of maternal mortality. Building upon this momentum generated by MDG 5, the SDGs establish a transformative new agenda for maternal health: to reduce the global MMR to less than 70 per 100 000 live births between 2016 and 2030 (target 3.1), and the Ending Preventable Maternal Mortality (EPMM) strategy, published in February 2015, has extended this to include the goal that by 2030 no country should have an MMR greater than 140 per 100 000 live births *(64)*.

Progress

The RHR Department, in collaboration with the WHO Department of Health Statistics and Information, and UNICEF, UNFPA, The World Bank and the Population Division of the UN Department of Economic and Social Affairs (UNPD), partnered with a team at the University of Massachusetts Amherst, USA, the National University of Singapore, Singapore, and the University of California at Berkeley, USA, to generate internationally comparable MMR estimates with independent advice from a technical advisory group (TAG) that includes scientists and academics with experience in measuring maternal mortality. Prior to publication, the RHR Department will lead the WHO country consultation process, responding to questions and concerns from Member States on the estimation process.

These estimates represent the final round of reporting for the MDG period. Due to the calls to improve country-level data, many countries prioritized the release of data on maternal mortality in 2015. As a result, the MMEIG refined the methodology undertaken to estimate global-, regional- and country-level trends in order to better utilize country-level data. The published estimates represent the most reliable and coherent internationally comparable estimates of maternal mortality to date.

The estimates have been published in an article in The Lancet, entitled "Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group"*(5)* as well as in a formal Interagency report: *Trends in maternal mortality: 1990–2015: estimates by WHO, UNICEF, UNFPA, World Bank Group, and the United Nations Population Division(4)*.

Understanding the context of the measurement needs, and with the insight gained from monitoring maternal mortality, the Department, in collaboration with partners – USAID, the Maternal Health Task Force (MHTF), UNFPA and UNICEF – has also led the process to develop the Ending Preventable Maternal Mortality (EPMM) strategy, goals and targets, and indicators for measurement of maternal health. The EPMM strategy was published in February 2015 and served as a reference to support the inclusion of the maternal mortality goals in the SDG framework, such as health target 3.1 *(64)*. To enable realization of this target, consensus on priority, methodologically robust maternal health indicators is needed. The Department, in collaboration with MHTF, USAID and the Maternal and Child Survival Program (MCSP), facilitated an iterative and collaborative process to reach consensus on indicators for global monitoring and reporting by all countries. By the end of September 2015, consensus was reached on 12 maternal health indicators and four priority areas for further testing and refinement.

These 12 core indicators will be harmonized with the Every Newborn Action Plan core metrics for a global joint maternal and newborn monitoring framework.

Planned activities

- The MMEIG will begin discussions on how to approach monitoring of maternal mortality for the SDG period in 2016.
- The MMEIG and the TAG will be convened to consider the further refinement of the statistical methodology, the use of predictor covariates, the use of data sources (such as census data collection), and improved alignment between different UN estimation processes.
- Country-level targets will be developed. The EPMM global goal requires all countries to reduce maternal mortality by two thirds to reach the global average of < 70 per 100 000 live births (SDG target 3.1). In addition to developing specific plans to assist the countries with the highest MMRs, assistance to countries with low MMR is also needed to reduce inequities within their populations to reach these targets.
- For the maternal health indicators, development of four priority indicators is needed as well as development of a process to finalize indicators intended to monitor social, political and economic determinants of maternal health and survival within national monitoring frameworks.
- A maternal and newborn metrics workgroup, led by WHO (the RHR and MCA Departments) will be formalized and a work plan will be developed.

3.3.4.2 Epidemiology and global monitoring in preterm birth

An estimated 14.9 million preterm births occurred globally in 2010, equating to 11.1% of all live births worldwide *(65)*. More than 60% of preterm births were in south Asia and sub-Saharan Africa, where 52% of the global live births occur. Preterm birth increases the risk of a range of perinatal morbidities, including respiratory distress syndrome, necrotizing enterocolitis, intraventricular haemorrhage and sepsis, as well as long-term effects such as cerebral palsy, blindness and deafness *(66, 67)*. Complications of preterm birth are the leading cause of death in these neonates, and account for over 15% of all deaths in children under 5 (0.965 million deaths) *(68)*.

Progress

Two priority activities in preterm birth epidemiology are being conducted:

- The global estimates of levels and trends of preterm birth were last updated in 2012 (for the period 1990–2010). However, they now require updating again in light of new data, continued improvements in statistical modelling methods, and following the conclusion of the MDG initiative in 2015. A working group has been established, and systematic reviews of civil registration and vital statistics (CRVS) data and published data on preterm birth have commenced.
- Given the inconsistencies in data collection and reporting in relation to preterm birth, there is a need for a clear, agreed classification system for preterm births that could be applied at health-care facility and national levels. The Department has initiated a systematic review to identify and evaluate classification systems for preterm births, based on critical characteristics of the systems identified by a panel of experts, and to assess the performance of systems in categorizing preterm births. Ultimately, we expect this study to propose the use of an international classification system for preterm births,

if such a classification already exists, or to inform the development of an internationally applicable classification system.

Planned activities

- The updated preterm birth estimates will be published in mid-2016.
- The systematic review of classification systems will be completed in mid-2016.

3.3.4.3 The WHO application of ICD-10 to perinatal deaths: ICD-Perinatal Mortality (ICD-PM)

The large number of perinatal death classification systems in the literature suggests that none of them is accepted as a global system that 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 *The WHO application of ICD-10 to deaths during pregnancy, childbirth and puerperium: ICD MM* (ICD-Maternal Mortality), systematically classifying maternal deaths *(6)*, 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

A technical consultation was convened in July 2014 on the development of *The WHO application of ICD-10 to perinatal deaths: ICD-PM* (ICD-Perinatal Mortality), a sister document to the ICD-MM (ICD-Maternal Mortality)*(6)*. Work to inform this process included a systematic review of existing perinatal classification systems *(69, 70)*and a Delphi process to inform the key components of a global perinatal death classification system *(71)*. Following this, the ICD-PM draft document was presented in December 2014 at the ICD Genitourinary and Reproductive Medicine TAG meeting, where it received broad support.

The ICD-PM has since been further developed and has several unique features, which are 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.

Pilot-testing of the proposed ICD-PM system has been undertaken on two perinatal death databases from South Africa and the United Kingdom. An invited mini-series of four papers based on this pilot-testing has been submitted to *BJOG*; the papers are currently under review.

A technical working group was convened on 10–11 November aiming to:

- reach consensus from experts in the field on the finalization of perinatal cause of death groups in the ICD-PM;
- reach consensus from experts in the field on the finalization of specific ICD-10 codes which apply to each perinatal cause of death group in ICD-PM;

- finalize specific circumstances or rules needed in applying ICD-PM.

All of the aims were achieved.

The ICD-PM has been introduced in a variety of global forums.

- An editorial introducing the ICD-PM and its principles has been invited for publication by the *Bulletin of the World Health Organization*.
- The ICD-PM and its role in addressing perinatal mortality has been outlined as an important next step in the first paper of *The Lancet* series on "Ending preventable stillbirths", entitled "Stillbirths: progress and unfinished business" to be published in January 2016 *(72)*.
- Oral presentations on ICD-PM were given at the FIGO World Congress in Vancouver, Canada, and the Global Maternal and Newborn Health conference in Mexico City, Mexico.
- The RHR Department collaborated with the MCA Department and gave a presentation at the WHO technical consultation on "Perinatal death review tool development" in Montreux, Switzerland, 17–18 September 2015; consensus was achieved for the ICD-PM to be the classification system used in this tool.

Planned activities

- A four-paper mini-series based on pilot-testing will be published.
- The ICD-PM will be published in 2016.
- Ongoing country support for dissemination and implementation will continue.

3.3.5 Dissemination and partnerships

3.3.5.1 WHO Reproductive Health Library

The WHO Reproductive Health Library (RHL) has been published by the RHR Department since 1997. RHL's objectives are:

- to systematically identify, simplify and disseminate high-quality evidence in reproductive health;
- to produce reliable, rigorous and relevant content;
- to ensure high-quality reproductive health evidence is universally available and accessible to those who need it.

Progress

In 2015, the focus has been primarily on optimizing the structure, development and publication of new RHL summaries, expanding the RHL collaboration and better understanding our users and their needs and preferences. We have improved the quality and breadth of RHL content, expanding to include non-Cochrane systematic reviews of interest to RHL users, who are primarily reproductive health-care providers working in LMICs. Greater emphasis is now placed on WHO guidelines and recommendations. Translations into official UN languages are updated on an ongoing basis. These efforts have been successful, with numbers of monthly visitors steadily increasing over the 2014–2015 period; RHL now receives over 250 000 visitors each month. Non-English content accounts for over 40% of RHL's traffic.

In 2015, RHL welcomed eight new volunteer contributors, and posted 37 new summaries (11% of current titles). The Cochrane Collaboration and Wiley have

committed to providing free access to the Cochrane Library for all RHL users, which will be implemented with the launch of the new RHL platform in early 2016.

In 2015, the Department engaged a developerto develop a new content management system for RHL, which will operate on the Drupal platform but remain integrated with the WHO information technology infrastructure. It will provide a modern and more sophisticated interface for RHL users. Simultaneously, new RHL apps are being developed for mobile phone and tablet platforms (on iOS and Android), as well as a USB-based RHL platform for offline access. These new products will be released during the first half of 2016.

Planned activities

A meeting of the RHL Board was held in September 2015 to review progress and discuss activities planned for 2016–2017. A strategic plan for RHL activities over 2016–2017 is currently being developed, which will emphasize new dissemination activities. Activities will include:

- ongoing user-testing for all RHL platforms, to improve the RHL user experience;
- better and sustained engagement with national champions, international agency partners and other key stakeholders to disseminate and promote RHL;
- implementing new RHL dissemination activities and products, including webinars, clinical algorithms and video and audio content.

3.3.5.2 "Maternal health" Lancet series (2016)

In 2006, *The Lancet* published the landmark "Maternal survival" series. In 2015, a new steering group was established to develop a follow-up *Lancet* series on "Maternal health", to commemorate 10 years since the publication of the original series.

Progress

Department staff are contributing to two papers in the new series, one on the global burden of maternal morbidity and mortality, and one systematic review of evidence-based guidelines for the care of low-risk in the antenatal, intrapartum and postpartum periods globally.

Planned activities

- The new series is currently being completed; the launch is planned for the Women Deliver Conference in May 2016.

3.3.5.3 "Ending preventable stillbirths" Lancet series (2016)

Progress

The Department collaborated with an interagency group in producing a follow-on series to the 2011 *Lancet* "Stillbirth series". In this five-paper series on "Ending preventable stillbirths", a renewed call to action for the post-2015 era is presented, reframed within the context of health, survival and overall quality of care for women and their babies. The series represents the work of 216 authors, investigators and advisors representing 43 countries and more than 100 organizations, and reports on the current state of stillbirths, highlighting missed opportunities, and identifies actions for accelerated progress to end preventable stillbirths and reach the SDG maternal, neonatal and child survival targets by 2030.

Planned activities

- The series will be launched on 19 January 2016 *(72)*.

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3.4 Preventing unsafe abortion

3.4.1 Introduction

Ensuring access to safe abortion and reducing the consequences of unsafe abortion is crucial to achieving Sustainable Development Goal (SDG) target 3.7: "By 2030, ensure universal access to sexual and reproductive health-care services". While continuing its multidisciplinary thrust towards that vision, the activities of HRP on preventing unsafe abortion in 2015 saw a special focus on normative guidance to expand access to safe abortion care, global policies related to abortion care, documenting the magnitude of unsafe abortion, and implementation research on non-physician providers of safe abortion care.

Major achievements

- The guideline on Health worker roles in providing safe abortion care and post-abortion contraception was launched.

- The Clinical practice handbook on safe abortion (published in 2014) was awarded first prize in the obstetrics and gynaecology category of the British Medical Association's 2015 Medical Book Awards.
- The evaluation of the comprehensive abortion care scale-up project in Moldova showed that 72% of all induced abortions are now done using WHO-approved methods.
- Preliminary results from the feasibility study on midwife provision of medical abortion in rural Kyrgyzstan show that this approach is safe, effective and feasible.
- As part of the Global Abortion Policies Project (GAPP), preliminary data collection on abortion-related laws and policies was completed for over 190 countries.

3.4.2 Research and development

3.4.2.1 Feasibility of midwife provision of early medical abortion in rural Kyrgyzstan

In 2009, the Kyrgyz Ministry of Health (MOH) requested technical support and funding from WHO and UNFPA to conduct a strategic assessment to evaluate prevention and care for unintended pregnancies, including access to and quality of abortion care. The primary objective of a strategic assessment is to facilitate a multidisciplinary team to identify and prioritize needs and follow-up actions for strengthening policies, programmes and services. The study was developed as a follow-up to a priority strategic assessment recommendation to train midwives to provide medical abortion up to nine weeks of gestation in order to extend safe abortion care to women living in rural, underserved areas of Kyrgyzstan. The MOH agreed to use Medabon®, which is a co-packaged mifepristone–misoprostol product. This project will demonstrate the feasibility, acceptability and effectiveness of training and supporting midwives to provide medical abortion in one reproductive health centre, one maternity hospital and 28 Felsher Obstetric Points.

Progress

Data collection was completed and data cleaning, entry and analysis were started in the fourth quarter of 2015. Preliminary data show that out of 507 medical abortions there were only 12 incomplete abortions or ongoing pregnancies, for a crude effectiveness rate of 97.6%.

Planned activities

- Data cleaning, entry and analysis will be completed in early 2016.
- Publication of the study results is expected during the second half of 2016.
- The Kyrgyz MOH anticipates that the findings will support the case for scaling-up Medabon® nationwide; however, this will require registration of Medabon®, inclusion of Medabon® on the national essential medicineslist and inclusion on the list of drugs

subsidized by national health insurance. Registration of Medabon® was initiated in September 2015 by the producer, Sun Pharmaceutical Industries Ltd.

3.4.2.2 Use of a checklist tool by community health workers to assess eligibility for early medical abortion

This study to assess the accuracy of assessment of eligibility for early medical abortion by community health workers (CHWs) using a simple checklist toolkit was conducted in Ethiopia, India and South Africa.

Progress

A manuscript reporting the results of the study was accepted in 2015 for publication in 2016 *(1)*. Accuracy was over 90% and the negative likelihood ratio was less than 0.1 at all three sites when used by clinician assessors. When used by CHWs, the overall accuracy of the toolkit was 77% in South Africa, 79.6% in India and 92% in Ethiopia. Agreement between CHWsand clinicians was moderate in India (0.4; 95%CI: 0.26–0.53) and South Africa (0.56; 95%CI: 0.45–0.68) and very high in Ethiopia (0.83; 95%CI: 0.75–0.92). Thus the checklist toolkit, as used by clinicians, was excellent at ruling out cases that were ineligible and moderately effective in ruling in eligible cases. Results were particularly encouraging for use by CHWs in Ethiopia, where they had more prior experience with use of diagnostic aids and longer professional training. However, at all sites these workers made errors in determining gestational age using the gestational age wheel. The paper concluded that research is needed to streamline the components of the tool, explore optimal duration and content of training for CHWs, and test feasibility and acceptability.

3.4.2.3 A randomized, placebo-controlled study of two prophylactic medication approaches in addition to a pain control regimen for early medical abortion with mifepristone and misoprostol

In this clinical trial aimed at evaluating different regimens for pain control during early medical abortion with mifepristone and misoprostol, participants will be randomized to one of three treatment arms: (i) tramadol 50 mg orally plus a placebo tablet; (ii) ibuprofen 400 mg orally plus metoclopramide; and (iii) two placebo pills. Participants in all three groups will take their assigned study treatment immediately before taking the misoprostol dose and then repeat the study treatment once more, four hours later. All women will also receive additional analgesia for use as needed during the medical abortion process. The trial will be conducted at four sites in three countries, including Nepal, South Africa and Viet Nam and recruit a total of nearly 600 participants.

The study hypothesis is that women receiving prophylactic analgesia will report lower maximal pain scores in the first eight hours following misoprostol administration compared to women receiving placebos for medical abortion through 63 days of gestation. Our primary objective is to determine whether prophylactic administration of (i) tramadol plus placebo or (ii) ibuprofen plus metoclopramide provides superior pain relief compared to analgesia administration after pain begins. Secondary objectives include identifying covariates associated with higher reported pain scores; determining any impact of the study medicines on medical abortion success; and qualitatively exploring women's physical experiences of medical abortion, especially their experience of pain, and how these can be improved. Data sources will include medical records, participant symptom diaries and interview data obtained on the day of enrolment, during the medical abortion, and at follow-up. Participants will be contacted via telephone on day 3 and return for follow-up will occur approximately 14 days following mifepristone, concluding study participation.

A subset of 42 women will also be invited to undergo in-depth qualitative interviews following study completion.

Progress

The protocol for this trial was finalized in 2015, but difficulties with local ethical board approvals, medication procurement, and packaging have continued to delay the initiation of this project.

Planned activities

- Site activation is planned to start in February 2016 in South Africa, with Nepal and Viet Nam to follow soon thereafter. Recruitment is expected to be completed within 12–18 months.

3.4.2.4 Systematic review on how women are treated while seeking and receiving abortion care

A systematic review of qualitative evidence on how women are treated while seeking and receiving abortion care is under way. Using the framework laid out in the *Safe abortion* guidelines *(2)* and based upon a recently published review on mistreatment during childbirth in health-care facilities *(3)*, this review aims to characterize women's experiences while engaging with health services at all stages of the abortion care pathway.

Progress

The team is about half way through the process, having conducted searches in approximately 13 health and social science databases, yielding 3307 titles and abstracts from both published and grey literature. Assessments of these articles resulted in the review of 364 full texts, of which approximately 40 will undergo quality assessment and data extraction in early 2016.

Planned activities

- The review will include perspectives from both women and health-care providers and is due to be finalized by mid-2016.

3.4.2.5 Multicountry study on abortion morbidity

Although abortion accounts for an estimated 8% (95%CI: 4.7–13.2) of maternal mortality worldwide, capturing accurate information on abortion is a challenge, especially in settings where abortion is legally restricted. In 2010, the WHO Multi-Country Survey (MCS) on Maternal and Newborn Health collected data on over 300 000 women who were admitted to health-care facilities for pregnancy-related care in 29 countries. Concerning abortion, the MCS only collected data on women with severe maternal outcomes (i.e. near-miss cases or maternal deaths). The MCS abortion-related data suggest that there is underreporting of abortion-related morbidity and mortality, emphasizing the need for evidence-based abortion services, which is in line with recent literature.

In light of these findings, HRP is undertaking a new MCS building on the experiences of the prior MCS to better capture the burden and severity of abortion-related complications and to document the management of these complications among women presenting to the participating health-care facilities. In addition, we will explore women's perceptions of the quality of the care received at the facility.

Progress

A Steering Committee meeting was convened in early 2015 to discuss the protocol, including a targeted discussion on the study's objectives and methods. This is a large,

prospective cross-sectional study with data collection to be conducted in 30 countries. The study will be implemented in three phases based on regions, starting with the African Region and ending with the Region of the Americas (see *Planned activities below*).

The data collection will be at both facility and individual levels, involving a review of medical records and exit surveys with eligible women using Audio Computer-Assisted Self-Interview (ACASI). With this systematic approach, and by assessing a wide variety of facilities and countries, the study will provide more information on abortion-related morbidity and abortion care provided at the facilities. In addition, findings from this study will further strengthen the research capacities of the participating countries. One example is the opportunity to collaborate with CLAP/SMR (El Centro Latinoamericano de Perinatología/Salud de la Mujer y Reproductiva) when implementing the study in the Americas, utilizing their SIP-A (El Sistema informatíco Perinatal), a recently launched medical record system focused on abortion.

The proposal for the MCS on abortion was submitted to the Research Project Review Panel (RP2) in October 2015, and the WHO Ethics Review Committee (WHO-ERC) in December 2015. As the protocol undergoes the technical and ethical review process, the WHO representatives for the participating African countries were contacted in late 2015.

Planned activities

- Implementation phase 1: WHO African Region – Algeria, Benin, Burkina Faso, Democratic Republic of the Congo, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Niger, Nigeria and Uganda. Data collection for this first phase is anticipated to commence in the first part of 2016.
- Implementation phase 2: WHO South-East Asia, Eastern Mediterranean and Western Pacific Regions – Bangladesh, India, Indonesia, Morocco, Myanmar, Nepal, Pakistan, the Philippines and Tajikistan.
- Implementation phase 3: WHO Region of the Americas – Argentina, the Plurinational State of Bolivia, Brazil, Cuba, Dominican Republic, El Salvador and Peru.

3.4.2.6 Randomized controlled trial on management of second trimester incomplete abortion

To date, there is no established medical regimen for management of incomplete abortion in the second trimester. There are several factors to investigate in relation to the medical management of second trimester incomplete abortion. One is the difficulty in providing surgical interventions in low-resource settings due to the scarcity of trained providers and sterile equipment, and poor access to high-level centres where surgical procedures are performed. In addition, in the context of the Ebola virus disease (EVD) crisis, or a similar outbreak, where women are having abortions or miscarriages and there is reticence to have direct contact with infected women, having an effective medical regimen for incomplete abortion is paramount.

Progress

The research protocol is in the final stages of development. Discussions were recently undertaken to finalize the study design.

Planned activities

- The research protocol will be submitted to the RP2 in early 2016. A principal investigators meeting will be organized in mid-2016 to review the protocol and discuss details of the trial operations.

3.4.2.7 Systematic review on women's awareness and knowledge of abortion legislation

A systematic review of quantitative evidence on women's awareness and knowledge of the legal status of abortion was conducted. As incorrect knowledge of laws may impact how women enter the health system or seek services, and likely contributes to the disconnect between official laws and practical applications of the laws, the objective of this systematic review was to provide a synthesis of evidence of women's awareness and knowledge of the legal status of abortion in their country.

Study settings and representativeness varied, making comparison difficult. Nevertheless, barring a few exceptions, findings from the review indicate that across all settings and subgroups, women's correct knowledge of abortions laws and legal grounds in their country appears to be low, with women's correct general awareness and knowledge of the legal status being less than 50% in 9 of the 16 studies that assessed this outcome.

Progress

The systematic review was completed and submitted for publication in the fourth quarter of 2015.

Planned activities

- The review will be published and disseminated in 2016.

3.4.2.8 Core outcome measures for abortion

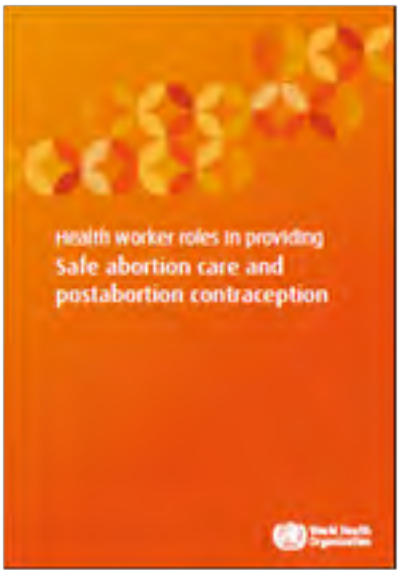
Progress

Preparation is under way of a proposal outlining plans to develop a set of core outcome measures (i.e. standardized clinical trial outcomes) in induced abortion. This project is a collaboration with the Core Outcome Measures in Effectiveness Trials (COMET) and Core Outcomes in Women's Health (CROWN) initiatives. The process for the creation of a set of core outcome measures includes systematic review of clinical trials, qualitative evaluation of patient-centred outcomes, Delphi surveys of relevant stakeholders, and dissemination of findings.

Planned activities

- Planning and scoping to assess feasibility of and interest in this project by the medical community is currently ongoing and will continue during 2016. We estimate that it will take 18–24 months to complete this project.

3.4.3 Norms, standards and tools



The guideline, *Health worker roles in providing safe abortion care and post-abortion contraception*, was launched in July 2015 *(4)*. The guideline provides evidence-based recommendations on the safety, effectiveness, feasibility and acceptability of involving a range of health workers in the delivery of recommended and effective interventions for providing safe abortion and post-abortion care and post-abortion contraception. The guideline was developed from a systematic search, synthesis and assessment of the evidence. The search identified 36 studies on safety and effectiveness and 204 qualitative studies that looked at acceptability and feasibility. Data came from both high-resource and low-resource settings and included a case study synthesis of five country contexts where abortion-related task shifting has occurred to various degrees (Bangladesh, Ethiopia, Nepal, South Africa and Uruguay). In keeping with WHO's broad and inclusive definition of health workers, a wide range of health worker types were considered.

Overall the guideline recommendations emphasize that safe abortion care and the management of incomplete abortion in the first trimester can be provided at the primary care level and by a range of non-physician providers including associate clinicians, midwives, nurses and auxiliary nurse midwives. Medical abortion, which uses medication instead of a surgical intervention, further simplifies the requirements in terms of infrastructure and skills needed and, in addition to the health workers listed above, medical abortion also makes it plausible to consider the roles of providers such as pharmacists and lay health workers who are located outside of a health-care facility. Although the evidence currently available was not sufficient to recommend independent provision of medical abortion by these cadres, their roles in specific components of care (e.g. assessing gestational age and providing information on the appropriate use of medication) has potential and should be tested under research conditions.

Table 1: Recommendations on safe abortion care in the first trimester

	Lay health workers	Pharmacy workers	Pharma-cists	Doctors of comple-mentary systems of medicine	Auxiliary nurses/ ANMs	Nurses	Midwives	Associate/ advanced associate clinicians	Non-specialist doctors	Specialist doctors
Vacuum aspiration for induced abortion	✗**	✗**	✗**	✓	✓	✓	✓	✓	✓*	✓*
Vacuum aspiration for management of uncomplicated incomplete abortion/ miscarriage	✗**	✗**	✗**	✓	✓	✓	✓	✓	✓*	✓*
Medical abortion in the first trimester	Recom-mendation for subtasks (see below)	✗	Recom-mendation for subtasks (see below)	✓	✓	✓	✓	✓	✓*	✓*
Management of uncomplicated incomplete abortion/ miscarriage with misoprostol	℞	✗	✗	✓	✓	✓	✓	✓	✓*	✓*

* considered within typical scope of practice; evidence not assessed.
** considered outside of typical scope of practice; evidence not assessed.

Source:* WHO, 2015 *(4)

This guideline is unique in that it recognizes women as an active part of the health system. Acknowledging this, the guideline includes evidence-based recommendations on self-management of medical abortion and self-assessment of abortion completeness in contexts where they have access to accurate information and have a backup health system should they need or want it. The guideline also supports self-administration of injectable contraception in specific circumstances.

As a follow-up to the print version of the guideline, a website including an interactive version is near finalization and will go live in January 2016 *(5)*. The purpose of the site is to provide stakeholders and providers at various levels with an easy-to-use tool that can help them to access information related to the guideline recommendations and safe abortion care interventions, as well as information on who can provide such services and the level of care at which they can be provided. The interactive website will allow users to easily view recommendations appropriate for different types of providers or specific to the different tasks, as well as providing access to a soft copy of the guidelines and additional supporting documents.

HRP continued dissemination activities around the *Clinical practice handbook for safe abortion(6)* at various international, regional and national meetings. The book is being actively used by partner organizations in their implementation efforts as well. In September 2015, the book was awarded first prize in the obstetrics and gynaecology category of the prestigious British Medical Association's annual "Medical Book Awards". The citation for the award in the *BMA Medical Book Awards 2015: Programme and Awards Winners noted that:*

This is concise, relevant and inviting to use with clear, helpful and accurate content. It uses a concise yet thorough format, inviting presentation with generous spacing to allow for ease of access to information. The use of figures and diagrams to summarise information helps consolidate reader's knowledge and understanding. A very portable design that could easily be used in the clinical setting. This book handles a difficult subject well. It gives clear facts that are well presented and ordered and the book is very "accessible" to its reader. I would definitely use the book in the clinical setting.

Planned activities

- Work on a focused update on medical abortion will be initiated in 2016. A preliminary scoping exercise to outline the main issues that require updating is under way.
- Work will also be initiated in 2016 in updating the monitoring indicators currently listed in the *Safe abortion guidance (2)*.

3.4.4 Monitoring and evaluation

3.4.4.1 Global Abortion Policies Project

The GAPP was initiated in the fourth quarter of 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 guidelines, *Safe abortion: technical and policy guidance for health systems (2)*. One of the main intended outcomes of the GAPP is to increase both the transparency of abortion laws and policies and the accountability of Member States that adopt and implement them. The GAPP will also identify policies (or policy packages) that facilitate enabling regulatory and policy environments for improving women's health and human rights through better access to and quality of safe abortion, including post-abortion care.

Progress

In 2015, the GAPP engaged nine regionally-based organizations and individuals with expertise in abortion policies and programmes to retrieve official national abortion policy documents and to extract selected data onto a questionnaire. A validation exercise conducted on a 10% sample of completed questionnaires demonstrated a sufficient number of issues to merit validation of all country questionnaires, following country review in late 2015.

Planned activities

- Following a review of the data and information collected, the information has been sent out to WHO regional and country offices for verification with their MOH counterparts.
- Following country review of the official source documents and questionnaires, all questionnaires will be validated by the Secretariat before being uploaded into the WHO–UNPD database and repository, which is currently under development.
- Country profiles will be developed, and global and regional analyses will be conducted and published in 2016.
- The interactive database and website that is being jointly developed builds on the software developed by the UNPD for researching, reviewing, updating and archiving information related to its World Population Policies Database.
- The web application for the GAPP will allow users to interactively create summary tables, graphs and maps, develop customized country profiles, and search and download legal and policy documents, and other related publications and information.

3.4.4.2 Global estimates of the incidence and safety of induced abortion

Monitoring global trends in abortion incidence is important for evaluating the impact of efforts to reduce unintended pregnancies. Prior estimates of global abortion incidence have been made for 1995, 2003 and 2008. These estimates relied on abortion data from various sources and qualitative assessments of exchangeability to make inferences from existing data to apply to countries and territories lacking data.

Progress

As part of a collaborative effort by way of a working group that includes HRP, the Guttmacher Institute and several external experts, these methods are being updated using a systematic model-based approach. The working group is estimating subregional, regional and global levels and trends for 1990–2014 using a Bayesian hierarchical model. The model is based on a theoretical framework in which the incidence of abortion is estimated as the sum of abortions in subgroups of women of reproductive age defined by their marital status, contraceptive need and use. The draft paper of the results of this exercise is currently under peer review.

To date, classification of abortions into unsafe and safe has been based broadly on their legal status. However, while this is one factor that plays a role, it is not the only factor and it is not a proxy for safety. As part of the same collaborative effort, HRP is leading the effort to develop new estimates of safe abortion based on the conditions under which abortion takes place (the setting, the provider and the method used). Lack of nationally or subnationally representative data has

presented particular challenges. A systematic search of all available databases without language restrictions supplemented by a search for country statistics and nationally representative surveys yielded limited data, especially from low- and middle-income countries. Thus the modelling approach will use a combination of direct data and covariates. The covariates were determined using the directed acyclic graphs (DAGs) approach to determine the causal linkages to the factors that constitute safety according to the WHO definition of unsafe abortion as well as practical considerations on systematic data availability. The preliminary approach was presented to an external Technical Advisory Group during 2015. Inputs from this meeting led to development of new covariates and numerous further revisions in the approach to the modelling of these estimates. This has extended the timeline for this initiative beyond what was originally anticipated.

Planned activities

- The results are expected to be finalized in the first quarter of 2016.

3.4.4.3 National evaluation of safe abortion care in Moldova

An external evaluation on comprehensive abortion services in Moldova was conducted in 2014–2015. This was in follow up to the technical support HRP has provided to the Moldovan MOH for scaling up services in six public sector model centres for comprehensive abortion care between 2007 and 2014.

Progress

The evaluation team reviewed abortion statistics and conducted site visits to six HRP intervention sites and 13 non-intervention sites selected in consultation with the MOH 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.

On 15 April 2015, a national workshop was convened by the MOH and the WHO Moldova Country Office to disseminate the findings of the project evaluation and to develop consensus about critical needs for future scale-up of comprehensive abortion care. The workshop was held at the MOH, with approximately 70 participants invited, including the director or vice-director of each institution that provides abortion services in the country. The meeting was chaired by Deputy Health Minister Octavian Grama.

Dr Rodica Comendant presented the 10-year history of implementing safe abortion interventions in Moldova. All of the participants agreed that it has been a remarkable achievement to change from 70% use of dilatation and sharp curettage in 2005, to the current situation, where curettage is used in only 28% of all induced abortions.

Dr Stelian Hodorogea presented the results of the evaluation covering the six model centres, including positive achievements and recommendations for further improvements. It is important to note that 72% of all abortions in the country are done using methods recommended by WHO, and 40% of all abortions are provided at the model centres.

Working in small groups, participants elaborated and presented their recommendations for making further improvements to the quality of abortion services in Moldova. The recommendations were mainly focused on: quality; access; monitoring and evaluation; provider training; and prevention of unintended pregnancy and education of the general population. The full list of recommendations and next steps is included in the final report (unpublished, available on request).

Planned activities

- The project team is currently drafting a manuscript on the 10-year process of strengthening abortion care in Moldova, which will be submitted for publication in the first half of 2016.
- An interactive map that shows the methods of abortion services used at each public health and medical facility in Moldova was developed and can be accessed by the general public on the website: www.avort.md. The website also warns visitors about outdated, unsafe, non-recommended abortion procedures, which should be avoided.

3.4.4.4 Synthesis of country polices related to health worker roles in provision of abortion and post-abortion care

Progress

Using data collected for the GAPP and an analysis of national guidelines for abortion care, post-abortion care and emergency obstetric care, HRP is synthesizing global policies on who is allowed to provide care, at what level of the health system such care is allowed, and the methods and gestational periods that are approved for such care. We expect this policy and practice review will supplement the new guideline on health worker roles in safe abortion care *(4)* and facilitate identification of policy-implementation gaps as well as areas of discordance with current WHO recommendations.

3.4.4.5. Evaluation of the WHO Strategic Approach

A process evaluation of the WHO Strategic Approach (SA) is being conducted by University of Toronto, Canada. The purpose of this evaluation is to document and assess the process by which SA has been used across 15 countries to address the issue of unintended pregnancy and unsafe abortion. Moreover, this evaluation will identify the contextual factors that have affected various outputs and outcomes of the SA to date. The evaluation methodology includes: (i) primary document review to analyse stage 1 of SA; (ii) secondary document review (documents accessed through country stakeholders and literature search) to analyse stage 2 and 3 of the SA; and (iii) semi-structured interviews with country stakeholders who have used the SA for policy and programme strengthening and with WHO staff who have or have had a role in development, operations or technical support of the SA.

Progress

To date, the research team has engaged with country stakeholders, initiated the document review phase, and has begun recruitment for interviews. Primary documents or SA reports have been reviewed for 12 countries and the secondary documents have been reviewed for six countries. A thorough literature search was conducted to identify additional sources related to the SA in both peer-reviewed publications and grey literature. Two in-person interviews have been conducted so far with WHO staff who have or have had a role in development and/or technical support of the SA. An interim report based on the preliminary findings of the document review has been drafted.

Planned activities

- During 2016, the research team plans to conduct semi-structured interviews with in-country stakeholders (depending upon availability). A draft report will be prepared by March 2016 and a final report will be available by April 2016.
- The findings from the process evaluation will be used to compare the outputs of the SA (both overall and at specific stages) and the perceptions of the SA across stakeholder groups to draw observations on the use of the SA in and across countries. A final comprehensive list of recommendations will be developed based on the evaluation findings.
- Recommendations may be of interest to developers and supporters of the SA (e.g. technical staff), those who are actively implementing the SA, and those countries that are interested in applying the SA to strengthen sexual and reproductive health policies and programmes in their own contexts.

3.4.5 Dissemination and partnerships

Progress

A collaborative working group focused on the dissemination and implementation of these guidelines has been initiated under HRP's leadership. The group includes professional bodies, nongovernmental organization (NGO) partners and others who will complement efforts to facilitate in-country adoption of these guideline recommendations.

Active dissemination of the new guideline, *Health worker roles in providing safe abortion care and post-abortion contraception*, is under way *(4, 5)*. Apart from its launch on the WHO website, a commentary on the guideline was also published *(7)*, and derivative policy briefs will be finalized in early 2016. The guideline has also already been presented at international forums including at the International Federation of Gynecology and Obstetrics (FIGO) 2015 World Congress in Vancouver. French, Russian and Spanish translations of the guideline are being finalized and will be launched in early 2016. An interactive website that provides information on the interventions, the level of care at which it can be provided and who can provide it will go live in January 2016 *(5)*. Other derivative products including a summary of the main recommendations are under development.

Efforts are also under way to work with the Inter-Parliamentary Union (IPU) to provide information on these and related safe abortion guidelines and technical support for IPU's work with parliamentarians to encourage parliamentary contributions to developing effective legislation in support of better outcomes in reducing maternal mortality.

Planned activities

- Regional and subregional dissemination and strategic planning workshops are planned for 2016.
- Options for developing a joint endorsement of these recommendations with professional bodies such as FIGO and the International Confederation of Midwives (ICM) are being explored.

3.4.6 References

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3.5 Sexually transmitted infections and reproductive tract infections; SRH–HIV linkages and multipurpose prevention technologies

3.5.1 Introduction

WHO global estimates for 2012 report 357 million new cases of curable sexually transmitted infection (STIs), including chlamydia, gonorrhoea, syphilis and trichomoniasis, in addition to 417 million prevalent herpes simplex virus (HSV-2) infections in adults*(1)*. In addition, an estimated 291 million women have prevalent human papillomavirus (HPV) infections*(2)*.

Given their 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, impact on national and individual economies and adverse effects on quality of life.

The Human Reproduction team at the WHO Department of Reproductive Health and Research including HRP, works to strengthen linkages between SRH and HIV interventions, to develop innovative multipurpose prevention technologies (MPTs) based on the Global Reproductive Health Strategy (2004), and to control STIs and other reproductive tract infections based on the Global Strategy for the Prevention and Control of Sexually Transmitted Infections: 2006–2015, approved by the Fifty-ninth World Health Assembly in May 2006, ResolutionWHA59.19.

Major achievements

- A comprehensive package of studies to evaluate dual HIV/syphilis rapid diagnostic tests (RDTs) in China, Colombia and Zambia was completed.
- Core protocols were developed for an independent laboratory-based and field (clinic-based) validation of point-of-care tests (POCTs) to detect *Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis and syphilis*.
- A pilot study investigating the persistence of Ebola virus (EBOV) in body fluids in a cohort of Ebola virus disease (EVD) survivors showed that EBOV may be present in semen well beyond six months post-EVD onset.
- Updated treatment recommendations were developed for *Neisseria gonorrhoeae, Chlamydia trachomatis, herpes simplex virus* (HSV) and *Treponema pallidum*.
- Cuba became the first country validated by the Global Validation Advisory Committee (GVAC) for elimination of mother-to-child transmission (EMTCT) of HIV and syphilis.
- Several articles related to SRHR of women living with HIV, including outcomes of a global community survey, were published in a special supplement to the *Journal of the International AIDS Society* and launched on World AIDS Day, 1 December 2015.
- Two research proposals relating to microbicides and MPT development and introduction were initiated: (i) biomedical measurement of user adherence; and (ii) preclinical development of simple and inexpensive depot injectable formulations for combination contraception and HIV prevention.
- To address the need for better STI data, in 2015 the Department published three new global STI estimates on (i) HSV-2 infection, (ii) HSV-1 infection and (iii) curable STIs.
- The draft Global Health Sector Strategy on sexually transmitted infections, 2016–2021, was developed.

3.5.2 Research and development

3.5.2.1 STI Implementation research: HIV/syphilis RDTs introduction studies in China and Colombia and field performance evaluation in Zambia

Early detection and timely intervention for pregnant women infected with HIV and/or syphilis is critical for dual EMTCT of HIV and syphilis. Dual HIV/syphilis RDTs hold potential to improve syphilis and HIV testing coverage, efficiency of services and laboratory testing quality. WHO and its partners (PATH, United States Centers for Disease Control and Prevention [CDC] and the Bill & Melinda Gates Foundation) have completed a comprehensive package of studies to evaluate dual HIV/syphilis RDTs in China, Colombia and Zambia.

Progress

The three studies conducted in China, Colombia and Zambia were completed in 2015 and final data analysis is expected to be complete in January 2016. Overall, the test kits were easy to use, and acceptance of dual testing among study participants in the Colombia and Zambia studies was very high, although it was low in the introduction study in China. Performance of the HIV and syphilis components

of the Chembio DPP® HIV-Syphilis Assay and SD BIOLINE HIV/Syphilis Duotest kits in the field, as compared to gold standard reference testing, were measured in the Zambia study and had lower sensitivity and specificity compared to previously published laboratory studies. Further exploration is planned on why sensitivity and specificity of the HIV and syphilis components of the dual tests conducted in the field varied from the laboratory studies.

In October 2015, the SD BIOLINE HIV/Syphilis DuoRDT for HIV and syphilis received WHO pre-qualification.

Planned activities

- Manuscripts will be prepared reporting on the results of the introduction studies in China and Colombia. The manuscript reporting on the Zambia field study will be finalized and submitted for publication.
- Dissemination of study results with in-country key stakeholders will be conducted by each principal investigator in the first quarter of 2016.

3.5.2.2 Development and evaluation of new STI diagnostic tools

Building on the achievements of 2014, and the second WHO technical consultation on point-of-care tests for STIs (STI POCTs), in July 2015 the Department plans to conduct an independent multicountry validation study of existing and promising (near) POCTs. The validation process of existing tests and the development of a roadmap are planned for 2016–2017.

Progress

At the second technical consultation of the WHO Advisory Group on STI POCTs, key elements of the roadmap identifying the processes and milestones to accelerate access to STI POCTs were discussed and agreed. A landscape analysis of existing (near) STI POCTs, as well as those in the pipeline and at the prototype stage, has been completed.

Core protocols for an independent laboratory-based and field (clinic-based) validation of POCTs to detect *Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis* and *syphilis* have been finalized. Assessment has been completed of sites in Australia, Ethiopia, France, Guatemala, India and Spain, which had expressed interest in participating in the field validation.

The Department's STI POCTs project has been disseminated through a dedicated WHO webpage, [13] presentations at several international forums and through peer-reviewed articles and other publications *(3–5)*.

Planned activities

- Laboratory-based validation of the selected STI POCTs and a multicountry clinic-based validation study in the selected countries, according to the core protocols, are planned for 2016.

3.5.2.3 STI prevention through evidence-based behaviour-change interventions

Behaviour-change interventions are considered an essential part of comprehensive STI/HIV prevention. Throughout the past decade, substantial research has informed the development of evidence-based behaviour-change interventions that contribute

13 Available at: http://www.who.int/reproductivehealth/topics/rtis/pocts/en/

to improved health outcomes, both from an STI/HIV prevention and from a safer behaviour perspective.

In early 2015, the Department reviewed and assessed existing evidence, leading to the publication of *Brief sexuality-related communication: recommendations for a public health approach*. Brief sexuality-related communication (BSC) aims to identify current and potential sexual health concerns and to inform and motivate those at risk to change their sexual behaviour or maintain safe sexual behaviour *(6, 7)*.

Progress

A concept proposal for a multicountry feasibility study on the use of BSC techniques in family planning programmes to prevent method discontinuation, STI and unwanted pregnancy was developed and communicated to potential donors.

Planned activities

- The protocol will be finalized in 2016 and fundraising will be carried out for a multicountry feasibility study on the use of BSC techniques in reproductive health services to reduce STI incidence, family planning method discontinuation and unwanted pregnancy.

3.5.2.4 STI prevention in key populations: SIALON II

The Department, in partnership with the European Commission, funded SIALON II, an integrated bio-behavioural study (STI/HIV, hepatitis C virus prevalence and behavioural factors) among men who have sex with men (MSM) in 15 western, central and eastern European countries. The study aims to better understand the main bio-behavioural patterns of the HIV and STI epidemics among MSM by gathering up-to-date information and facilitating trend analysis to better inform STI/HIV prevention policies in this key population.

Progress

Primary analysis of the SIALON II data is complete and an official report has been published *(8)*and disseminated through several events at WHO and international forums. [14] A peer-reviewed article on the SIALON II methodology has been published *(9)*. Protocols for the secondary analyses of the SIALON II data have been developed *(10)*.

Planned activities

Four peer-reviewed articles will be submitted to high-impact journals:

- syphilis prevalence and its correlation with HIV prevalence
- validation of WHO sexual health indicators
- assessment of behavioural patterns through a cluster analysis
- validation of rapid diagnostic tests for syphilis and of syphilis-testing algorithms for surveillance purposes.

3.5.2.5 Microbicides and multipurpose prevention technologies (MPTs)

Lack of adherence is probably the most important factor contributing to lack of clinical efficacy for many HIV-prevention products. Recording vaginal temperature is an alternative and interesting biomarker option for monitoring adherence to microbicide-releasing

14 http://www.sialon.eu/en/news/sialon-ii-presented-at-the-chafea-hiv-cluster-meeting-in-athens.html?id=137

vaginal rings. Proof-of-concept has been demonstrated of a novel vaginal temperature-recording device comprising a miniature temperature-recording implant encapsulated within non-medicated silicone elastomer vaginal tubing *(11)*.

Progress

A three-year research project, for the biomedical measurement of user adherence using a temperature-recording vaginal ring device, has been approved by the Research Project Review Panel (RP2) for a phase 1 clinical study. The project, based at the School of Pharmacy, Queen's University Belfast, Northern Ireland, United Kingdom, will support preliminary clinical evaluation of the device.

Unlike other methods for measuring user adherence, this temperature-recording vaginal ring device is able to continuously and quantitatively capture environmental temperature data, such that ring removal and insertion events are readily determined. The new approach to measuring user adherence will likely provide important insights into the patterns of vaginal ring use.

Planned activities

- The proposed study will begin in early 2016.

3.5.2.6 Evaluating impact and cost–effectiveness of topical microbicides: core scenarios for HIV-prevention models

New HIV-prevention products in development, including 30-day vaginal rings, long-acting injectable contraceptives and MPTs, must compare favourably with HIV-prevention interventions in other high-risk groups such as oral pre-exposure prophylaxis (PrEP).

Progress

To help identify when and where new methods can be used most effectively, the Department brought together key researchers and stakeholders to critically review available models of cost–effectiveness of topical antiretrovirals for HIV prevention in women (microbicides), and to identify methodological differences between models. During the session at the International AIDS Society (IAS) Conference in Vancouver, Canada, in July 2015, discussion focused on how new HIV-prevention methods for young women can best be promoted and funded.

Planned activities

- Core scenarios of epidemiological settings and implementation approaches will be developed to facilitate comparisons between models and adaptations to new population groups and settings.

3.5.2.7 Persistence of Ebola virus in body fluids of survivors

A pilot study is investigating the persistence of EBOV in body fluids in a cohort of EVD survivors. Convenience samples of 100 male EVD survivors, at different time points since EVD onset, were recruited through survivors' networks. Semen samples were collected at baseline and analysed by reverse transcriptionpolymerase chain reaction (RT-PCR) and virus isolation to assess persistence of the virus and to examine the concordance between RT-PCR and viral isolation test results.

Progress

Preliminary analysis showed that EBOV may be present in semen well beyond six months post-EVD onset. Poor correlation between RT-PCR and virus isolation showed that virus isolation may not be a good surrogate for infectivity. Although Ebola RNA detection by RT-PCR does not necessarily indicate that live, infectious virus is present, long-term RNA persistence suggests the presence of live virus. Full genome sequencing may be good surrogate for infectivity.

Planned activities

- Virus isolation of these specimens is planned. The Department will continue to support WHO recommendations that male EVD survivors who do not know the RT-PCR status of their semen should abstain from sex or use condoms when engaging in sexual activity for at least six months.
- Rapid support will be provided for the launch of programmes to help EVD survivors understand and mitigate the risk of sexual transmission, including provision of semen testing, preventive behavioural counselling and education regarding the risks to survivor communities and sexual partners of survivors.

3.5.3 Norms, standards and tools

3.5.3.1 Guideline for the prevention, management and control of STIs

As recommended by the STI Guideline Development Group (GDG), updating of the guidelines on treatment of major STIs, and development of guidelines on syphilis screening and treatment for syphilis in pregnant women, are being prioritized. The development of the STI guidelines follows a rigorous process based on the new WHO standards of guideline development approved by the Guidelines Review Committee (GRC).

Progress

During the first STI GDG meeting the scope of the STI guidelines was agreed. Following the meeting a prioritization exercise was conducted and 23 population, intervention, comparator and outcome (PICO) questions were developed. Systematic reviews for the 23 PICO questions were conducted, and modelling was performed to inform the algorithms for syphilis screening and treatment in pregnant women. Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence profiles for each PICO question/outcome were developed to assess the quality of evidence from the systematic reviews. Evidence-to-decision tables were produced to facilitate the discussion and development of recommendations.

The second STI GDG meeting was held in October 2015 to assess the quality of evidence and finalize the evidence-to-decision tables. Draft recommendations and key texts have been developedfor inclusion in the guidelines document. STI treatment guidelines for gonorrhoea, chlamydia, HSV and syphilis are being finalized and submitted to the GRC for approval.

Based on suggestions from STI GDG members, additional systematic reviews are being conducted of randomized control trials and observational studies on syphilis screening and treatment of pregnant women, and the outcomes and cost–effectiveness of syphilis screening.

Planned activities

- The updated WHO STI treatment guidelines approved by the GRC will be disseminated. Countries will be supported through the regional offices to adapt the guidelines.
- Based on the results of the syphilis screen and treatment systematic reviews and the revised modelling of different testing algorithms, a virtual STI GDG meeting will be organized to finalize recommendations for syphilis screening and treatment in pregnant women. The final recommendations will be disseminated and countries supported to adopt the guidelines.

3.5.3.2 Global validation of EMTCT of HIV and/or syphilis

The global plan towards EMTCT of HIV and congenital syphilis aims to reduce the number of children born with HIV or syphilis infection to very low levels, below public health significance. A GVAC was convened in June 2014 and met to validate the first country applying for validation of elimination in June 2015. The HIV Department is responsible for mother-to-child transmission (MTCT) of HIV and the Department is responsible for the elimination of congenital syphilis.

Progress

The GVAC developed criteria, processes and tools to assist countries in applying for validation. This will ensure the validation process is standardized and transparent, and that interventions to reach the targets have been implemented in a manner consistent with international, regional and national human rights standards.

In June 2015 the GVAC recommended that Cuba be validated for EMTCT of HV and syphilis. This is the first country to be validated.

Planned activities

- Many countries from several regions are poised to apply for global validation. Country missions to verify elimination will be conducted in 2016 as necessary.
- A process for pre-elimination is being developed. Countries that have made significant progress in reducing MTCT of HIV and syphilis, but are not eligible for validation of elimination, will be eligible to apply for pre-elimination if the following conditions are met: first visit antenatal care (ANC) > 95%; HIV and syphilis testing of pregnant women > 90%; HIV treatment of HIV-positive pregnant women > 85%; syphilis treatment of syphilis-positive pregnant women > 90%; and HIV MTCT rate < 5%. Countries that meet these criteria will be required to submit a five-year plan towards validation of elimination. The plan will include strengthening ANC programmes and SRH services, laboratory capacity, and data monitoring and evaluation systems.

3.5.3.3 SRH/HIV linkages

The Department leads policy, programme and advocacy activities in strengthening linkages between SRH, human rights and HIV, including supporting national assessments of policy, systems and service delivery of linked interventions, as 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.

(i) Guidance on SRH and human rights of women living with HIV

The 2006 publication, *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(12)*, needs updating as there have been significant changes in the lives of women living with HIV globally in the past 10 years.

Progress

A number of steps have been taken to update the 2006 guidelines *(12)*. The planning proposal for the new guideline has been approved by the GRC. Several literature and systematic reviews have been completed as well as a report on the outcomes of a global values and preferences survey *(13)* and these were collated into a special supplement to the *Journal of the International AIDS Society (14)*, which was launched on World AIDS Day 2015. In order to build capacity and further involvement of the community of women living with HIV, several sessions were organized at international conferences including the IAS Conference in Vancouver, Canada, in July 2015 and the FIGO World Congress also in Vancouver in October 2015.

Planned activities

- Further literature and systematic reviews are planned on:
  - elective caesarean section for women living with HIV;
  - health sector-based interventions to address gender/power/decision-making/self-efficacy around safer sex and reproductive decision-making among women living with HIV;
  - relationships between gender, food security, safer sex and HIV medication adherence.
- A job aid for health workers is in development on supporting safe disclosure of HIV status among women who fear or are experiencing violence and who undergo HIV testing.
- It is expected that the final guideline will be submitted to the GRC at the end of 2016.

(ii) Emerging research priorities for safer conception strategies among HIV-affected individuals and couples in low-resource settings

Safer conception strategies aim to minimize the risk of HIV acquisition during pregnancy and can be implemented through an integrated approach linking sexual and reproductive health with HIV interventions.

Progress

The Department has led discussions to identify priorities to advance research and programme action on improving access to and implementation of safer conception services to optimize maternal, partner and child health in the context of HIV and pregnancy. An open-meeting session was convened at the July 2015 IAS Conference that highlighted uptake and experiences with safer conception strategies among HIV-affected couples and individuals with immediate fertility desires.

Planned activities

- A special supplement highlighting key aspects of safer conception for serodiscordant couples will be developed for expected publication in early 2017.

(iii) Delivering new HIV-prevention methods to young women through SRH services

Although HIV infections among adolescents have declined by 43% since 2001, progress in implementing prevention strategies has been uneven. Young women, particularly girls, continue to be affected more than young men, with 64% of new infections occurring in girls aged 15–19.

Progress

A proposal has been drafted to identify approaches to delivering HIV prevention, including oral PrEP, to young women through reproductive health services. This includes determining the components of a minimum service package for prevention in women and girls; identifying the challenges behind poor product adherence in clinical trials among young women; and developing strategies for identifying and retaining subgroups at highest HIV risk in care.

Planned activities

- In the context of ongoing demonstration projects related to the introduction of microbicides for women, together with partners involved inthe Project Advisory Committee (PAC), which ischaired by the Department, collaborations will be explored to build a research consortium to gain a better understanding of how to deliver HIV prevention to young women within SRH services and interventions.

(iv) Development of SRH/HIV linkages toolkit and infographic

In order to help countries to link their SRH and HIV programmes effectively, the SRH and HIV Linkages Resource Pack was compiled in 2010. This resource pack is managed and updated twice yearly by the Interagency Working Group on SRH and HIV Linkages, which is co-convened by WHO and UNFPA *(15)*.

Progress

To make best use of this significant body of work, a simple-to-use online toolkit is being developed that will guide users through its resources. As many of the resource materials are not country-specific (except for the rapid assessments on SRH and HIV linkages, and select case studies *[16]*), a country-specific infographic is being developed focusing on the convergence of HIV, SRH and human rights at the policy/legal, health systems and service delivery levels, emphasizing outcomes that are jointly beneficial.

Planned activities

- The toolkit and 24 country-specific infographics will be finalized, including countries that have requested the development of a country-specific infographic (Bangladesh, Botswana, Chad, Côte d'Ivoire, Eritrea, Ethiopia, Indonesia, Lebanon, Lesotho, Madagascar, Malawi, Morocco, Mozambique, Namibia, Nigeria, South Africa, Sudan, Swaziland, Togo, Tunisia, Uganda, United Republic of Tanzania, Zambia and Zimbabwe).

3.5.3.4STI vaccines

New STI vaccines are a major priority for sustainable global STI control. In 2014, the Department and global partners published a comprehensive roadmap outlining the critical next steps for STI vaccine development *(17)*.

Progress

To address the roadmap call for better STI data, in 2015 the Department published three new global STI estimates: HSV-2 infection *(18)*, HSV-1 infection *(19)* and curable STIs *(1)*.

In addition, the Department began work on an individual-level meta-analysis of STI prevalence and incidence using combined data from 18 prospective HIV-prevention studies. To advance modelling work, the Department coordinated a review of existing HSV-transmission models and convened an HSV vaccine impact-modelling consultation. To stimulate investment in STI vaccines and catalyse vaccine development, the Department developed a detailed work plan and budget for a comprehensive business case for HSV vaccine development. In collaboration with the Immunization, Vaccines and Biologicals Department (IVB), HSV vaccine was presented to the advisory committee guiding development of WHO-preferred product characteristics.

Planned activities

- The global burden of neonatal herpes will be estimated.
- The final analysis will be carried out on the individual-level meta-analysis of STI prevalence and incidence, and papers will be prepared for publication.
- The review of HSV transmission models and a summary of the HSV vaccine impact-modelling consultation will be published.
- Further work will be carried out to generate a comprehensive business case for HSV vaccine development and to prepare preferred product characteristics for HSV vaccine with the IVB Department.
- Collaboration will continue with the United States National Institutes of Health (NIH) to advance the STI vaccine roadmap. An article providing an update on implementation of the roadmap will be published.

3.5.3.5 Global Health Sector Strategy for sexually transmitted infections (STIs)

Three interlinked Global Health Sector Strategies have been developed by WHO for consideration by the 69th World Health Assembly in 2016. These proposed strategies address three major public health issues – HIV, viral hepatitis and STIs – in the post-2015 environment. The 2016–2021 strategies cover a critical phase for all three health areas as they guide actions needed to meet ambitious SDG targets for 2030 focused on ending these epidemics as major public health threats.

Progress

A broad consultative process was held throughout 2015 involving key partners, including Member States, organizations in the UN system and other multilateral agencies, donor and development agencies and initiatives, civil society, nongovernmental organizations, scientific and technical institutions and networks, and the private sector. More than 90 Member States participated in consultations held in all six WHO regions from April to July 2015. To supplement these consultations, and ensure the broadest participation, the Secretariat hosted a widelypromoted public online consultation for six weeks during the period April–June 2015. This was available in all official languages.

Considerable cost and time savings were achieved through managing a joint consultative process that covered the three strategies. The WHO website was used to document the consultation process and provide links to background documentation and consultation meeting reports. These links for the three strategies are as follows:

HIV: http://www.who.int/hiv/strategy2016-2021/en/

Viral hepatitis: http://www.who.int/hepatitis/strategy2016-2021/en/

STIs: http://www.who.int/reproductivehealth/ghs-strategies/en/

Participants in the consultation process expressed broad support for the three strategies and highlighted a number of areas for consideration.

Each of the strategies address the continuum of health sector interventions and services that are needed to curb the epidemics, including interventions to reduce vulnerability and risk, prevent transmission, enable early and accurate diagnosis, link individuals to care, deliver quality treatment and provide chronic care.

The strategies also promote a public health approach,

- Strategic direction 1 – Information for focused action – Focuses on the need to understand the epidemic and response as a basis for advocacy, political commitment, national planning, resource mobilization and allocation, implementation and programme improvement.
- Strategic direction 2 – Interventions for impact – Addresses the first dimension of universal health coverage by describing the essential package of high-impact interventions that need to be delivered along the continuum of health services to reach country and global targets, and that should be considered for inclusion in national health benefit packages.
- Strategic direction 3 – Delivering for equity – Addresses the second dimension of universal health coverage by identifying the best methods and approaches for delivering the continuum of high-impact health interventions and services to different populations and in different locations, so as to achieve equity and ensure quality.
- Strategic direction 4 – Financing for sustainability – Addresses the third dimension of universal health coverage by identifying sustainable and innovative models for financing of the response and approaches for reducing costs so that so that people can access the necessary services without incurring financial hardship.
- Strategic direction 5 – Innovation for acceleration – Identifies those areas where there are major gaps in knowledge and technologies where innovation is required to shift the trajectory of the response so that the 2020 and 2030 targets can be achieved.

The STI targets (2030) are: 90% reduction in *Treponema pallidum* incidence compared with 2018; 90% reduction in *N. gonorrhoeae* incidence compared with 2018; ≤ 50 cases of congenital syphilis per 100 000 live births in 80% of countries; and 80% HPV vaccine coverage in adolescents aged 9–13 years in 80% of countries*(20)*.

Planned activities

- The strategy will be presented to the Executive Board in January 2016 and at the World Health Assembly in June 2016.
- Work will begin with WHO regions to start the adoption and adaptation of the strategies with Member States

3.5.4 Monitoring and evaluation

3.5.4.1 Antimicrobial resistance in N. gonorrhoeae

Monitoring the susceptibility patterns of N. gonorrhoeae is essential to detect and track emerging resistance and to adjust treatment recommendations for optimal outcomes.

WHO is working to make the Gonococcal Antimicrobial Surveillance Programme (GASP) as effective as possible and to address its many challenges, including limited national leadership, commitment and funding in many countries.

Progress

Susceptibility data for at least one antibiotic have been reported by 50–60 countries. Europe accounts for the majority of reporting countries, while the African and Eastern Mediterranean regions are the least represented. Overall, the most recent GASP data available from 2012 and 2013 show continued widespread gonoccocal resistance to quinolones and azithromycin, and emergence of decreased susceptibility to extended-spectrum cephalosporins.

To improve monitoring of antimicrobial resistance (AMR), country-level capacity is being enhanced by developing and implementing a minimum package for gonococcal AMR surveillance and laboratory antimicrobial susceptibility testing (AST). Together with CDC, an enhanced GASP protocol has been developed to improve the quality of gonococcal AMR surveillance and laboratory AST, including linking gonococcal isolates with epidemiological data. Thailand is being supported to implement the enhanced GASP protocol. In Kenya, an assessment and on-site laboratory AST strengthening were conducted to improve the laboratory capacity of Kenya as a subregional GASP focal point in Africa. India is being supported to adapt the enhanced GASP protocol as an important component of strengthening STI surveillance.

WHO's carefully selected gonococcal reference strains ensure the validity and comparability of laboratory data and are used for internal and external quality assurance. The reference strain panel, which previously included eight carefully selected strains, has now been updated. The 14 novel 2015 reference strains have detailed phenotypic and genetic characterization, including genomic characterization. The six new strains included those with high-level as well as low-level resistance; several related to treatment failures to cefixime, ceftriaxone and azithromycin; and strains causing false-negative results in porA-based gonococcal nucleic acid amplification tests. The new 2015 WHO *N. gonorrhoeae* reference strains were presented at the World STI & HIV Congress in Brisbane, Australia, in September 2015 *(21)*. An article is currently being drafted for peer review.

A manual for the early implementation of the Global AMR Surveillance System (GLASS) has been published. The manual assists countries to develop a national AMR surveillance programme, implement a systematic approach to AMR monitoring, and utilize indicators for measuring implementation of the national surveillance programme. *Neisseria gonorrhoeae* is one of the priority pathogen–antibacterial combinations on which GLASS will gather data *(22)*.

A common platform for reporting AMR in gonorrhoea data into GLASS is being developed in partnership with the AMR surveillance team.

Planned activities

- The enhanced GASP protocol will continue to be implemented in three countries. Based on the lessons learnt, a standardized training package on data collection and laboratory testing for gonococcal AMR monitoring will be developed. Training will be organized at the 17th World Congress of the International Union Against Sexually Transmitted Infections (IUSTI), in Marrakesh, Morocco.

- GASP will be extended by integrating it within the GLASS network. Countries will be supported to collect gonococcal AMR data through GLASS.

3.5.4.2 STI surveillance and estimations

The global burden of STIs remains high. In 2012 there were an estimated 357 million new infections (roughly 1 million per day) of the four curable STIs – chlamydia, gonorrhoea, syphilis and trichomoniasis *(1)*. In addition, more than 500 million people were estimated to have a genital herpes infection with either HSV-1 *(19)* or HSV-2 *(18)*. STI prevention and control has contributed to progress towards multiple Millennium Development Goals (MDGs) and continues to support progress towards the new SDGs.

Surveillance is a key element of WHO's STI prevention and control strategy, and STI data are an important component of second-generation surveillance systems for HIV. More effective surveillance is required to provide the data needed to guide the next phase of the STI control strategy post-2015.

Progress

Ten STI reporting indicators have been integrated in the Global AIDS Response Progress Reporting (GARPR) system since 2011 for syphilis and 2013 for gonorrhoea, urethral discharge and genital ulcer indicators. Overall, 53–56 countries reported on each indicator. The greatest number of countries reporting on STI syndromes was from the Africa region, with only one country reporting from Europe. Antenatal care syphilis reporting is generally more robust, with approximately 85 countries reporting, and is incorporated into health information systems in more countries.

The GARPR data for 2013 to 2014 are being collated and will be disseminated through a report on global STI surveillance, which is currently being drafted. An STI surveillance assessment has been conducted in India; based on the assessment, support is being provided to enhance STI reporting and develop a protocol for etiological monitoring in the country. Zimbabwe was also supported to strengthen STI reporting. STI data are being collected for the country-level STI estimation.

The 2012 curable STI estimates were finalized and presented at the World STI & HIV Congress in Brisbane, Australia, and a peer-reviewed paper was published in *PLoS One (1)*. In addition, global estimates of both HSV-2 and HSV-1 infections for 2012 were published *(18, 19)*.

Because of the limitations of the current STI estimation process for developing global and regional estimation, generation of national STI estimates is crucial. Initial work has begun to develop a tool to assist countries to estimate the burden and trends of STI in the Spectrum suite of health modelling. A Spectrum-type estimation of gonorrhoea and syphilis burden levels and trends was pilot-tested for the Plurinational State of Bolivia, Cambodia, Mongolia and Zimbabwe through available data from GARPR, online reports and databases *(23)*.

A pre-software version of STI Spectrum has been developed. A technical expert consultation on the country-level STI burden, and trend estimation and development of the Spectrum STI estimation model, was held in November to present the initial country STI estimations by STI Spectrum. During the consultation recommendations were made on what data should be input and what assumptions should be made in developing the STI Spectrum modelling tool.

Planned activities

- The Department will continue to coordinate with the HIV Department to improve STI indicator reporting through GARPR. As GARPR is currently being evaluated, the definitions and instructions on how STI indicators should be reported and measured will be reviewed and refined. Selected countries will continue to be supported to participate in strengthening the Global STI Surveillance System.
- Based on inputs from the technical consultation on the STI estimation process, the STI Spectrum software modelling tool will be developed. The modelling tool will be pilot-tested on-site in an additional six countries (Cuba, Indonesia, Morocco, Namibia, Peru and Sri Lanka) by generating in-country STI estimates to adjust the STI Spectrum modelling tool and to test the feasibility of this approach.

3.5.5 Dissemination and partnership

3.5.5.1 Gonococcal Antimicrobial Surveillance Programme (GASP) network

GASP is a worldwide laboratory network of regional coordinating centres/focal points. Each designated regional focal point, in partnership with the WHO regional office, collates data on antimicrobial susceptibility patterns in gonorrhoea in 50–60 countries. The regional focal points provide technical support to countries to strengthen laboratory capacity and to support the external quality assurance programme, including maintenance and distribution of WHO reference panels.

Progress

A partners' meeting on GASP was held in September after the World STI & HIV Congress, to review implementation of the *Global action plan to control the spread and impact of antimicrobial resistance* in Neisseria gonorrhoeae *(24)*, including strengthening the GASP network collaboration and linkages with the Global Action Plan on AMR *(25)*.

Planned activities

- Regular teleconferences will be held with the regional coordinating centres and focal points, and an annual meeting of the GASP network will be organized.
- The GASP website platform will be improved to strengthen international collaboration and information sharing.

3.5.5.2 Project Advisory Committee (PAC) for Microbicide Introduction

The Department leads and coordinates policy and programme research on biomedical interventions for woman-initiated prevention products through a PAC that coordinates and advises stakeholders and researchers working with the United States Agency for International Development (USAID) on microbicides. The critical focus of the microbicide introduction projects is to deliver and expand antiretroviral-based prevention options for women and girls, grounded in a comprehensive SRH and human rights approach.

Progress

The first PAC meeting in October 2015 brought together key stakeholders to identify areas for collaboration and coordination of efforts. This includes oversight of five demonstration projects for microbicide introduction to:

- expedite and sustain access to microbicides in countries and among populations where they are most needed;

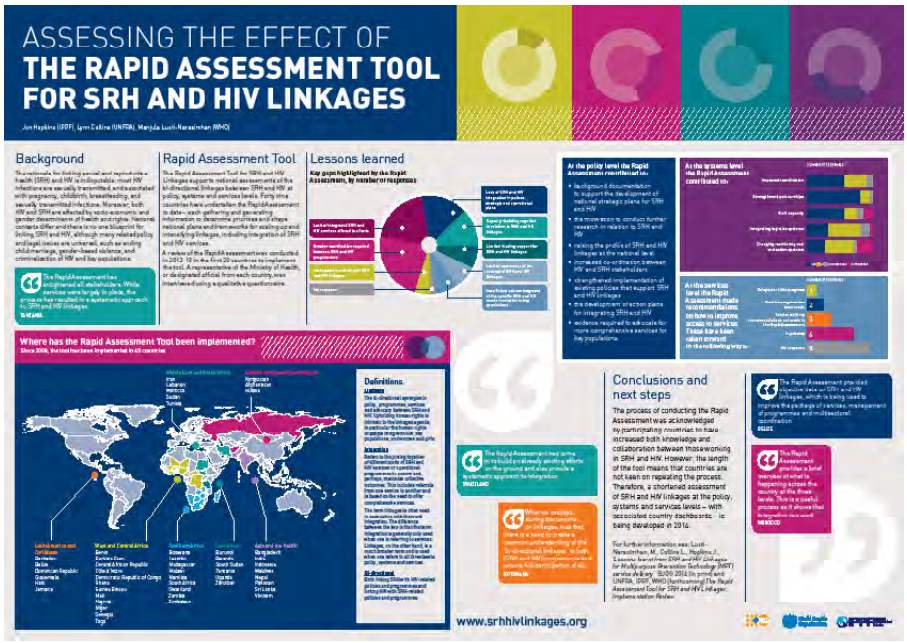
- develop cost–effective and scalable models for implementation of microbicides and other forms of PrEP for women;
- increase uptake and correct and consistent use of microbicides by women at high risk for HIV infection;
- support women's agency to use microbicides safely and reduce vulnerability to intimate partner violence;
- inform policies and define programme considerations related to use of microbicides and risk of resistance.

Planned activities

- In addition to ongoing coordination activities, technical support will be provided to countries, including building on existing efforts and demonstration projects on oral PrEP to support context-specific policies and programmes that are sensitive to the SRH needs and rights of women and young girls.
- Based on results of the phase 3 clinical trial results for the dapivirine intravaginal ring, a regional stakeholders' meeting will be held in sub-Saharan Africa to review trial results and develop consensus on priority pilot research activities.

3.5.5.3 Interagency working group on SRH/HIV Linkages

The Department has been working on the finalization and dissemination of the indicator compendium as well as a template for a country-level snapshot to capture the key activities on SRH/HIV linkages at country level.



Progress

Country level snapshots have been developed for 24 countries in collaboration with UNFPA and IPPF.

Planned activities

- The report Connecting sexual and reproductive health and HIV: navigating the work inprogress *(26)*, which documents the key activities to date since 2004, will be updated and disseminated.

- Several sessions are planned at international conferences to support countries in using existing tools related to SRH/HIV linkages.

3.5.5.4 Initiative for Multipurpose Prevention Technologies

The Initiative for Multipurpose Prevention Technologies (IMPT) is an international collaboration of product developers, researchers, health-care providers, policy-makers, epidemiologists, advocates and supporting agencies committed to safely and swiftly bringing new MPTs to market. The Department plays an active role on the Steering Committee of the IMPT and provides technical support to the Scientific Advisory Working Group (SAWG) and co-chairs the STI sub-working Group *(27)*.

Progress

Several sessions on new developments related to MPTS were highlighted at international conferences. The SAWG sub-working group on STIs conducted a mapping of key products related to STIs in the development pipeline. The MPT Product Pipeline Database was developed to serve as a comprehensive resource outlining information on MPT products and product candidates. [15]

Planned activities

- A meeting of the STI sub-working group is planned in 2016 to highlight the importance of the STI vaccine roadmap as well as build upon the successes of the implementation of HPV vaccine to raise awareness of further research for MPTs related to STIs.

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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 WHO Department of Reproductive Health and Research (RHR), 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

- To date, 8500 women have been enrolled in ESTAMPA, "Multicentric study of cervical cancer screening and triage with HPV testing", at five study sites: Colombia (2), Honduras (1), Paraguay (1) and Uruguay (1). Over 90% of human papillomavirus (HPV)-positive women have undergone colposcopy procedures.
- In a study in Swaziland, 655 women aged 15–49 years were screened with VIA, 14.8% were positive for signs of cervical pre-cancer and all underwent treatment.
- Recruitment of study participants in AISHA, "An implementation study on rapid HPV testing in Tanzania", was carried out between May and August 2015.
- The WHO, UNFPA, The World Bank, UN Women, UNAIDS, UNICEF, the International Atomic Energy Agency (IAEA),the International Agency for Research on Cancer (IARC) and the United Nations Office on Drugs and Crime (UNODC) have come together with the objectives of reducing morbidity and mortality from cervical cancer, strengthening health-care delivery systems, and detecting, treating and palliating cervical cancer. The primary expected result of the project is to establish a coordinated approach for planning and implementing cervical cancer prevention and control programmes.

3.6.2 Research and development

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

HPV testing for primary cervical cancer screening of women over 30 years old is likely to become the standard of care in the near future in many areas of the world. However, a single HPV test has low positive predictive value and may lead to unnecessary overtreatment and generate avoidable distress. ESTAMPA is a multicentre study, in which about 50 000 women aged 30–64 years will be screened with HPV in 10 Latin American countries.

The study aims to compare visual, cytological and molecular triage methods, or combinations of these methods, in terms of their performance and cost-effectiveness among HPV-positive women participating in HPV-based screening programmes.

Progress

To date, there are five study sites: Colombia (2), Honduras (1), Paraguay (1) and Uruguay (1), and 8500 women have been enrolled. Over 90% of HPV-positive women have undergone colposcopy procedures, showing very high adherence to the study protocol.

Quality assurance activities include: HPV retesting of a number of positive and negative samples; subscription by HPV laboratories to the Certified College of American Pathologists (CAP) programme; a first review of liquid-based cytology (LBC) preparations; and a review of the pathology. The latter is ongoing and results are expected in early March 2016.

The second Data Safety and Monitoring Board (DSMB) meeting was held in May 2015 and recommended that the study continue. The DSMB requested an enhanced clinical management plan to ensure the continued safety of study participants, particularly that those who exit the study prematurely continue to have access to cervical cancer screening.

Planned activities

- In 2016 study sites will be added in the Plurinational State of Bolivia, Brazil, Chile and Mexico, and the recruitment and follow-up of participants will continue.
- Validation of a tool to evaluate the impact on women of an HPV-positive diagnosis is nearly complete and the tool will be applied to a subset of women next year.
- A protocol evaluating other psychosocial aspects associated with the introduction of HPV testing in Latin America is being developed.

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

A rapid HPV test has been developed that is cheaper and easier to perform than conventional tests. However, it is not clear how the test performs at different levels of the health system in low- and middle-income countries (LMICs).

This is a cross-sectional, multicentre study carried out in 10 centres across three regions in the United Republic of Tanzania. Cervical specimens from 2295 women will be processed at primary health care centres, district hospitals, and regional and national reference laboratories. The level of agreement between test results from the different laboratories will indicate if rapid HPV testing is a reproducible and reliable screening test when operated at different levels within the health system.

The impact of introducing HPV testing in the existing visual inspection with acetic acid (VIA)-based cervical cancer screening programme will also be assessed. 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. This is a close collaboration between the Department and the Prevention and Implementation Group of IARC, which is based in Lyon.

Progress

Amendments to the study protocol, including an increased sample size due to samples untested or tested too late, were approved by local and WHO ethical committees. Study sites were set up and staff members were trained in Dar es Salaam region, the first to carry out the study. Recruitment of study participants began in May 2015 and was completed by August. A data monitoring visit was carried out by the WHO/IARC Principal Investigator in October 2015.

Planned activities

- Recruitment of an additional 257 women to increase the sample size, as noted above, will be carried out in Dar es Salaam from December 2015 to January 2016.
- The study will be rolled out in the other regions: screening will take place in Kilimanjaro and Morogoro regions from February to September 2016; and one-year follow-up will begin in Dar es Salaam and Kilimanjaro from August to December 2016.
- Preliminary data analysis will be carried out and results presented to stakeholders in the United Republic of Tanzania in February 2016.

3.6.2.3 HPV infection and HPV-related conditions among sexually active women in the Kingdom of Swaziland

This is a PhD project of the University of Kwazulu-Natal. The project aims to estimate the prevalence of HPV infection and other sexually transmitted infections (STIs) in sexually active women in Swaziland. Cervical samples are collected from women attending cervical screening in five different sites around the country, before performing VIA and treating those who test positive.

Progress

Recruitment was completed in July 2015 with 657 women aged 15–49 years enrolled in five sites. Testing has been completed for HPV and STIs (except syphilis). Of 67 women (14.8%) with a positive VIA result, 65 have been treated with cryotherapy and two have been referred to a gynaecologist due to the size of the lesions. HPV-positive women, who had a negative VIA result and hence were not treated after VIA, are being recalled to be treated with cryotherapy.

The overall age-adjusted high-risk HPV prevalence was 42.1%, that of HIV infection was 43.1%, and 22% of women screened positive for both infections.

The LBC slides for HPV-positive women have been prepared and read by the local pathologist; those for HPV-negative women are under preparation. These results will be cross-tabulated with HPV and other STIs and summarized by factors such as age and region.

Planned activities

Follow-up visits to women with positive VIA or HPV will begin in December and continue through February 2016. Data analysis will start after completion of this second visit.

- A manuscript on results for women previously screened with VIA from 2009–2014 in two hospitals (Mbabane Government Hospital, Hhohho Region, and Raleigh Fitkin MemorialHospital, Manzini District) is under preparation and will be submitted for publication in 2016.

3.6.2.4 Cervical cancer screening and treatment algorithms (CESTA) study

The aim of the study is to provide clear evidence on the benefits, side-effects and cost–effectiveness of three screen-and-treat algorithms that are recommended in the second edition of WHO's *Comprehensive cervical cancer control: a guide to essential practice*, notably (i) VIA and treat; (ii) HPV test and treat; and (iii) HPV test, triage by VIA and treat (ablative treatment) *(2)*.

This project addresses the research gap underlined in 2013 by the international expert panel and will provide the evidence needed to implement cervical cancer prevention in LMICs. An international advisory group meeting was held in 2014 at IARC in Lyon to provide guidance for the study design.

This study is a close collaboration between the Department and the IARC's Prevention and Implementation Group in Lyon.

Progress

Several meetings were held between the Department and the Prevention and Implementation Group to develop the study design. The study will be carried

out in two centres from one country in each of Africa, Asia and Latin America in order to compare the performance of the different algorithms in different regions. Potential collaborators were contacted in El Salvador, India and Zambia.

Planned activities

- In 2016, the Department plans to finalize the study protocol and submit it to the WHO Ethics Review Committee (WHO-ERC).
- The Department will continue to maintain contacts with potential sponsors for grant submission, select participating countries and centres, and prepare sites in the first country in order to start the study.

3.6.2.5 Cervical cancer screening and treatment in reproductive health care settings

The goal of this project is to integrate cervical cancer screening and treatment using VIA and cryotherapy into existing family planning and reproductive health services using public–private partnerships with Population Services International (PSI), Marie Stopes International (MSI) and IPPF. The countries that are participating in this project include: Kenya, Nigeria, Ugandaand the United Republic of Tanzania. Lessons learnt from this project will be published in a series of reports which will add to the body of evidence to inform current and future programmes on the role of reproductive health services in the prevention and control of cervical cancer. In addition, two research components are planned, one of which will focus on "Assessment of the effectiveness of patient referral models between cervical cancer screening and treatment" while the second focuses on "Assessment of service delivery models for integration of cervical cancer screening into existing sexual and reproductive health networks".

Progress

After the implementation phase, several meetings took place to review data and progress, and in particular to share lessons learnt and identify strategies to reduce loss to follow-up, including use of the single-visit approach in outreach, relocation of cryotherapy machines to optimal sites, and use of call centres and referral facilitators. Awareness-raising, not only for women but also for men – to increase partner approval of screening and treatment – was also an important part of the programme. Strategies to improve quality control focused on the quality of the acetic acid used and exploring a single supplier, ongoing training for health workers, increased supervision and mentorship, as well as continuing monitoring and evaluation of positivity rates, and patient follow-up.

Planned activities

- This project will continue to promote scale-up in terms of service integration and the number of women screened by adapting and employing strategies to (i) improve quality; (ii) improve rates of follow-up; and (iii) continue monitoring and evaluation.
- Several regional meetings will be scheduled to continue disseminating information and sharing lessons learnt.

3.6.3 Norms, standards and tools

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

The objectives of the project are to (i) contribute to effective strategic planning at country level for cervical cancer prevention and control; (ii) update national tools based on WHO guidelines; and (iii) foster capacity-building in countries to implement and assess interventions. The countries participating in this project include Ghana, Guinea, Kenya, Madagascar, Malawi, Nigeria, Senegal, Sierra Leone, Zambia and Zimbabwe.

Progress

Baseline situational assessments for all countries – which included six components: (i) demographics, (ii) burden of disease, (iii) governance and management, (iv) laboratory services, (v) monitoring and (vi) financing – were completed by national programme coordinators for noncommunicable diseases, cancer control or reproductive health. Additional information was supplied through post hoc country consultations. The findings have been disseminated.

Advocacy and information, education and communication (IEC) tools have been developed and are currently under review. The strategic planning training manual is currently being revised based upon reviewer feedback. An experts meeting occurred in May 2015 to present the findings of the baseline assessment, to further review the tools and to determine the next steps for information dissemination, including future training workshops.

Planned activities

- A manual for training master trainers in advocacy and IEC skills for cervical cancer will be finalized in 2016.
- Finalization of VIA/cryotherapy training tools and training of master trainers will also take place, as will strategic planning workshops.
- There will be coordination between this project and the IDCCP (see section 3.6.4 below) for pilot-testing of the costing tools before the tool is published in the third quarter of 2016.
- In 2016, there will be monitoring and evaluation of the project, which is in its final year. The outcome will be a series of reports outlining lessons learnt and recommendations for strategic cervical cancer programming.
- The Department is also trying to integrate at least one of the project's participating countries as a priority country for the UN Joint Programme for Cervical Cancer Prevention and Control (see section 3.6.5.1).

3.6.4 Monitoring and evaluation

3.6.4.1 Improving data for decision-making for cervical cancer programmes (IDCCP)

In 2014, the IDCCP initiative began with the objective of improving information in selected country contexts – including information on readiness, opportunities and challenges – for implementation of surveillance, monitoring and evaluation of programmes to screen and treat cervical cancer. To reach this goal, the programme is developing globally standardized tools and guidance on adapting and implementing

high-quality surveillance and information systems to provide data for national programmes that track and prevent cervical cancer.

Progress

- Data systems assessments were conducted in Botswana, Ethiopia, Guatemala,Kenya and Zambia. The data systems assessment for the United Republic of Tanzania will be conducted in 2016.
- A global consultation on the toolkit was held in Montreux, Switzerland, in June 2015, for coordination and feedback on the draft toolkit.
- Pilot-testing for the population-based surveillance component of the toolkit has been completed in Georgia and Zambia, and questions have been revised based on the feedback from the pilot-testing and from the global consultation.
- Pilot-testing of the costing tool occurred in Zambia, providing data as well as feedback on the tool.
- The final drafts of the facility-based surveillance tools for surveillance of services, patients and programmes have been completed and will go through final editing by all partners before production.
- The global web-based knowledge-management and data platform has been completed, ready for production.

Planned activities

- Review of tools and expert consultation on the data systems assessment, population-based surveillance, facility-based surveillance, costing, patient and programme monitoring, outcomes evaluation and knowledge management will be completed in 2016.
- Translation, editing and production of the tool will also be completed.
- A stakeholder meeting will be planned and coordinated at which the finalized tool will be presented and promoted for country-level strategic planning.

3.6.5 Dissemination and partnerships

3.6.5.1 The UN Joint Programme for Cervical Cancer Prevention and Control

WHO, UNFPA, The World Bank, UN Women, UNAIDS, UNICEF, IAEA, IARC and UNODC have come together with the objectives of reducing morbidity and mortality from cervical cancer, strengthening health-care delivery systems, and detecting, treating and palliating cervical cancer. The primary expected result of the project is a coordinated approach for planning and implementing cervical cancer prevention and control programmes.

Progress

The parties involved in the Joint Programme have agreed by consensus on a Convening Body, Administrative Agent and Steering Committee, for which Agency members have been chosen to represent their organization.

The parties involved have agreed the goals and objectives of the programme: (i) to secure funding for joint programme projects; (ii) to finalize and begin coordination with six first-instance countries; and (iii) strategic planning between the steering committee and convening body for projects in first-instance countries.

Planned activities

- As of 22 January 2016, a formal Cooperation Agreement will be approved by consensus of all engaged Parties of the Joint Programme.
- The first meeting of the Steering Group will be held during the sixth UN Task Force meeting in New York, USA, 6–8 February 2016.
- Strategic planning for first-instance countries will commence in 2016.

3.6.6 References

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2. Comprehensive cervical cancer control: a guide to essential practice, second edition. Geneva: World Health Organization; 2014 (http://apps.who.int/iris/bitstream/10665/144785/1/9789241548953_eng.pdf, accessed 1 February 2015).

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 the achievement of the highest standard of sexual and reproductive health of populations, the Department places special emphasis on responding to the needs of women and girls who have been subject to gender-based violence, particularly intimate partner violence and sexual violence, and harmful practices such as female genital mutilation (FGM) and child, early and forced marriage. Research activities include strengthening the evidence base on the magnitude of these problems; testing interventions to reduce violence and harmful practices or mitigate their consequences; and 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 at risk of, or affected by, these issues. The Department is also involved in developing norms and tools for the health sector response to these issues, and in supporting countries to develop policy and implement these tools.

The following sections summarize key activities carried out and key products delivered during 2015, as well as plans for 2016 to achieve the above goals and related mission of the Department.

Major achievements

- The survey methodology of the WHO multi-country study on women's health and domestic violence against women was used to conduct Cambodia's national population-based prevalence survey on violence against women. The survey results were published in November 2015.
- The Department led the development of a draft global plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children. The plan will be submitted to the WHO Executive Board in January 2016.

- A set of job aids developed by WHO in collaboration with the United Nations Office on Drugs and Crime (UNODC) and supported by UN Action, entitled *Strengthening the medico-legal response to sexual violence*, was published in November 2015.It is also available in French and will be field tested in Kenya and possibly also in the Democratic Republic of the Congo.
- The Department contributed to the establishment of the Working Group on Violence against Women of the International Federation of Gynecology and Obstetrics (FIGO).
- The Guideline Development Group (GDG) meeting for the WHO guidelines on the management of health complications from FGM was held in September 2015, during which current, evidence-based recommendations were formulated to improve health care of women and girls living with FGM. The draft guideline is currently being written.

3.7.2 Research and development

3.7.2.1 Violence against women

Progress

(i) Violence against women in antenatal care (ANC) study in South Africa

The Department is supporting a study in three public ANC clinics in Johannesburg, South Africa, to test an empowerment counselling intervention for women exposed to intimate partner violence during pregnancy. Evidence shows that women exposed to violence can benefit from a properly implemented response by health workers. This study aims to add to evidence for the efficacy and feasibility of a health sector-based approach to responding to intimate partner violence. Funded by the Flemish Government, the study is being carried out in collaboration with Wits Reproductive Health and HIV Institute (WRHI) in Johannesburg. The primary objective is to reduce intimate partner violence and mitigate its consequences, as well as 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 access to community resources.

Recruitment into the randomized controlled trial was completed at the end of 2015 in three clinics. Over 400 women were recruited and will be followed up until their six weeks postpartum visit when follow-up data are collected.

A process evaluation is also under way to provide evidence of whether, how and why the intervention is affecting participants in the study and to understand the challenges and benefits of implementation as reported by the nurse researchers. Findings from the process evaluation will provide important contextual information for interpreting the findings and scaling up the intervention if the study results show efficacy.

(ii) Prevalence study in Cambodia

The Department has been supporting the WHO Country Office in collaboration with the Ministry of Women's Affairs and the National Institute of Statistics in Cambodia to carry out a national prevalence study on violence against women using the methodology of the WHO multicountry study on women's health and domestic violence against women.

Data collection was carried out in April and May 2015 following comprehensive training of interviewers.

In November 2015 the final results were officially released in Phnom Penh during a high-level launch in which the Department participated *(1)*.

(iii) Research capacity-building activities (secondary data analysis workshop)

Following the recently completed national prevalence study on violence against women (see section ii), a workshop was convened by the Department in collaboration with the country office and the National Institute of Public Health to promote use of the prevalence data set and build research capacity. The workshop was an opportunity to build the capacity of students and researchers to carry out secondary data analysis and to generate evidence on violence against women relevant to the Cambodian context. It will contribute to a wider initiative to build capacity on conducting research, data analysis and data use on violence against women.

The Department also supported several research proposals and a research workshop on violence against women as part of the institutional and research-strengthening activities of the HRP Alliance.

(iv) Field testing of Self-Help Plus in Uganda

In response to the need for brief mental health interventions for women suffering from violence and its consequences, which can be provided at low cost and by non-specialists, the RHR Department, with the WHO Department of Mental Health, has been involved in a process to develop a brief psychological intervention named Self-Help Plus. The intervention is based on five two-hour sessions that can be led by a trained lay person complemented by audio guides for self-use.

Research to assess the feasibility and acceptability of such an intervention is being implemented with partners in Uganda, among Sudanese refugees, including women affected by sexual violence. Resources are being sought for a randomized clinical trial to be undertaken in 2016.

Planned activities

- **WHO multicountry study on women's health and domestic violence against women questionnaire update:** An updated version of the questionnaire of this multicountry study was finalized in 2015 and will be made available on the Department's webpage, with an accompanying question-by-question manual. This version builds on extensive experience of implementing the questionnaire in over 20 countries, technical improvements (e.g. on measurement of mental health outcomes), and efforts to improve consistency across surveys (such as Demographic and Health Surveys and studies of male perpetration). The Department will disseminate an updated version of the questionnaire and accompanying tools, and will provide support to countries wishing to implement violence against women surveys.
- **Study to assess efficacy of a counselling intervention to address violence during pregnancy in South Africa:** The Department will finalize the intervention research on addressing violence against pregnant women in South Africa and present the results.
- **Operations research: integrating gender-based violence with HIV and sexual and reproductive healthservices:** The Department supports a number of countries to implement a health-sector response to violence against women based on the WHO clinical and policy guidelines, *Responding to intimate partner violence and sexual violence against women (2). As addenda to Health care for women subjected to intimate partner violence or sexual violence: a clinical handbook(3)*, the Department

has produced two job aids on: (i) how to provide family planning counselling in the context of violence, and (ii) how to support safe disclosure of HIV status in the context of violence. Operations research on implementation by the health-sector response using the WHO clinical and policy guidelines*(2)* and its derivative products will provide insight on their impact on providers and patients.

- **Developing a research agenda with a focus on health-sector contributions:** The Department will develop a research agenda on addressing violence against women, with a focus on priorities for research related to the role of the health sector in response and prevention.

3.7.2.2 Female genital mutilation (FGM)

Progress

As part of the guideline development process, a series of systematic literature reviews were conducted:

- 10 quantitative systematic reviews on health interventions for preventing and treating health complications from FGM;
- four qualitative systematic reviews on the contexts and conditions surrounding health interventions for girls and women living with FGM;
- one review on the interventions and impact of gender equality and human rights approaches to FGM.

Jointly, all systematic reviews served as evidence for the guideline recommendation-making process.

A systematic literature review on interventions for health-care providers caring for women with FGM was conducted through searching the published and grey literature. The review found two studies that met the inclusion criteria. While some evidence was found to indicate improved knowledge and care for women with FGM, the lack of evidence shows the need for rigorous research and evaluation of interventions aimed at providers treating women and girls with FGM.

Planned activities

- The Department will publish all systematic reviews conducted for the guideline development process as an integrated journal supplement.
- A protocol will be developed for an intervention study aimed at providers and patients to improve service provision and health outcomes of women and girls with FGM.
- A counselling package will be produced for women with FGM to be delivered in health settings aimed at improving maternal, sexual, and reproductive health outcomes.
- The epidemiological evidence base of FGM will be increased through secondary data analysis of WHO database and Demographic and Health Survey (DHS) data sets.

3.7.2.3 Child, early and forced marriage

Progress

Publication of research priorities on child marriage: While there has been growing recognition of the scale and impact of child marriage and increasing investment to address it the past few years, knowledge gaps remain, particularly around effective approaches to addressing child marriage at scale. To address these gaps in knowledge

and to identify research priorities on ending child marriage and supporting married girls, the Department organized an expert group meeting in December 2013 in collaboration with Girls Not Brides and UNICEF. Meeting participants included leading researchers and academics, international and national nongovernmental organizations, development agencies, private foundations and UN agencies.

Participants discussed existing evidence, research gaps and potential priorities in relation to five key areas: (i) prevalence and trends of child marriage, (ii) causes of child marriage, (iii) consequences of child marriage, (iv) efforts to prevent child marriage, and (v) efforts to support married girls.

The issue of understanding child marriage in the broader context was also discussed. The research priorities were described in full in a 2015 *Reproductive Health* article *(4)*.

3.7.3 Norms, standards and tools

3.7.3.1 Violence against women

Progress

(i) WHO clinical and policy guidelines and implementation tools

A clinical handbook, *Health care for women subjected to intimate partner violence or sexual violence*, published in 2014 *(3)*, was widely disseminated and adapted for use to strengthen capacity of health-care providers including in Afghanistan, Cambodia, Uganda and Viet Nam.

- In Cambodia, technical support was provided to an initiative to strengthen the capacity of health-care professionals on intimatepartner violence and sexual violence based on the clinical handbook along with a pre- and post-test assessment. The training of health-care providers was conducted by WHO and in-country partners (GIZ and Care).
- Over 45 health-care providers participated in three-day workshops and a subsequent follow-up workshop, including midwives, nurses and medical doctors from health-care facilities in Phnom Penh and Kampong Thom.
- In Afghanistan, the handbook was translated into local languages and will be part of the job-aids and training materials supplied to health-care providers and health-care facilities. The Department has been supporting the country office and the Ministry of Public Health to develop the first national health sector protocol to respond to gender-based violence in Afghanistan, and on a study to assess the readiness of health-care facilities and providers to strengthen the response to gender-based violence.

Support has also been provided to ministries of health, in-country partners and WHO regional and country offices on their efforts to implement the WHO guidelines and clinical handbook in multiple contexts, including for updating national protocols/guidelines, developing training materials or preparing action plans, e.g. in Afghanistan, Cambodia, India, Moldova and Papua New Guinea.

- In Uganda the Ministry of Health has conducted a readiness assessment to identify strengths and gaps in national efforts to address gender-based violence (GBV). In 2015 the national guidelines for health sector response on GBV and Uganda's National GBV training manual were updated in line with the WHO guidelines/clinical handbook *(3)*.

The clinical handbook has been translated into French, Spanish and German.

(ii) Addressing violence against women: manual for health managers

As a complementary volume to the clinical handbook for health-care providers *(3)*, the Department has developed a health systems manual for health managers to design, plan, manage and implement health services to respond to intimate partner violence and sexual violence. This manual will be finalized for field testing in early 2016. Like the handbook, the new manual is a practical how-to guide including job aids, tips and examples. It uses the WHO health systems building blocks within a framework that is widely recognized and used by health managers.

(iii) Violence against women curricula for health-care providers

Building on the WHO clinical and policy guidelines *(2)* and clinical handbook *(3)*, WHO is developing curricula for in-service and pre-service training, aiming to strengthen the knowledge, skills and attitudes of health-care professionals and to ensure they can respond effectively to women suffering abuse and its consequences.

Two expert meetings were organized in 2015 to gather inputs for development of the curricula. Meetings were held in Washington, DC, on 23 March and in Geneva on 1–2 June, bringing together a total of 35 specialists in training for health-care professionals/students and in health-care for women subjected to violence, working in over 15 countries in universities and civil society organizations. An important outcome was a minimum outline for the curricula, including essential topics to be covered, core competencies to develop, and key considerations about structure, format and delivery methods. The meetings also identified key implementation challenges and potential allies and networks that could support the development, pilot-test and rolling out of the curricula.

The Department has initiated a process to select one or more contractors to develop the curricula based on the outcomes of the expert meetings. The team is communicating with the two top-ranked bidders to explore options for collaborative work in order to build on their complementary strengths in terms of curriculum development and achieve efficiency gains.

(iv) Strengthening the medico-legal response to sexual violence

It is increasingly acknowledged that ending impunity for perpetrators of sexual violence, including in conflict settings, and achieving justice and assistance for victims of sexual violence are important parts of the response to sexual violence. While there have been significant advances, there remains a lack of clarity about what medico-legal evidence should be collected to support national and international criminal justice processes.

Medico-legal evidence is at the intersection of medical and justice processes. Appropriate implementation requires coordination between the range of actors and sectors involved in prevention of, and response to, sexual violence; these include health services, social services, forensic medicine, forensic lab services, police/investigation and the legal system, including lawyers and judges.

Released in November 2015, this practitioner-focused toolkit *(5)* addresses key knowledge gaps within and between sectors to help support service provision and coordination of the medico-legal response to sexual violence in low-resource settings, and in humanitarian and post-conflict settings. It was developed in collaboration with the United Nations Office on Drugs and Crime (UNODC), supported by United Nations Action against Sexual Violence in Conflict (UN Action).

(v) Inter-Agency Standing Committee (IASC) guidelines for gender-based violence interventions in humanitarian settings

The Department contributed to the updating of the 2005 guidelines for addressing gender-based violence in emergencies. In particular, the health section of the new (2015) *Guidelines for integrating gender-based violence interventions in humanitarian action: reducing risk, promoting resilience and aiding recovery (6)*was aligned with WHO guidelines and tools.

Planned activities

(i) Adaptation and implementation of clinical handbook and development of toolkit to strengthen health systems response to violence against women

- The Department will continue to support countries interested in adapting and implementing the clinical handbook and the addenda on family planning and HIV testing and counselling, in collaboration with the WHO regional offices. This includes providing technical support for a national initiative to strengthen the capacity of health-care providers on violence against women in Uganda. WHO will also support supervision, coaching and on-job mentoring based on the clinical handbook in selected districts. Partners such as the International Planned Parenthood Federation (IPPF) have also expressed interest in using the clinical handbook and accompanying tools to strengthen the capacity of health-care providers to respond to violence against women.
- To support the implementation of the clinical handbook and other tools, the Department will prepare a toolkit to strengthen the health systems response to intimate partner violence and sexual violence. All of these tools will support the health component of the UN Joint Programme on Essential Services Package for Women Affected by Violence.

(ii) Clinical guidelines for children and adolescents who have been sexually abused

- Building on the experience of the clinical guidelines for addressing intimate partner violence and sexual violence and the need articulated by countries to provide guidance on clinical management of children and adolescents who have been sexually abused, the Department is undertaking the development of these guidelines in collaboration with the Department for Management of Noncommunicable Diseases, Disability, Violence and Injury Prevention. The guidelines will follow the standard WHO guidelines development process. A scoping document has been developed and discussed with the Guidelines Review Secretariat, and the first meeting of the GDG will take place in February 2016.

(iii) Violence against women curricula for health-care providers

- The two contracting institutions will start developing the curricula early in 2016. This will include development of the content along with a range of accompanying materials including videos and Powerpoints. The draft content will be pilot-tested with partner organizations in LMICs and final versions of two curricula (pre-service and in-service) and their accompanying guidelines for implementation are planned for late 2016.

(iv) Strengthening the response to sexual violence in conflict

- The set of job-aids on strengthening the medico-legal response to sexual violence in conflict will be field tested, in partnership with Physicians for Human Rights and UN Action, in Kenya.
- Together with the WHO Mental Health Department, the Department will implement capacity-building for health workers from Syria in providing an effective response to gender-based violence, with a focus on mental health and sexual and reproductive health.

3.7.3.2 Female genital mutilation

Progress

Guidelines are being developed for the management of health complications related to FGM.The second GDG meeting was held in September 2015 and formulated evidence-based recommendations to improve health care of women and girls living with FGM. The draft guideline, containing recommendations on the prevention and management of health complications related to FGM, is currently being written.

Planned activities

- The draft guidelines on the management of health complications related to FGM will be submitted to the Guidelines Review Committee in early 2016. The Department aims to obtain approval for publication by May 2016.

3.7.4 Monitoring and evaluation

3.7.4.1 Violence against women

Progress

The WHO database on prevalence of violence against women was updated in 2015. A revised methodology is being developed for updating the global and regional 2013 estimates and for developing country estimates. The country estimates will be relevant for reporting on the SDG indicators for measuring intimate partner violence and non-partner sexual violence.

Planned activities

- Establishment of an interagency group for country estimates: To align the violence against women estimates with other global estimates of the Department, an interagency advisory group is being convened to provide technical inputs into an enhanced methodology for developing models for country-level estimates. UN partner agencies and co-sponsors will be invited to participate in the interagency advisory group.
- Capacity-building on violence against women research and data analysis and use: The Department is well placed to play a leading role in generating evidence relevant for the SDG violence against women indicators by supporting countries through technical assistance for prevalence studies using the WHO questionnaire instrument and building research capacity to analyse data. The Department is also discussing with partners the development of a one-week course on research on violence against women, and will explore this with HRP Collaborating Centres that may be interested in hosting such a course.

3.7.4.2 Female genital mutilation

Progress

The Department has submitted proposals to ICD-11 to include FGM types 1–4.

A key barrier to eradicating FGM and developing strategies for minimizing negative health outcomes is the lack of quality evidence/data available. The International Classification of Diseases and Related Conditions (ICD) is currently being revised towards ICD-11. This is a major opportunity to introduce FGM and the four sub-types into the classification, which will contribute to the collection of data that will help to inform policy decisions and resource allocation, reduce long-term suffering and disability, and improve training to FGM caregivers.

A manuscript entitled "FGM, measurement and ICD-11" is currently being written and will be submitted for publication in a peer-reviewed journal. The paper will highlight the clinical importance of adding FGM to the international version of the classification during the ICD revision process.

FGM can cause immediate and long-term consequences that vary depending on type, setting and the woman's experience. The prevalence of complications of the various FGM types has commonly been discussed as a gap in research. Creating an FGM-specific set of codes, in combination with the inclusion of FGM and the four subtypes, will aid better understanding of the true extent of harm caused by FGM and enable greater specificity of the clinical information collected.

Planned activities

- In line with SDG No. 5 (to "achieve gender equality and empower all women and girls") and to support global monitoring of FGM, the Department has recently proposed including the following indicator as part of the SDGs: percentage of girls and women aged 15–49 years who have undergone FGM. The proposed indicator is currently under revision and was recently classified by the Inter-Agency and Expert Group on SDG Indicators (IAEG) as a "green" indicator that has received general agreement or for which only small modifications are proposed.

3.7.5 Dissemination and partnerships

3.7.5.1 Violence against women

Progress

(i) Global plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children

Following a request to the Director-General, under the leadership of the Department, WHO has undertaken an extensive consultative process to draft the global plan of action on violence for submission to the Executive Board in January 2016. The consultative process included regional consultations covering all six WHO regions, two web-based consultations, a global expert consultation and a formal meeting with Member States. The draft plan of action has been revised based on these various inputs and will be submitted to the Executive Board in January 2016 *(7)*.

(ii) Essential services for women subjected to violence: a UN joint initiative

The Essential services for women subjected to violence initiative started as a UNFPA and UN Women initiative in its first phase. This initiative aimed to develop global norms and standards for services for women, including health, police, legal, social services, as well as coordination across sectors. In partnership with UNFPA and UN Women, WHO is offering its clinical and policy guidelines and clinical handbook *(2, 3)* as the health sector normative standard for this initiative so that there is no duplication of standards. In the second phase, this is now a joint UN initiative, with WHO leading on the health component together with UNFPA. The WHO–UNFPA partnership will implement the norms, guidelines and standards for the health response to violence against women.

(iii) Sexual Violence Research Initiative (SVRI) Forum 2015 [16]

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 LMICs. The bi-annual SVRI Forum was held in September 2015. This forum is the main conference for exchange of research results and scientific information on sexual violence, intimate partner violence, child sexual abuse and sexual violence in conflict. The Department played a leading role in conference planning and contributed to several sessions and panels, including as scientific chair of the conference. The Department also hosted a conference workshop on ethical and safety issues in research on violence, a panel discussion on tools for a health sector response, and a panel discussion on the November 2014 Lancet series, and participated in the launch of the Inter-Agency Standing Committee (IASC) *Guidelines for integrating gender-based violence interventions in humanitarian action*, to which WHO contributed in the health chapter *(6)*.

Planned activities

- Global plan of action to strengthen the role of the health system in addressing violence, in particular against women and girls: Based on a proposed set of indicators included in the draft global plan of action on violence, the Department will conduct a baseline assessment and report on the violence against women element for the global plan of action. This will include an assessment of countries' national protocols, guidelines or standard operating procedures on violence against women and their alignment with WHO guidelines.
- Clinical handbook and toolkit: A number of countries are requesting support from the Department in field testing the clinical handbook *(3)*, including Namibia and Uganda. In addition, through collaboration with IPPF the handbook will be field tested in Pakistan, Uruguay and Zambia. Ongoing efforts to support Afghanistan, Cambodia, India and Viet Nam in implementing tools and guidelines related to the health sector response to violence against women will continue in 2016. The manual for health managers and the toolkit for supporting these efforts will also be disseminated in 2016.
- FIGO Working Group on Violence against Women: The Department will provide support to this effort, including drafting a short statement on FIGO's commitments to addressing violence against women for sharing with member associations.

16 For the detailed programme see: http://www.svri.org/forum2015/

3.7.5.2 Female genital mutilation

The GDG met in September 2015 to review and grade evidence for the clinical guidelines on FGM. The results of the systematic reviews for the clinical guidelines were presented at the FIGO World Congress in Vancouver in 2015.

Planned activities

- The Department plans to launch the guideline on the management of health complications related to FGM in May 2016 during the Women Deliver conference in Copenhagen, Denmark.
- The guideline will be published in English and, in order to increase uptake and dissemination in FGM high-prevalence countries, will also be translated into French and Arabic.
- The Department plans to produce and distribute a briefing document that will officially present the upcoming guideline. This document will be made available for all WHO Country Offices, emphasizing offices in regions where FGM is practised.

3.7.6 References

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7 Global plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children. Geneva: World Health Organization; 2016 (final draft under discussion).

3.8 Sexual and reproductive health in humanitarian settings

3.8.1 Introduction

In 2015, the Department has continued to address issues of sexual and reproductive health (SRH) in humanitarian settings. The disastrous impact of Ebola virus disease (EVD) on maternal, newborn and reproductive health, however, has undoubtedly become the focus since late 2014. Starting in September 2014, the Department's Humanitarian Settings team shifted to focus primarily on the growing outbreak of EVD. Through a combination of fieldwork assignments in outbreak regions by a medical officer, [17] the Adolescents and at-Risk Populations team (AGH) actively participated in the ongoing research and development of emergency and normative guidance. This led to the Department becoming the WHO SRH focal point for the outbreak, collaborating with partners around the world affected by and working on the response, to ensure that the most up-to-date and appropriate evidence-based information and guidance was disseminated and readily available.

As the outbreak caseload is now more controlled and efforts to maintain a resilient zero are place, the countries of high transmission, Guinea, Liberia and Sierra Leone have now been declared free from human-to-human transmission for EVD. However, the health, care and ongoing needs of EVD survivors is becoming a higher priority. There are approximately 17 000 survivors across the three worst-affected countries, with ongoing medical and psychosocial complaints including joint and muscle pain, eyesight problems and in some cases reproductive health-related complications such as amenorrhoea and erectile dysfunction *(1)*. Although the incidence of EVD has significantly decreased, transmission is ongoing and the risk of reintroduction due to virus persistence has emerged as a substantive near-term threat to achieving and maintaining zero EVD in the region. The July 2015 outbreak in Liberia, which was likely due to virus persistence in a male survivor who had recovered months earlier, reaffirmed the possibility of transmission restarting. While the risk of reintroduction due to virus persistence in some survivors is declining over time, it is significant due to the sheer number of people affected in this outbreak.

The Humanitarian Settings team has also continued to work on other pressing humanitarian needs throughout 2015. This included continued participation in global advocacy efforts for reproductive health in humanitarian crises, and in the UN Secretary-General's renewed Every Woman Every Child (EWEC) global movement, now called Every Woman Every Child Every Adolescent Everywhere, with the word "everywhere" speaking specifically to humanitarian and fragile settings and the unique vulnerabilities they cause for women, adolescents and newborns. The team is also developing a new humanitarian framework for action for identified gaps in, and opportunities to strengthen, the evidence base for SRH interventions across all humanitarian and fragile settings, especially essential services that target immediate needs.

3.8.2 Research and development

3.8.2.1 Ebola virus disease outbreak

Note: Other research on Ebola virus persistence is covered in section 3.5.2.7: Persistence of Ebola virus in body fluids of survivors.

17 This medical officer and WHO focal point for SRH in crises was jointly supported by the MacArthur Foundation and the Pandemic and Epidemic Diseases Department, closely coordinated by the Ebola Response team. The medical officer has led the work on Ebola and pregnancy since October 2014.

Progress

The following publications were developed from a need to collate current evidence on the persistence of Ebola virus (EBOV) within a context of reintroduction of EVD through survivors' body fluids (semen, vaginal secretions and breast-milk). These documents and the interim guidance have been and will be used to form more long-term guidance on safe practices and handling of fluids and tissues in the context of an EVD outbreak *(2, 3)*.

Planned activities

- The research study "The impact of Ebola virus epidemic on maternal and neonatal health in areas of EBOV transmission" will help to better understand the impact of the Ebola epidemic on maternal and neonatal health outcomes and services moving into the recovery phase. This has been and continues to be coordinated through the Department'sRMNCAH Ebola Task Force.
- The Department will undertake analysis of routine data from before, during and in the aftermath of the EVD outbreak, in collaboration with other research institutes.

3.8.2.2 Humanitarian crises and fragile settings

Progress

Little is known about the effects of conflict and displacement on the provision of SRH services. To better understand this association the Department undertook an analysis of the 2013 Health Resources Availability Mapping System survey in conflict-affected Mali *(4)*.

A special supplement for *The BMJ* was published in 2015, including two papers related to women's, children's and adolescents' health in humanitarian and other crises *(5, 6)*.

The "Systematic review on maternal morbidity in humanitarian settings" is part of the effort to estimate the global burden of maternal morbidity, feeding into the development of measurement tools for monitoring effective interventions, and effective and context-adapted interventions to reduce maternal morbidity in humanitarian settings. Humanitarian crises represent unique contexts for implementation, measurement and monitoring of health-care interventions. This systematic review is under way; it is being jointly carried out together with the team that is working on maternal morbidity.

Planned activities

- The Humanitarian Settings team is developing a framework for action for the next biennium. Led by the AGH team, the framework will extend across the Department through crosscutting activities addressing reproductive, maternal and perinatal health, abortion, family planning, sexual health, and gender-based violence for populations affected by humanitarian crises and fragile settings. There will be a special focus on the vulnerabilities of women and adolescents. The framework will also involve expertise from the Emergency Risk Management Department and the Global Health Cluster Lead. So far we have conducted a scoping review of SRH interventions in humanitarian and fragile settings between 2005 and 2015 that has informed the development of the framework by identifying gaps and research opportunities. Priority areas for the Department are currently under development.
- A costing analysis for essential SRH interventions in humanitarian and fragile settings is planned for early 2016. This will involve external expertise to assist with the technical aspects of financial analysis, projections and costing.

- Building onto the operational framework of the new UN Global Strategy for Women's, Children's and Adolescents' Health, the Humanitarian Settings team in collaboration with the AGH Digital Health and Innovations team, is organizing a meeting on monitoring innovations for SRH in humanitarian crises and fragile settings. This will bring together UN agencies (e.g. UNICEF, the UN Office for the Coordination of Humanitarian Affairs [OCHA] and the UN High Commissioner for Refugees [UNHCR]) and governmental bodies (e.g. the United States Centers for Disease Control and Prevention), as well as nongovernmental organizations (NGOs) and project implementers, designers and architects to disseminate knowledge on available and current innovations for humanitarian settings.

3.8.3 Norms, standards and tools

3.8.3.1 Ebola virus disease outbreak and pregnancy guidance

Progress

- The following publications have been developed by Department staff under the leadership of the Ebola Response team from the Pandemic and Epidemic Department.
- The *Ebola virus disease in pregnancy* document *(7)* provides guidance for: screening and triage of pregnant women in the context of an EVD outbreak; infection prevention and control precautions for pregnant women at risk of EVD transmission during childbirth and complication management; management of pregnant EVD cases, contacts and survivors; and lactation and EVD.
- Reproductive and maternal-health-related sections of the derivative adaptations for the Sierra Leone and Liberia viral haemorrhagic fever guideline *(8)*have been developed with additional support form the departmental technical leads.
- A guide to providing safe delivery and newborn care in an Ebola outbreak*(9)*, developed in collaboration with UNICEF and Save the Children, was released at the end of 2014. It provides support for routine and essential maternal and newborn care in the context of an EVD outbreak, complete with emergency kits for maternal and newborn health in this specific context.

Planned activities

- The Department will support the update to the 2014 publication *Clinical management of patients with viral haemorrhagic fever: a pocket guide for the front-line health worker(8)*.
- The Department will support a 2015–2016 update to the 2014 publication *A guide to the provision of safe delivery and immediate newborn care in the context of an Ebola outbreak(9)*.

3.8.3.2 Humanitarian crisis and fragile settings

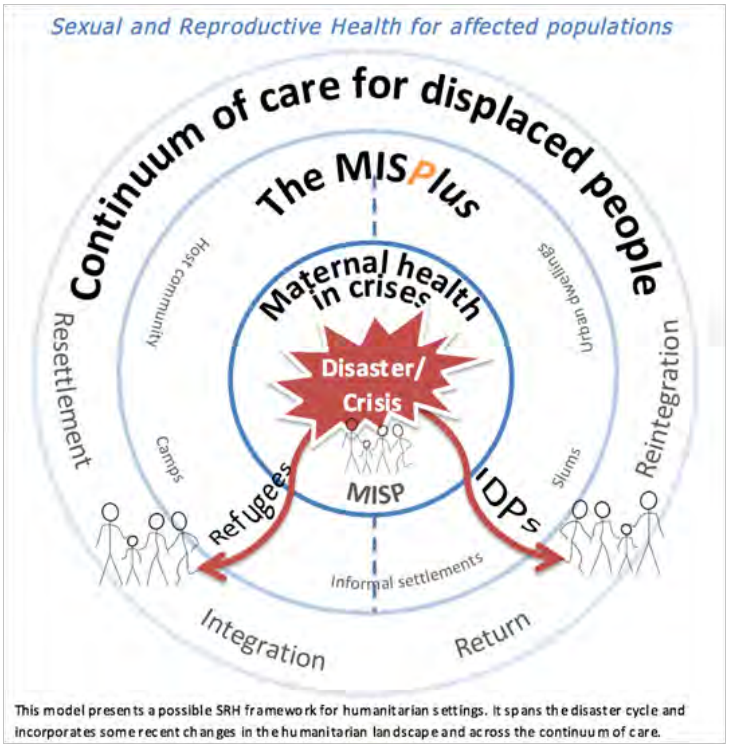
Planned activities

- The Department plans to develop a best-practice implementation guide for essential RMNCAH services for emergency and humanitarian settings. The guide will be grounded in evidence-based recommendations from WHO normative guidance to support early prioritization and access to essential and lifesaving services. It will likely build on the infrastructure of the Minimum Initial Service Package for Reproductive Health in Crises (MISP), but not be limited by the five objectives. Furthermore, it will support early, sustainable and targeted scale-up of comprehensive SRH services

into the health system. This approach will be called the MISPlus and will support, for example, safe abortion services and a choice of contraceptive methods, and will encourage the uptake and availability of WHO-recommended commodities, innovations and guidance in every setting (see the model in Figure 3.8.3.2 below).

- The Department is also planning to provide technical support to the Inter-Agency Working Group for Reproductive Health in Crises (IAWG) to update and strengthen the MISP by trying to align it more closely with current WHO-recommended essential interventions, commodities and service-delivery methods.

Figure 3.8.3.2: A model framework for sexual and reproductive health in humanitarian settings



IDP: internally displaced people; MISP: Minimum Initial Service Package for Reproductive Health in Crises

3.8.4 Dissemination and partnerships

3.8.4.1 Ebola virus disease outbreak

Progress

- Medical officer deployments to Liberia and Sierra Leone to provide expertise and support to the country offices related to clinical management of pregnant women with EVD, and restoration of essential reproductive and maternal health services. This work supported ministries of health in Liberia and Sierra Leone, partners on the ground and the Ebola Response team.
- Participation in WHO Advisory Group on the EVD response, providing technical inputs on pregnancy and EVD.

- Partnerships within WHO between the AGH team, the Ebola Response team, and country offices in Sierra Leone and Liberia, have been strengthened through the ongoing Ebola-related work.
- The Humanitarian Settings team was invited to speak on a panel discussion at the International Federation of Gynecology and Obstetrics (FIGO) World Congress in 2015 in Vancouver. The medical officer spoke about WHO's integrated reproductive and maternal health approach within the Ebola operational response through field deployment and collaborative development of evidence-based, experientially-informed standard operating procedures, guidance and training on the clinical management of EVD in pregnant women, and management of pregnant contacts. This operational approach focuses on the shift from a "risk aversion" to a "risk management" approach.

Planned activities

- The Department plans active participation and involvement with the Interagency Collaboration on Ebola, a collaboration between OCHA, WHO and other humanitarian partners which replaces the role of the UN Mission for Ebola Emergency Response (UNMEER) in the Ebola-affected regions.
- Similarly participation and technical support will be provided to the UN Global Ebola Response Coalition, led by the UN Special Envoy on Ebola, David Nabarro.

3.8.4.1 Ebola virus disease outbreak

Progress

- The Department actively participated in the Third UN World Conference on Disaster Risk Reduction (DRR) in Sendai, Japan, held 14–18 March 2015, and lobbied for the inclusion of SRH in the Sendai Framework for DRR 2015–2030. This effort resulted in the inclusion of SRH in *Priority 3.30.J*, which prioritizes SRH in efforts to build resilience for DRR at the national and local level:

To strengthen the design and implementation of inclusive policies and social safety-net mechanisms, including through community involvement, integrated with livelihood enhancement programmes, and access to basic health-care services, including maternal, newborn and child health, sexual and reproductive health, food security and nutrition, housing and education, towards the eradication of poverty, to find durable solutions in the post-disaster phase and to empower and assist people disproportionately affected by disasters (10).

- At the University of Geneva's Centre for Education and Research in Humanitarian Action, Department staff designed and developed course materials and taught on the master's course in Humanitarian Emergencies, as well as in thematic seminars.
- Violence against women was integrated into SRH in humanitarian settings through several training courses, such as in June 2015 at the "WHO and Health Cluster emergency surge training for humanitarian practitioners".
- The Department participated in the IAWG through active membership of the IAWG Steering Committee, as well as through involvement in the Surge Capacity and MISP sub-working groups. This work is in support of, and closely aligned to, the humanitarian and fragile settings work-stream of the new UN Global Strategy for Women's, Children's and Adolescents' Health 2016–2030.

Planned activities

- The Department will engage with UN, international organizations, international NGOs (INGOs), NGOs, governmental bodies and other international forums in the build-up to the first World Humanitarian Summit in Istanbul, in May 2016. This includes discussions with IAWG on collective messaging and streamlining advocacy efforts for maximum impact to prioritize SRH in humanitarian crises and fragile settings. These efforts are being streamlined with the UN Global Strategy and the Green Light Indicators for the SDGs.
- The Department serves on a task force advising UNFPA and the Norwegian Refugee Council's Surge Crisis Support Initiative. In March 2016 there will be a training course for new SRH Field Coordinators, staff from both NGOs (international, national and local) and UN agencies. Similar to the training in September 2014 in Uganda, the Humanitarian Settings team will support the development of training materials and resources.
- The Department will plan a contribution to, and participation in, the IAWG Annual Meeting 7–9 March 2016 on "New partnerships and approaches to the changing humanitarian landscape"in Dakar, Senegal. This will bring together humanitarian and development agencies currently working on reproductive health in humanitarian settings, as well as new implementers and advocacy groups.
- The Department will collaborate with the WHO Syrian Country Office to initiate reproductive health and gender-based violence (GBV) programming in connection to ongoing coordinated mental health and psychosocial programmes in Syria, including in non-government-controlled areas. This will continue work started in December 2013 in Beirut, Lebanon, when 35 obstetricians/gynaecologists were given refresher training on new WHO GBV guidelines, as well as updates to emergency obstetric care technical areas, including postpartum haemorrhage, pre-eclampsia and eclampsia.

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3.9 Infertility

3.9.1 Introduction

WHO estimates that one in every four couples in developing countries is unable to become pregnant when they desire to have children, and, through a 20-year trend analysis, WHO has shown that these percentages have not significantly changed, with little progress made towards decreasing this burden of disease *(1)*.

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, it is defined as male sterility; and, if there is a low or very low viable sperm count, then the risk of pregnancy in the female partner is not zero, and the male may be defined as either infertile or "subfertile". The term "subfertility" is often used as an equivalent for both females and males, as a more patient-friendly term for infertility. For example, in some countries in Europe, Asia and sub-Saharan Africa the term subfertility is preferred. WHO recognizes both terms; however, where the two are 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. 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 reproduction requires an ovum and a sperm, but also the successful outcomes of reproductive medicine interventions are healthy partners

or intended parents, and healthy children. The Department 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 the objective of ensuring healthy outcomes for partners, mothers and newborn babies.

Major achievements

- A workshop on the fertility intentions of HIV-affected individuals and couples was held with support from the Brocher Foundation.
- The Department initiated development of guidance on diagnosis, management and treatment of infertility/subfertility and interventions that provide fertility care.

3.9.2 Norms, standards and tools

3.9.2.1 Guidance on diagnosis, management and treatment of infertility/subfertility and interventions that provide fertility care

The systematic reviews, Grading of Recommendations Assessment, Development and Evaluation (GRADE) tables and preliminary work by evidence teams were completed for six prioritized areas and a supportive set of terminologies that address in/subfertility and fertility care interventions in August 2015. A consensus technical consultation and Steering Committee meeting were held in late September 2015, with a limited gathering of global stakeholders and experts from all WHO regions, who have been identified from many groups and organizations, including UNFPA, International Planned Parenthood Foundation (IPPF), Population Council, Geneva Foundation for Medical Education and Research, fertility specialists, obstetrician/gynaecologists, andrologists, demographers, economists, social scientists, psychologists, patient advocates and patients. The consultation also included WHO regional advisors on teleconference.

Progress

A workshop on the fertility intentions of HIV-affected individuals and couples was held at and with support from the Brocher Foundation, Geneva, Switzerland, to begin the process of scoping the field, and developing an evidence-based algorithm for care and population, intervention, comparator and outcome (PICO) questions for systematic assessment.

Recommendation tables – with strength of evidence, evidence tables, research gap analysis and supporting materials, including updated terminology – were all in process of being finalized for submission to the WHO Guidelines Review Committee (GRC).

Provisional outcomes include the following:

- Female fertility status diagnosis and management: 30 recommendations (recs), 10 best practice points (BPPs).
- Female polycystic ovary syndrome diagnosis and management (80% infertile): 28 recs, 24 BPPs.

- Female ovarian stimulation fertility interventions: 27 recs, 5 BPPs.
- Male fertility status diagnosis and management: 26 recs, 1 BPP.
- Male and female fertility interventions, intrauterine insemination of sperm with or without ovarian stimulation: 19 recs, 7 BPPs.
- Male and female fertility interventions, in vitro fertilization and intra-cytoplasmic (ova) sperm injection: 19 recs, 2 BPPs.

A review of evidence concerning the scoped field of environmental factors and effects on health, including reproductive health parameters, was discussed during the "Summit on environmental factors and reproductive health" at the International Federation of Gynecology and Obstetrics (FIGO) World Congress in Vancouver, 2 October 2015 *(2)*.

Planned activities

- Further literature and systematic reviews are planned to address fertility interventions for HIV-affected individuals and couples.
- Executive clearance of guidelines through the GRC will be finalized.
- Guidelines and associated derivative products will be published and disseminated, including but not limited to policy briefs and other methods to provide high-level advocacy around the emerging field of infertility.

3.9.3 Norms, standards and tools

3.9.3.1 Research to address diagnosis, cause and consequence of infertility

The goal is to initiate small pilot research projects to generate proof of concept and provide potential for collaboration and funding in expanded areas of public health research in infertility and access to fertility care. Through these research projects, we can begin to map the causes and consequences of infertility, and address unmet need to fertility interventions, worldwide.

Progress

The FertiSTAT research project in the Sudan, carried out in collaboration with the Sudan Country Office, pilot-tested a fertility-awareness tool; the write-up of a PhD thesis is in progress *(3)*.

A project for policies, systems and services to integrate fertility care is being developed and is based on an older tool developed for the integration of HIV into reproductive health care that had been successfully implemented in partnership with IPPF, UNFPA, WHO, UNAIDS, Global Network of People Living with HIV, International Community of People Living with HIV/AIDS, and Young Positives. Developing this new guide for countries is critical to assist countries in their integration of fertility care into reproductive health care and provides an efficient mechanism for the dissemination of guidelines and tools in infertility diagnosis, management and treatment*(4)*.

Preliminary research and a pilot survey to gather data on national policies and regulations governing infertility in association with the International Federation of Fertility Societies (IFFS) was carried out in January–August 2015, prior to the initiation of the surveillance, which began in September 2015.

During 2015, a revision and update of a research synthesis and analysis of the literature demonstrating an association between intimate partner violence and infertility was

completed. Previously performed in 2014, an update was required in 2015. This systematic review was published in 2015 *(5)*.

A cross-disciplinary research synthesis and development of a new paradigm for care for HIV-affected individuals and couples addressing elimination of mother-to-child transmission, reproduction and infertility needs was completed and published in 2015 *(6)*.

Research analysis of existing evidence on the reproductive health impacts of exposure to toxic environmental chemicals led to the publication of a paper with policy recommendations for future research and greater advocacy on and awareness of this issue. The work was carried out in collaboration with global experts and FIGO as part of the symposia and workshop at the FIGO World Congress, October 2015 *(2)*.

Research for a vaginal insemination cohort paper, completed in 2014, was written up and published in 2015 *(7)*.

In January 2015 a WHO–Brocher Foundation workshop was held to review research/evidence on overcoming barriers and addressing rights to access to fertility care interventions for HIV-affected women and their partners. An informal literature review was carried out for development of PICO questions, with research synthesis to address barriers and enablers to accessing fertility care for reproduction. A paper from this work was accepted for a WHO *JAIS* supplement in 2015 *(8)*.

A systematic assessment of the evidence on partner and child transmission from washed semen in HIV-affected males was submitted to *Fertility and Sterility* and published in 2015 *(9)*.

Planned activities

- Development of pilot (research) multicountry study to test evidence-based algorithms for assessment of causes of a male and female infertility.
- Development of service delivery protocols/practice guides/tools for clinical standards.
- Programme of work that will assist in support of advocacy and awareness of infertility.

3.9.4 Disseminations and partnerships

3.9.4.1 Partnerships in infertility

Progress

Successful collaborative activities, as defined in detailed plans of work with nongovernmental organizations (NGOs) in official relations in the field of infertility/subfertility care, have been carried out, as well as joint conferences and side-meetings in association with workshops, meetings and conferences. Collaborations include active participation with: IFFS (giving presentations and moderating sessions at regional and national workshops, surveillance on policy); the American Society for Reproductive Medicine (ASRM) (online courses, Embryo Transfer simulator, Access to Care symposium and summit); the International Committee Monitoring Assisted Reproductive Technologies (terminologies and global surveillance reports); and the FIGOCommittee for Reproductive Medicine (Fertility Tool Box™; joint symposia, FIGO World Congress, October 2015).

WHO made presentations on various aspects of global access to care at several dedicated symposia including at: the FIGO World Congress in Vancouver, Canada;

the European Society of Human Reproduction and Embryology (ESHRE) Conference in Lisbon, Portugal; the ASRM annual conference in Baltimore, USA; and the opening plenary of the Global Conference on Reproductive Health and In Vitro Fertilization in Berlin, Germany.

International annual and regional conferences invited WHO to provide plenary presentations on topics in infertility, spanning topics including global public health prioritization; prevalence; access to diagnosis, management and treatment for fertility care; ethics and issues associated with lifestyle, environment, reproductive fitness and quality of life; and psychosocial issues. These conferences included: IFFS–WHO regional conference in Chile; Third meeting of REDTranscender Fertility Society, São Paulo, Brazil; IPPF Executive Europe Conference in Dublin, Ireland; IPPF Europe Collaborating Agencies Conference in Brussels, Belgium; Region of the Americas ASRM Conference in Washington, DC, USA; ASRM Conference in Baltimore, USA; African Fertility Society Conference in Lagos, Nigeria (WHO was invited, but unable to attend).

Planned activities

- The Department will disseminate infertility guidelines, associated products and surveillance reports.
- Collaborative activities with ESHRE will continue, including support for ESHRE's application to be submitted in 2016 for consideration to gain the status of an NGO in official relations with WHO, which, if successful, would then be discussed at the WHO Executive Board meeting in January 2017, and would support the development of a new plan of work in infertility.
- Regional- and country-level activities will continue through robust, collaborative plans of work with the official NGOs in the field (including the dissemination of normative guidance, workshops, trainings and surveillance).
- There are plans to work with two NGOs in the field (official NGO ASRM, and ESHRE, in the process of applying to be an official NGO), and discussions are ongoing to develop a programme to jointly identify infertility experts and residents for volunteers/interns to assist the Human Reproduction team in the area of infertility, specifically supported through participating NGOs.

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3.10 Sexual Health

3.10.1 Introduction

While "sexual health" is often subsumed within reproductive health, it is in fact a wider term, as sex does not always involve reproduction. In most discussions about sexual and reproductive health (SRH), there tends to be a focus on issues such as family planning and access to safe abortion. While these are undoubtedly important topics, other sexual health and sexuality issues tend to be inadequately researched. The work of the Department on sexual health is an integral part of several key thematicareas such as adolescent SRH, 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 the development of ICD-11. A range of sexual-health-related activities are therefore included in the relevant sections of this Annual Technical Report.

Major achievements

- A report on sexual health, human rights and the law was published in June 2015. Drawing from a review of public health evidence and extensive research into human rights law at international, regional and national levels, the report shows how states in different parts of the world can and do support sexual health through

legal and other mechanisms that are consistent with human rights standards and their own human rights obligations.

- A new chapter in the 11th revision of one of WHO's hallmark publications, The International Classification of Diseases (ICD-11) is dedicated to "Conditions related to sexual health". To accompany this, a publication on the importance and rationale of the new ICD-11 "Sexual health" chapter was published in *Reproductive Health Matters* in November 2015.
- An interagency statement on ending violence and discrimination against lesbian, gay, bisexual, transgender and intersex (LGBTI) people was released with the support of 12 UN agencies on 29 September 2015.
- The Department committed to carrying out a sexual health research prioritization exercise, using the Child Health and Nutrition Research Initiative (CHNRI) approach.
- The guideline *Brief sexuality-related communication: recommendations for a public health approach* was published and widely disseminated in 2015.

3.10.2 Research and development

3.10.2.1 Sexual health research prioritization

Progress

A research prioritization exercise is being carried out for sexual health. The Department is undertaking a Child Health and Nutrition Research Initiative (CHNRI) approach – originally developed to help decision-makers, including donors, to effectively allocate limited resources to reduce morbidity and mortality priorities – to rank the relative importance of research options in sexual health. The modified CHNRI approach (described below) will be used as the basis for the sexual health research prioritization.

Currently, the sexual health research prioritization project plan has been developed, and the scoping process has begun.

Planned activities

- Based on CHNRI research prioritization methods, the sexual health research prioritization includes the following stages:
  - Phase 1: Gathering technical experts, defining context
  - Phase 2: Listing research options in a systematic way
  - Phase 3: Scoring of all listed research options by five criteria relevant to priority setting
  - Phase 4: Applying CHNRI scoring system to full list of research questions
  - Phase 5: Addressing stakeholders' values.

This exercise is scheduled to commence in early 2016.

3.10.2.2 ICD-11 Sexual dysfunctions case–control internet-based study

The Department is currently heavily involved with the revision of the 10th edition of the International Classification of Diseases (ICD-10) to develop the ICD-11, which presents a key opportunity (this process is explained fully in section 3.2). As part of this process, the Department has been involved in the ICD-11-related research, in collaboration with the WHO Department of Mental Health and Substance Abuse, described below.

Progress

The Department developed a sexual dysfunction protocol to validate proposed changes to the ICD-11 classification using ICD-11 field testing. These field trials will be jointly carried out between the RHR Department and the Department of Mental Health and Substance Abuse. The RHR Department received an exemption waiver from WHO Ethics Review Committee and the HRP Research Project Review Panel.

The new diagnostic criteria will be tested in a series of Internet-based field studies using standardized case vignettes to test whether the ICD-11 diagnostic criteria produce more consistent diagnostic behaviour than do the ICD-10 diagnostic criteria. These vignettes will be implemented across a global, multilingual and multidisciplinary sample of approximately 12 000 professionals from more than 130 countries. [18]

Planned activities

- The field tests are scheduled to begin in 2016. Study activities will include: finalizing the programming in Qualtrics software, pilot-testing the case-vignettes, pilot-testing the tool, data collection and data analysis.

3.10.2 Research and development

3.10.3.1 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 RHR Department worked with the ICD Secretariat at WHO and the Department of Mental Health and Substance Abuse in facilitating updates on sexual-health-related conditions within the ICD.

Progress

The RHR Department led the process of developing a new proposed chapter on "Conditions relating to 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 Topic Advisory Group (TAG) convened by the Department reviewed this proposal prior to its submission to the official ICD-11 commenting website. [19]

A manuscript was written describing the rationale and outline of the new ICD-11 sexual health chapter *(1)*. Publication is planned for the beginning of 2016.

A manuscript on the "sexual dysfunctions" block of the ICD-11 sexual health chapter was drafted and is currently undergoing final edits before submission to *Journal of Sexual Medicine or Archives of Sexual Behavior*. The manuscript outlines the detailed changes to the sexual dysfunction categories and their diagnostic criteria between ICD-10 and ICD-11.

A systematic review of national laws, regulations and policies and their implications on proposals for changes to the classification of "gender incongruence" and "paraphilic disorders" in ICD-11 were conducted in five countries (Brazil, India, Lebanon, Mexico and South Africa), recognizing that medical diagnostic classifications are embedded in a complex legal, regulatory and policy environment.

18 Further information available at: www.globalclinicalpractice.net

19 Available at: http://apps.who.int/classifications/icd11/browse/l-m/en

Planned activities

- In 2016, 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.
- The legal and policy analysis of "gender incongruence" and "paraphilic disorders" classification in ICD-11 have been conducted and the results are being compiled into various publications. Articles are expected to be published in 2016.

3.10.3.2 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.

Progress

The report on sexual health, human rights and the law was published in June 2015 *(2)*. This report demonstrates the relationship between sexual health, human rights and the law. Drawing from a review of public health evidence and extensive research into human rights law at international, regional and national levels, the report shows how states in different parts of the world can and do support sexual health through legal and other mechanisms that are consistent with human rights standards and their own human rights obligations.

A new commentary, entitled "Sexual health, human rights, and law", was published in *The Lancet* in August 2015 *(3)*. This commentary highlights and helps to bring attention to the report that was published in June 2015.

A follow-up meeting took place in Geneva on 4–5 December 2015. The meeting aimed to: discuss the findings of the WHO report on sexual health, human rights and the law identify next steps for its implementation with respect to research, funding and advocacy discuss findings of WHO scoping review on sexual health research priorities develop a joint work plan for the implementation and dissemination of the report.

Planned activities

- The Department will prepare policy briefs on specific aspects of sexual health and human rights issues, such as decriminalization, comprehensive sexuality education, and others that are based on the report.
- Briefings will be held on the report with United Nations Treaty Monitoring Bodies.
- The Department will provide input on the development of the regional Sexual and Reproductive Health and Rights Strategy for the WHO European Region.

3.10.4 Monitoring and evaluation

3.10.4.1 LGBTI political statement

Progress

An interagency statement on ending violence and discrimination against LGBTI people was released with the support of 12 UN agencies on 29 September 2015 *(4)*.

3.10.5 References

1. Chou D, Cottler S, Khosla R, Reed GM, Say L. Sexual health in the International Classification of Diseases (ICD): implications for measurement and beyond. Reprod Health Matters. 2015;3(46):185–92.

2. Sexual health, human rights and the law. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/175556/1/9789241564984_eng.pdf, accessed 18 January 2016).

3. Khosla R, Say L, Temmerman M. Sexual health, human rights, and law. Lancet. 2015;386(9995):725–6. doi:http://dx.doi.org/10.1016/S0140-6736(15)61449-0.

4. Interagency statement on ending violence and discrimination against LGBTI people. Geneva: International Labour Organization, Office of the United Nations High Commissioner for Human Rights, United Nations Development Programme, United Nations Educational, Scientific and Cultural Organization, United Nations Population Fund, United Nations High Commissioner for Refugees, United Nations Children's Fund, United Nations Office on Drugs and Crime, UN Women, World Food Programme, World Health Organization, Joint United Nations Programme on HIV/AIDS; 2015 (http://www.who.int/reproductivehealth/publications/gender_rights/lgbti-un-statement/en/, accessed 18 January 2016).

4. Cross-cutting topics

4.1 Human rights and gender equality

4.1.1 Introduction

During 2015 there was a flurry of activities in the area of human rights and gender equality. The Departmentcontinues to be a key actor on human rights, gender equality, and SRH among development partners, including international and regional nongovernmental organizations and academic institutions. The Department 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 rights.

As an interagency body with expertise in SRH, gender equality and human rights, the Department is an authoritative source when it comes to contributing to the development, clarification and interpretation of international human rights standards.

Major achievements

Major strides have been made during 2015 in relation to the work of gender equality and human rights. These include:

- The Department led the process for development of the *Women and health* report for the World Health Assembly, focusing on the unfinished agenda and emerging priorities related to women's health.
- The Department published a landmark report on *Sexual health, human rights and the law* (see section 3.10 on sexual health for further details).
- The Department continued to support treaty monitoring bodies (TMBs) in their work on SRH. This included ongoing support to the Committee on Economic, Social and Cultural Rights (CESCR) in the development of their draft General Comment on the right to SRH, and to the UN Human Rights Committee in the development of their General Comment on the right to life.
- A special series was published in *The BMJ* on women's, children's and adolescents' health, with a specific focus on SRHR and human rights.
- The Department led advocacy efforts for inclusion of SRHR in the post-2015 sustainable development agenda.

4.1.2 Research and development

As a premiere research institution, the Department makes a unique contribution to the development and advancement of a research agenda on SRH. It is this with this in mind that the Department has undertaken various activities focusing on identifying research capacity, priorities and needs in relation to SRH, human rights and gender equality.

4.1.2.1 Identify research priorities related to SRH, human rights and gender equality

Knowledge gaps remain on how to effectively promote gender equality and human rights within SRH programmes and policies, as well as how attempts to promote gender equality

and human rights can improve SRH outcomes. To address this gap, the Department is undertaking an exercise to identify thematic and cross-cutting research priorities for integrating gender equality and human rights in SRH policies and programmes.

Progress

To address this gap WHO conducted a systematic review of:-

- existing evidence and gaps on interventions to address/promote gender equality in the context of SRH programmes and policies
- existing evidence and gaps on interventions to address/promote human rights in the context of SRH programmes and policies.

The findings of this review were discussed in an expert meeting which identified research domains based on human rights and gender equality.

Planned activities

- The findings of the review will be published as a peer-reviewed publication in 2016.

4.1.2.2 Research capacity-strengthening

Progress

The Department provided training to Long-term Institutional Development grantees and Collaborating Centres in the WHO African and Eastern Mediterranean Regions on the integration of human rights and gender equality into research related to SRH.

Planned activities

- The Department will undertake a research prioritization exercise in 2016–2017, including the development of a mixed methodology for research priority setting. A global survey will be undertaken subsequently in this regard, leading to the publication of the research priorities in 2017.
- The Department will also undertake further research capacity-strengthening work in 2016–2017, including the development of a module on the topic.
- Furthermore in 2016 the Department will work on developing generic guidance for implementation of SRH programmes based on a human-rights-based approach. The focus of this activity will be development of action-oriented generic guidance on the operationalization and implementation of SRH programmes based on a human-rights-based approach. This was identified as a key area of recommendation by the independent Expert Review Group (iERG) at the stakeholders meeting in January 2014.

4.1.3 Norms, standards and tools

The Department continues to contribute to the development and interpretation of human rights and gender equality standards in relation to SRH.

4.1.3.1 Ensuring attention to sexual and reproductive health and human rights and their integration in key global and multilateral processes

The year 2015 marked a key opportunity for the promotion and protection of the SRH and human rights agenda by ensuring the integration of these issues across key international development processes, particularly the renewed Every Woman Every Child (EWEC) global strategy, the post-2015 sustainable development agenda and Beijing+20.

Progress

The Department led the process of developing technical content for the renewed global strategy on women, children and adolescent health grounded in international human rights standards. In this regard the Department led the publication of a special supplement to The *BMJ* entitled "Towards a new Global Strategy for Women's, Children's and Adolescents' Health" *(1)*.

The Department also led the process of developing the World Health Assembly paper, *Women and health (2)*, which reaffirmed the Beijing Declaration.

In addition, the Department also led an exercise for integrating SRHR within the SDGs *(3)*.

Furthermore, the Department provided technical inputs into key normative developments on SRH and human rights, which include:

1. UN TMBs
    - Dissemination of the Department's work
    - Contribution to the development of CESCR's draft General Comment on the right to SRH
2. Human Rights Council
    - Child, early and forced marriage (CEFM), and female genital mutilation (FGM)
    - Implementation of technical guidance on maternal mortality and human rights
    - Ongoing technical support
3. Other mechanisms
    - Ongoing technical support
    - Parliamentarians.

Planned activities

- During 2016–2017 the Department will undertake the development of a framework and tool for quality of care in the context of human-rights-based approaches to contraception. Furthermore the Department will be working with the UN TMBs and others to develop normative standards for these approaches.
- The Department will continue leading the exercise to develop human-rights-based indicators for those SDGs related to SRH.

4.1.4 Monitoring and evaluation

4.1.4.1 Development of human-rights-based indicators for contraception

Progress

The Department is leading an exercise to develop human-rights-based qualitative and policy indicators for contraception. A methodology has been developed, along with the mapping of existing indicators, and a priority list of indicators has been identified using the international human rights norms and standards.

Planned activities

The Department will be pilot-testing the monitoring and evaluation tool in three countries in 2016 and will convene an expert meeting for validation in mid-2016, to be followed by the dissemination of the tool in 2017.

4.1.5 Dissemination and partnerships

4.1.5.1 Sexual health, human rights and law

The Department published its landmark report on Sexual health, human rights and the law in 2015 *(4)*.

Progress

An expert meeting including representatives from UN agencies, public health experts and human rights specialists was organized by the Department to discuss research priorities in the area of sexual health and the implementation of the findings of the WHO report *(5)*.

Planned activities

Dissemination workshops are planned with UN TMBs in 2016, along with specific activities with WHO regional offices in the European Region and the Region of the Americas. In addition, partnerships are to be developed with UN agencies and civil society organizations for further dissemination of the report.

4.1.6 References

1. Temmerman M, Khosla R, Bhutta ZA, Bustreo F. Towards a new Global Strategy for Women's, Children's and Adolescents' Health. BMJ. 2015;351:h4414. doi:10.1136/bmj.h4414.
2. Women and health: 20 years of the Beijing Declaration and Platform for Action. Geneva: World Health Organization; 2015 (A68/16; http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_16-en.pdf, accessed 22 January 2016).
3. Temmerman M, Khosla R, Say L. Sexual and reproductive health and rights: a global development, health and human rights priority. Lancet. 2014;384(9941):e30–1. doi:10.1016/S0140-6736(14)61190-9.
4. Sexual health, human rights and the law. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/175556/1/9789241564984_eng.pdf, accessed 22 January 2016).
5. Khosla R, Say L, Temmerman M. Sexual health, human rights, and law. Lancet. 2015;386(9995):725–6. doi:10.1016/S0140-6736(15)61449-0.

4.2 Innovations

4.2.1 Introduction

The use of digital innovations in SRH can reduce barriers to accessing reproductive health services; improve the quality and/or reduce the cost of services; increase accessibility to critical services and timely information; and improve the efficiency and effectiveness of health-care providers. These innovations play a critical role in helping to realize universal coverage of RMNCAH services, and provide the tools needed to monitor progress towards international targets such as the MDGs and SDGs. The digital innovations portfolio of the Departmentstrengthens health systems in support of reproductive health goals by aiming to:

- foster the development and validation of innovations that improve SRH in populations with the greatest need

- develop and support mechanisms that improve the awareness, availability and use of innovations that improve SRH
- support research that aims to understand and overcome barriers that prevent innovations from achieving widespread adoption
- support evidence synthesis to ensure that appropriate guidance is available to decision-makers who are in a position to compare the value of, invest in, and adopt digital innovations.

Note: This section focuses on the Department's work related to the use of digital innovations, while specific health intervention innovations are reported in sections of the report covering other health domain areas.

Major achievements

- The Department conducted formative research across three THRIVE [20] research sites to inform functional and data requirements for multiple RMNCH frontline workforce cadres. This effort also led to the creation of a common RMNCH community-health information system data dictionary.
- *The MAPS toolkit:mHealth assessment and planning for scale* was launched. This resource is intended to assist implementers to systematically assess their scale-up efforts, and to plan for corrective actions and next steps.
- The Department released the *WHO practical guide to engaging with mobile network operators for reproductive, maternal, newborn, child and adolescent health*, a tool to address the common challenges faced among mHealth implementers in securing partnerships with telecommunications companies.
- Development began of a WHO technical guidance document related to assessment and prioritization of digital innovations to strengthen health systems, including health information systems. These efforts were initiated in relation to the restoration of health services in Sierra Leone.

4.2.2 Research and development

4.2.2.1 OpenSRP and the THRIVE multi-site research study

The Department's Open Smart Register Platform (OpenSRP) [21] is a comprehensive, tablet-based mobile health platform that allows frontline health workers to register and track the health of their entire client population along the continuum of care for RMNCAH. The long-term goal of OpenSRP is to leverage mobile digital capabilities to assist with population enumeration, denominator capture, service provision, and health and vital events notification and reporting – in a platform that is integrated into the national data backbone infrastructure. WHO is leading a consortium of researchers, technologists, government stakeholders and implementers to guide the development of the OpenSRP digital health platform across multiple countries.

The year 2015 marked the official start of the THRIVE phase 1 study, established to conduct research to assess frontline health workforce needs, and to inform the adaptation of OpenSRP with regard to local contexts and begin deriving a generic reference package

20 The Technologies for Health Registers, Information, and Vital Events (THRIVE) Consortium is a group composed of leading academic, research, donor, and IT institutions that is focused on adaptation, large-scale deployments, and impact assessment of the OpenSRP platform and associated technology innovations in multiple countries.

21 Available at: http://smartregister.org/

that can be widely used. Throughout the year, research site teams conducted a series of mapping exercises in three sites, capturing the data streams and workflows of targeted health worker cadres, as well as prototyping the technology requirements of OpenSRP.

Progress

To date, OpenSRP has been successfully adapted and deployed for at least one health worker cadre per site across Bangladesh, Indonesia and Pakistan. Despite this progress in adapting the platform, much work remains in disentangling and optimizing the inefficiencies of legacy paper-based health management information systems (HMIS). The transition from legacy paper-based systems and the culture change required for the uptake of digital registers have been identified as key areas of focus going forward with the adaptation and mainstreaming of OpenSRP. Additionally, continued formative research is needed to expand on data analytics/dashboards for measurement and accountability within supervisory structures.

Applying the formative research methods developed under the first THRIVE research phase, the Department has prepared a suite of tools to guide new adopters on adapting OpenSRP to their local context. This adaptation and implementation protocol will be used to complete the release of a generic reference WHO version of OpenSRP that can then be a starting point for new adopters, including new ministries, outside of the context of the THRIVE research study.

The Department hosted two THRIVE research study scientific and technical meetings in order to assess research findings, harmonize research methods and technology adaptation plans for OpenSRP, and plan for strategic integrations with national health information systems. The first meeting, held in February in Bangladesh, was co-hosted by the Ministry of Health, which opened the meeting with a commitment to apply OpenSRP in the country's efforts to digitize the health workforce. The second scientific coordination meeting was held in conjunction with the Fourth Asian eHealth Information Network (AeHIN) General Meeting in Bali, Indonesia, and allowed research teams to share findings to date and map out plans for disseminating outputs from the formative phase as well as developing strategies to refine their OpenSRP tools for more cadres, in preparation for research pilot deployments.

Lastly, OpenSRP was selected as a finalist for two "Transitions to scale"grants (deployments in Bangladesh and South Africa) by Grand Challenges Saving Lives at Birth. Although OpenSRP was not awarded the grants, the opportunity to showcase the Department's innovation in a global forum has helped to generate additional investments (e.g. UBS Optimus, QualComm, the United States Agency for International Development [USAID], the United States President's Emergency Plan for AIDS Relief [PEPFAR]) and interest in the adoption of this digital platform in other settings (e.g. the Philippines, South Africa).

Planned activities

- Over the next year, the THRIVE Consortium plans to expand the adaptation of and formative research on OpenSRP to an additional site in Africa, in order to diversify the research findings, adaptation and deployment experiences of OpenSRP to new settings.
- The Department plans to have a generic "reference" version of OpenSRP ready by April 2016, with clear steps on deployment requirements. This generic reference version of the platform – which will be populated with WHO guidelines, minimum data elements and indicators – will serve as a baseline to be accessed and downloaded, with a clear description of the process for adaptation and deployment. This version

will build on adaptation experiences from the different research sites and allow new adopters to begin applying OpenSRP to new countries.

- Additionally, the THRIVE Consortium will build on the gains of the adaptation process to ensure uptake and government mainstreaming of OpenSRP in the current research sites. This includes extending the OpenSRP functionalities to include other health worker cadres and engaging in ways that reduce duplication of workflows, and strengthen the ability to enumerate populations and track health service delivery. Another key focus area is strengthening linkages with overall health information system architecture in the effort to assist with indicators for global reporting.
- The Department will be leading efforts to consolidate the research findings on the formative process from phase 1, in order to develop adaptation and protocols for new research sites and new potential adopters of the OpenSRP tool. In addition to sustaining these research efforts, the Department plans to launch and coordinate the phase 2 randomized controlled trial for OpenSRP, starting in 2017. The components of this adaptation protocol include guidance on data mapping and needs assessment, transitioning the needs assessment into functional requirements for developing the technology, design process to prototype and develop user feedback, training on deployment and competency checks, as well as common indicators for monitoring implementation.
- Lastly, the Department has proposed an adaptation of OpenSRP for deployment in Sierra Leone supporting the rebuilding of health systems following the Ebola virus disease (EVD) outbreak, subject to grant funding.

4.2.3 Norms, standards and tools

4.2.3.1 UN EWEC Innovation Working Group catalytic mHealth grant mechanism

The UN's EWEC Innovation Working Group (IWG) catalytic mHealth grant mechanism was established in 2011 to improve the potential of existing mHealth innovations to scale and contribute to maternal, newborn and child health. This mechanism is managed by the UN Foundation, with the Department providing technical assistance to awarded projects through mechanisms such as the development of normative tools to guide scale-up.

Progress

In 2015, the Department published two products to optimize implementation among the broader community of actors in the field: *The MAPS toolkit: mHealth assessment and planning for scale(1)* and *A practical guide for engaging with mobile network operators for reproductive, maternal, newborn, child and adolescent health(2)*.

The MAPS toolkit*(1)*facilitates projects systematically assessing and undertaking corrective actions in their scale-up of mHealth innovations. It was publicly launched in September at an event convened by the mHealth Working Group, one of the widest networks of mHealth implementers globally. Over 550 individuals have downloaded the Toolkit with over 30 projects completing and submitting an electronic version of the Toolkit to the Department in order to develop metrics of scale and conduct further refinements. The Toolkit was also translated into French to ensure broader reach.

A practical guide for engaging with mobile network operators for reproductive, maternal, newborn, child and adolescent health(2) is a tool to guide implementers on engagement

with mobile network operators. It tool aims to address the recurring challenges faced by mHealth implementers in partnering with telecommunication providers in the private sector, understanding that this remains a tenuous area. The tool was launched at a regional digital health conference hosted in Malawi by USAID and the UN Foundation.

Planned activities

- The Department is developing a web version of the MAPS toolkit to enable interactive use of this resource and curating experiences related to the scale-up of mHealth deployments. The project data results will also enable the Department's team to finalize analyses on the validation of the MAPS toolkit and develop concrete benchmarking measures on levels of scale for mHealth innovations.

4.2.3.2 Technical guidance document on the use of digital innovations for RMNCAH

The potential of digital health strategies to address shortfalls in health systems is driving demand and heightening expectations in low- and middle-income countries. Global health agencies are beginning to advocate for prudent use of mHealth solutions, guided by evidence demonstrating usability, functionality, reliability and impact under real-world conditions. Furthermore, the launch of a number of global health initiatives – including the SDGs, the Global Measurement Summit, the post-Ebola recovery phase for West Africa, as well as the Global Financing Facility for RMNCAH and Global Strategy 2.0 – highlight the critical need for practical and relevant guidance on which investments into mHealth strategies should be made as a complement to financing essential national level health infrastructure approaches. In response to this global need for government decision-makers, the Department has initiated the development of an interagency technical guidance document to inform government-led investments of mHealth strategies for strengthening RMNCAH essential services.4.2.4 Monitoring and evaluation

Progress

The Department convened a task force of authors for contributing to the development of this technical guidance document. This is an interagency and interdepartmental effort that will provide clear guidance on the use of information and communication technologies (ICTs) to strengthen RMNCAH, in preparation for wider use of digital data systems for national measurement and accountability towards universal health coverage.

Planned activities

- The Department will continue convening and coordinating the task force in refining the methodology and content of the technical guidance document.
- The Department will conduct evidence syntheses of identified thematic areas needed for developing the guidance document.
- Further detailing and development of the technical guidance document is planned for 2016. The Department will finalize and publish the document for Member States to utilize when reviewing and prioritizing investments in digital innovations for RMNCAH.

4.2.3.3 Prioritization of digital systems for RMNCAH health information systems post-Ebola

The EVD outbreak overwhelmed health systems in the three affected West African countries, with adverse effects on the provision of essential routine, safe, quality health services. In these countries, the shock to health systems has been profound, with the health workforce severely compromised and public confidence undermined.

Furthermore, the Ebola response exposed the reality of many government-led and independent health information systems, not necessarily linked with one another, each reflecting inconsistent data content, workflows and information flows. In 2015, the Department was awarded funding to establish a process of joint review of national mHealth digital ICT assets related to one or more health domains that are of high priority for health systems recovery, and subsequently use the validation of this methodology to further inform the digital health guidance tool.4.2.5 Dissemination and partnerships

Progress

The development of an mHealth bottleneck analysis tool was initiated. This tool will be used for systematically identifying health system gaps that can potentially be addressed through digital innovations. As a first step to informing the planning and prioritization of digital health strategies for RMNCAH, the Department also conducted stakeholder interviews with implementers and department heads within the MOH of Sierra Leona. These interviews laid the groundwork for understanding the digital health landscape in the Ebola recovery period and for recognizing both the barriers and opportunities for developing a digital heath strategy in Sierra Leone.

Planned activities

- In collaboration with Sierra Leone's MOH, the Department will conduct an inventory of all ICT/mHealth/eHealth implementation projects targeting RMNCAH services or HMIS data needs in Sierra Leone. This will enable the systematic mapping of all projects to include information on the essential health interventions addressed, digital strategies used (e.g. text messaging, data collection), and health system constraints targeted.
- A stakeholder workshop on planning and prioritization of digital strategies for RMNCH will be held, convening implementers, MOH programme teams, the HMIS unit, relevant UN bodies and others.
- Continuous engagement will be sought with the MOH for coordination and review of existing (and planned) digital health projects, including participation in the national digital health Technical Working Group.
- The Department will publish a technical document specific to Sierra Leone that includes a validated gap-assessment tool and processes for facilitating government-led prioritization of digital health strategies to address priority needsfor strengthening RMNCAH services and health information systems.

4.2.4 Monitoring and evaluation

4.2.4.1 Monitoring and evaluation technical assistance through IWG catalytic mHealth grant mechanism

Progress

During 2015, the Department has provided monitoring and evaluation (M&E) technical assistance to mHealth 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. WHO and partners also supported a sample of grantees in the following areas: impact assessment, costing and cost-effectiveness analysis, process documentation, and evaluation.

Planned activities

- The Department will publish a WHO M&E toolkit for mHealth implementers. This tool 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.

4.2.4.2mHealth Evidence Reporting and Assessment tool

The mHealth Evidence Reporting and Assessment (mERA) tool aims to standardize the quality of mHealth evidence reporting and present criteria for disseminating mHealth findings. mERA has been developed and tested iteratively by the members of the mHealth Technical and Evidence Review Group (mTERG) and their respective institutions over the last two years.4.2.5.1 UN Innovations Working Group

Progress

The mERA tool was accepted for publication by a peer-reviewed journal as a guidance tool to standardize the reporting of mHealth research findings in journal publications *(3)*.

4.2.5 Dissemination and partnerships

4.2.5.1 IWG catalytic grant mechanism technical assistance and knowledge-sharing workshops took place in Kenya

Progress

The Department co-hosted workshops with the UN Foundation (UNF) on topics related to technical assistance needs for IWG grantees. These included:

- a sustainable financing workshop in Nairobi, which included Global Fund, Open Capital Advisors, and Grand Challenges Canada speaking on the Global Financing Facility and other financing mechanisms that ministries can leverage
- a hands-on learning workshop for 100 participants at the mHealth Global Forum in Washington, DC.

Planned activities

- Although the UN IWG catalytic mHealth grant mechanism will be coming to a close at the end of 2015, the Department plans to sustain partnerships with UNF and jointly seek opportunities for providing technical assistance to further advance the field of digital health and the scale-up of evidence-based strategies.

4.2.5.2 THRIVE Consortium

Progress

The Department acted as the secretariat of THRIVE Consortium for OpenSRP and evaluation of digital innovations.

During 2015, the Department also presented at and co-facilitated meetings at AeHIN on the topic of digital community-health information systems for RMNCAH.

Planned activities

- The Department will continue its role as secretariat for the THRIVE multi-site study
- In its collaboration with AeHIN on deployments of OpenSRP, the Department will work on the development of a knowledge-sharing network related to this

area, evidence for decision-makers, and an interactive, web-based version of the MAPS toolkit for countries.

4.2.6 References

1. The MAPS toolkit: mHealth assessment and planning for scale. Geneva: World Health Organization; 2015 (http://www.who.int/reproductivehealth/publications/mhealth/maps/en/, accessed 3 February 2016).
2. A practical guide for engaging with mobile network operators for reproductive, maternal, newborn, child and adolescent health. Geneva: World Health Organization and United Nations Foundation; 2015 (http://www.who.int/reproductivehealth/publications/mhealth/mobile-operators-mhealth/en/, accessed 3 February 2016).
3. Agarwal S, LeFevreAE, Lee J, L'EngleKL, MehlG, Chaitali S, Labrique A and the WHO mHealth Technical Evidence Review Group (mTERG). Guidelines for reporting of health interventions using mobile tools: the mHealth Evidence Reporting and Assessment (mERA) checklist. BMJ. 2016 (in press).

4.3 Biostatistics and data management

4.3.1 Introduction

The Biostatistics and Data Management Unit provides statistical and data management support to research projects of the Department and supports the strengthening of research capacity in biostatistics and data management.

The services of the Unit contribute to the quality of theDepartment'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 were provided for 23 clinical trials and epidemiological studies during 2015.
- The Unit conducted on-site research training on data entry and data management for staff in six collaborating countries participating in projects with the Department: Argentina, Kyrgyzstan, Mozambique (twice), Singapore, South Africa and the United Kingdom.

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 2015, support was mainly provided to 23 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.

1. **Peri-coital oral contraception with levonorgestrel – a prospective, open-label, single-arm, multicentre study to evaluate efficacy, safety and acceptability:** The team assisted in the dissemination of preliminary study findings during the investigators' meeting in January 2015. Following completion of the final analysis, the manuscript "A prospective, open-label, single arm, multicentre study to evaluate efficacy, safety and acceptability of peri-coital oral contraception using levonorgestrel 1.5 mg" has been submitted for publication.

2. **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:** Following completion of final statistical analysis, the manuscript has been submitted for publication and is currently under review.

3. **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 200 000 antenatal care (ANC) visits have been registered in the study logbook and copies have been uploaded to Dropbox. Data of all ANC visits have been entering in the web-based data management system (OpenClinica). The trial intervention has been deployed in all 10 participating clinics. In addition to the ANC visits, different surveys were conducted in the collaborating clinics, such as the women's exit survey (about 2000 women), the women's satisfaction survey (about 600 women), the nurse survey (for all nurses participating in the trial from 10 clinics), and data audit (for three clinics). On-site monitoring and refresher training sessions by our Unit for the local data management teams were conducted twice in the country during 2015. The Steering Committee met in Maputo in December 2015. Data verification and further data cleaning are done regularly.

4. **Non-inferiority of short-term catheterization following fistula repair surgery:** The article "Breakdown of simple female genital fistula repair after 7 day versus 14 day postoperative bladder catheterisation: a randomized, controlled, open-label, non-inferiority trial" was published in The Lancet in 2015 *(1)*.

5. **Feasibility and safety study of a new device (Odón device) for assisted vaginal delivery (phase I trial):** Data collection for testing the safety and feasibility of the device was collected in Argentina and the first and second recruitment periods were completed. The datasets are completed and ready for data analyses. The device is currently under revision to improve its quality. The data collection forms are being revised according to the new device before data collection restarts. The Steering Committee met in May 2015 to discuss the next steps for this trial.

6. **A randomized, placebo-controlled study of two prophylactic medication approaches 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.

7. **Training midwives in Kyrgyzstan to provide safe abortion care with mifepristol and misoprostol:** Data collection started in September 2014 and was completed in September 2015, with 556 women recruited in two regions (32 sites). Data entry was completed in site in December 2015. Regular online sessions were held to assist the data manager in achieving data management tasks. Data cleaning was planned for December 2015 – January 2016, and final analysis was planned to start in January 2016.

8. **Addressing violence against women in antenatal care: testing an intervention in South Africa and Mozambique:** Data collection started in May 2014. About 13 400 data forms were uploaded to Dropbox for about 1500 women screened and 410 enrolled. Data entry was outsourced in Geneva and completed for 13 400 data forms. Regular online sessions were held with in-site data managers. Trial data were monitored regularly. Query management was carried out in Geneva. A meeting of the Data Safety and Monitoring Board (DSMB) was held in August 2015 and a decision to continue recruitment until the end of December 2015 was taken. Follow-up will continue until the last woman completes the study.

9. **Long-term calcium supplementation in women at high-risk of pre-eclampsia – a randomized placebo controlled trial (The Calcium and Pre-eclampsia [CAP] trial):** Data management was outsourced to Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina. During 2015, the Unit provided statistical assistance that included the preparation of a progress report for the DSMB meeting in February, as well as for the fourth Steering Committee meeting in March.

10. **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:** Data collection in sites is currently ongoing, and the Unit is assisting data manager in the International Agency for Research on Cancer (IARC) on best ways of improving data quality and cleaning data.

11. **Carbetocin RTS (room temperature stable) for preventing postpartum haemorrhage – a randomized non-inferiority controlled trial:** The trial will be conducted in 11 countries with the target sample of 30 000 cases. The official recruitment for the trial began in June 2015 in Birmingham, United Kingdom. Data collection has started in four countries (Egypt, Nigeria, Singapore and the United Kingdom). The data management for this trial was outsourced to Centro Rosarino de Estudios Perinatales (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.

12. **Multicentre randomized clinical trial of two implantable contraceptives for women, Jadelle® and Implanon®:** The final three-year follow-up statistical analysis was completed. The article "A 3-year multicentre randomized controlled trial of etonogestrel- and levonorgestrel-releasing contraceptive implants, with non-randomized matched copper-intrauterine device controls" was published in October in the journal Human Reproduction *(2)*. The analysis of the post-three-year data is complete, and manuscript writing is currently under way.

13. **"UPTAKE" – A context-specific health sector and community-based participatory approach in a human rights framework, to address unmet need for contraception:** The Unit is continuing to provide statistical expertise for the study.

14. **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 provided statistical expertise for the study in 2015.

15. **Adolescent Health Experience after Abortion or Delivery (AHEAD) – decreasing rapid repeat pregnancy:** The Unit provided statistical expertise for the study during 2014–2015.

16. **Sperm suppression and contraceptive protection provided by norethisterone enanthate (NET-EN) combined with testosterone undecanoate (TU) in healthy men:** Final statistical analyses were completed and the manuscript has been submitted to a peer-reviewed journal for publication.

17. **Gentle assisted pushing in the upright posture or upright posture alone compared with routine practice to reduce prolonged second stage of labour:** Study material has been completed, including data forms, data-management system, standard operating procedures (SOPs) and manual of operations. Data-management and training on SOPs were conducted in May 2015. Data collection started in early March 2015. About 750 women were screened and 310 enrolled in four study sites in East London, South Africa. About 1070 data forms have been received. Decentralized data entry is regularly done in two of the four sites and about 735 screening forms and 305 delivery forms have been already entered in OpenClinica. Regular query management is carried out in Geneva. Continuous monitoring of trial data and regular online sessions with data managers have been carried out to assist and ensure good study progress. On-site monitoring visits were conducted in May and August 2015. A DSMB meeting is planned for early 2016.

18. **Global, regional and national levels and trends in preterm birth for 1990 to 2013 – protocol for WHO estimates:** A complex data collection tool for data extraction has been designed. The data management system was developed in OpenClinica and testing was completed in November 2015. Online training of the reviewers was conducted in early December 2015. Testing of the system by reviewers is ongoing. Online extraction of the data was planned to start in mid-December 2015.

19. **Efficacité d'un ensemble d'intervention de services de planification familiale du post-partum sur l'adoption de contraceptifs jusqu'à 8–9 mois après l'accouchement – intervention complexe à méthodes mixtes:** The data collection tool was designed during November – December 2015, in preparation for a workshop on postpartum family planning, which was scheduled for mid-December 2015 in Geneva.

20. **How women are treated during facility-based childbirth – development and validation of measurement tools in four countries:** Discussions with the Department's project manager on requirements for the data management system and study materials started in November 2015.

21. **A two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women in preterm labour in facilities in sub-Saharan Africa and South Asia to improve newborn outcomes:** Discussions with the Department's project manager on requirements for the data management system to be adopted started in November 2015.

22. **Study of dual HIV and syphilis rapid diagnostic tests in antenatal clinics in Colombia:** The team contributed to protocol development, involving study design, sample size calculation and statistical methodologies, and including

development of statistical analysis plan (SAP). The finalization of the statistical analysis is currently ongoing, following completion of the data collection.

23. **Persistence of Ebola virus in body fluids of EVD survivors in Sierra Leone:** This study consists of two phases: the pilot phase and the main study phase. For the pilot phase, which started in 2014, the team contributed to the development of the SAP, conducting preliminary analyses of the follow-up data, and regular monitoring of endpoints in the course of follow-up. The team is also involved with the conduct of the regular monitoring of the data and endpoints for the main study, which started recently.

24. As part of their statistics support to research conducted by the Department and elsewhere, the members of the Unit co-authored several articles published in 2015, including a statistical methodological paper *(1–9)*.

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

Planned activities

- In 2016, the Unit will continue to offer support in data management and statistics to different research projects of the Department, outsourcing when this is needed.
- The Unit will continue to work on more methodological papers.

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 2015, on-site training in data management as well as the use of web-based data-management system was provided to local staff participating in research projects at four countries (Argentina, Mozambique, Singapore and the United Kingdom), 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.

Planned activities

- In 2016, the Unit will continue to support research capacity-strengthening, in terms of data management and statistics training, at the country level in relation to the ongoing and new research projects.
- The Unit will also contribute to the research capacity-strengthening workshops and trainings organized by the Department and/or WHO in this area, and as needed.

4.3.3 References

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4.4 Advocacy and communications

4.4.1 Introduction

Through its advocacy and communications work, the Department aims to promote uptake of its evidence-based outputs to build awareness of key issues in SRHR, and to raise funds and ensure the continued commitment and engagement of Member States, WHO, and other agencies and partners.

Major achievements

- In 2015, the Department worked to implement the communications strategy that was developed in 2014 with the participation of partners, funders and staff, and with the guidance of a leading global communications firm. This included a new focus on intensive communications work around a number of key publications and events, including a heightened presence on social media.
- In 2015, 32 new WHO publications in English were produced and distributed (see Annex B).
- In 2015, the Department began to distribute its publications on USB sticks at conferences in preference to hard copies. During the year, over 4000 USBs were distributed, containing over 120 publications in multiple languages.

- The Department produced and distributed 45 translations of existing Department publications (see Annex B).
- Research results and knowledge syntheses were published in the scientific press, in 203peer-reviewed articles (see Annex B). There was a noticeable increase in the number of times these articles were cited by others, including increased relevance and impact.
- There were 2.7 million page views of the Department's "Reproductive health" webpage, 3.1 million of the WHO Reproductive Health Library (RHL) website, and 18 000 video views on the RHL and HRP YouTube channels.
- In 2015, HRP launched a podcast channel, making available professional-quality podcasts recorded in-house. Five podcasts on with health experts speaking on technical topics and subjects of public interest were produced in 2015.
- The Department's outputs were widely disseminated, and SRHR were advocated for, at many different conferences, symposia and international meetings (see Annex B).
- A wide range of international days were marked by the Department. Web features were prepared for these days, which were well supported by the WHO central communications services.
- The Department's work saw an increased number of highlights on the WHO homepage.
- WHO's Family, Women's and Children's Health cluster launched a new website to promote activities and publications that cut across the departments, including RHR / HRP, and to provide a space where high-level advocacy efforts can be highlighted. The website is hosted at: http://www.who.int/life-course/
- HRP's Twitter account (@HRPresearch) saw a steady increase in followers during 2015, from approximately 315 at the end of 2014 to approximately 1000 at the end of 2015. The account was used to disseminate information about the Department's work and latest news.
- A new format was designed for HRP News, the Department's electronic newsletter, and during the year 10 issues were sent out. The number of recipients now stands at 4254, an increase of over 1000 during 2015.
- A TEDx Chisinau talk from Moldova entitled "Why we shouldn't shy away from sexual education" was viewed more than 9500 times.
- The Compendium of WHO recommendations for postpartum family planning (PPFP) was developed. This is an interactive online tool to search for recommendations specific to PPFP:http://srhr.org/postpartumFP/
- An online tool to search WHO guidelines for recommendations related to SRHR was developed and launched. This tool enables users to search across multiple WHO guidelines to find all recommendations relevant to the search term. The project includes embeddable search features that can be included on any website:http://search.srhr.org/
- A fully interactive website was launched to facilitate access to the recommendations of the WHO guideline entitled Health worker roles in providing safe abortion care and post-abortion contraception. The website allows for recommendations to be filtered by cadre and tasks, and provides access to the clinical, technical and policy guidelines on abortion:http://srhr.org/safeabortion/

4.4.2 Achievements in advocacy and communications

4.4.2.1 Implementation of the communications strategy

In 2015 the Department continued to implement the communications strategy, which was developed for 2014–2016, following the advice of the Scientific and Technical Advisory Group (STAG) and the engagement of Grayling, a global communications firm.

The overarching framework of the communications strategy is for the Department's research outputs to inform policy and practice in SRHR. 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 evidence-based guidelines, norms, standards and tools on SRHR;

iii. to increase ownership and commitment from co-sponsors;

iv. to improve internal communications.

As outlined in the Department's Annual technical report 2014, the three-pillar communications strategy was developed to effectively house the actions proposed and ensure 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"

In 2015, the Department worked to implement actions in line with the aims of the Communications Strategy's interlinking three pillars.

Communications focal points have been appointed for each of the three technical teams. Weekly departmental communications group meetings now take place to plan: the communications actions for all research articles and peer-reviewed publications; internal and external events with partners and collaborators, as well as high-level advocacy and events; international days; global strategies for health priorities; and the launch and publication of the Department's information products.

The Department's use of social media has increased. Alongside the launch and growth of the HRP Twitter account (@HRPresearch) during 2014–2015, a growing number of staff members now have personal accounts, which they use to promote the research, activities and event attendance of the Department.

Research published by Department staff has been routinely disseminated externally through the Departmental website, HRP News, Twitter, and when appropriate through partner communities such as the Implementing Best Practices initiative. In addition, all research is routinely shared internally with Department staff by the communications team.

Weekly communications meetings are now held with WHO Department of Communications, WHO Assistant Director General's Office, and the communications focal points of departments within WHO Cluster of Family, Women and Children's Health, improving communications across and within WHO about the Department's outputs.

A significant number of the Department's research outputs and information products, as well as recognition of International Days, were highlighted on WHO homepage and through WHO social media. Department staff have also taken part in #AskWHO Facebook chats on key health issues, such as contraceptive eligibility and the herpes simplex virus.

The support of high-profile WHO leadership to highlight campaigns around international days has been secured, most noticeably the support of the Director-General, Assistant Director-General and Departmental Director for the International Day for the Elimination of Violence against Women.

The profile of the HRP brand has been raised, using the new logo on all new information products. The branding has also been highlighted with the use of banners and shared information products at world health events such as the World Health Assembly, the International Federation of Gynecology and Obstetrics (FIGO) World Congress, and information "marketplace" meetings with Heads of WHO Country Offices at WHO headquarters. At these events, staff members of the Department were able to talk with visitors and share information on departmental products and priority areas of work.

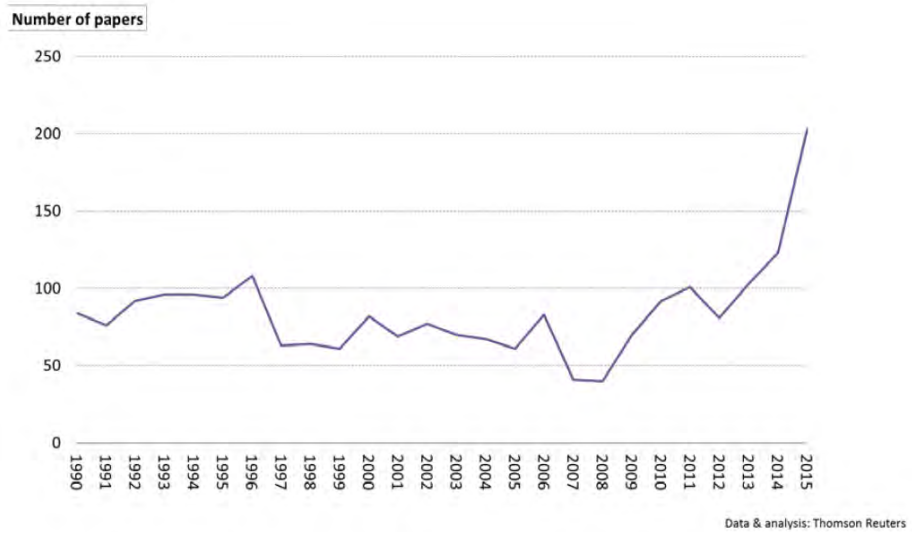
Department staff have taken part in international communications planning teleconferences with partners for high-profile world meetings such as the International Conference of Family Planning and Women Deliver.

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 203articles in 2015 (see Annex B: Indicator report). These articles were analysed following the same methodology used in recent years. 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 freely accessible worldwide, regardless of region, academic affiliation or institutional membership.

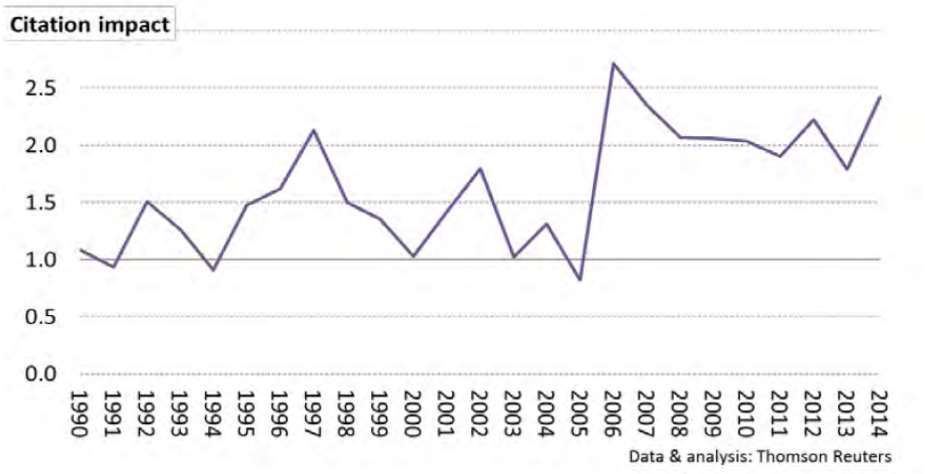
Figure 4.4.1: Number of scientific papers published by the Department, 1990–2015



Normalized citation data for 2015 will not be available until well into 2016, so the citation impact analysis and author analysis presented in Figures 4.4.2–4.4.4 covers the period ending in 2014.

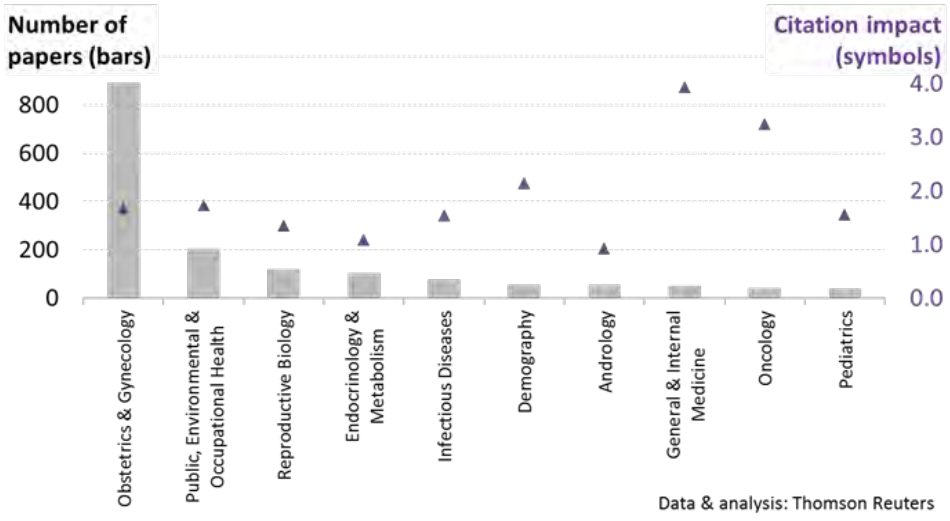
The citation impact of Department papers averaged 1.42 during the period 1990–2007 and then rose to 2.2 during the period 2008–2013, already more than twice the global average. In 2013, the Department's citation impact dipped slightly, due to the publication of a number of extremely highly cited papers in 2012, but nevertheless remained well above the global average. In 2014 the citation impact rose to 2.42 – a significant increase. Trends in citation impact are shown in Figure 4.4.2.

Figure 4.4.2: Trends in citation impact of papers published by the Department, 1990–2013



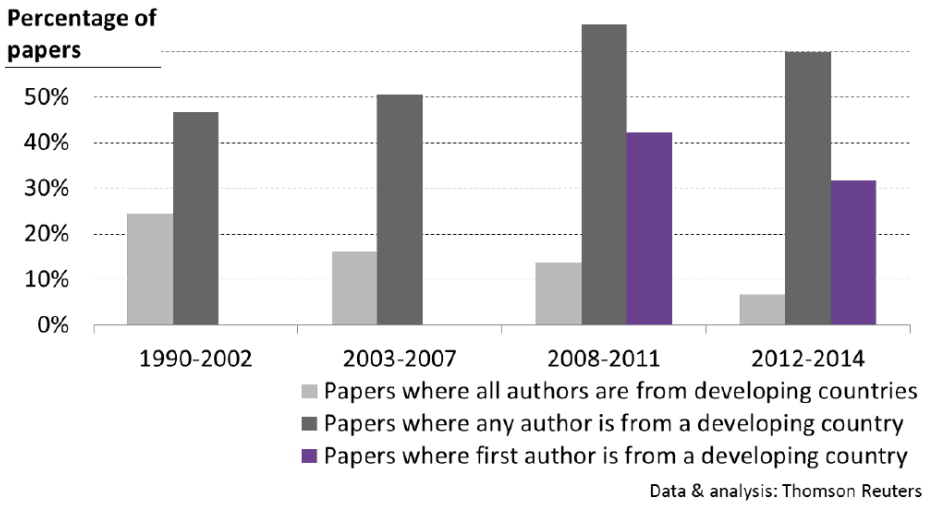
An analysis of the categories of journal in which the Department published research articles revealed that obstetrics and gynaecology journals account for the highest share, with more than one third (40.9%) of the papers falling into this category. This research is well cited within its category, with 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, 1990–2014



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 its 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



Taken together, these indicators of research performance are significantly above the world average, and are indicative of research that is of strong international standing.

Planned activities

- In 2016, the Department aims 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, clinicians, policy-makers and health-care programme managers. In 2015, 33 new publications in English were produced and distributed (see Annex B).

(i) Guidelines

The Department issued seven new guidelines (including handbooks and decision-making tools) in 2015. These were introduced and demonstrated at many workshops, with participants including ministry of health staff, programme managers and health-care providers.

(ii) Global and regional estimates and projections

The Department issued new estimates on maternal mortality, published by WHO. Additionally, estimates on herpes simplex virus (HSV)-1, HSV-2, and curable sexually transmitted infections were published in peer-reviewed journals.

(iii)Technical publications including evidence briefs, fact sheets and statements

In addition to the above guidelines and estimates, the Department issued 21 other technical publications on a range of subjects in 2015, as well as four Programme

Reports (t*he Annual technical report 2014,Highlights of 2014* and reports for the Policy and Coordination Committee [PCC] and STAG) (see Annex B).

4.4.2.4 Electronic newsletter

In 2015, the Department redesigned and renamed its monthly electronic newsletter HRP News. This was produced regularly during the year. After a professional redesign, the newsletter now highlights recent news and published research, events updates and information on upcoming events and opportunities. It also includes a monthly "Message from the Director", links to social media, and the latest research shared on WHO's RHL. The newsletter now uses an intelligent web platform which produces a tracking and analytics report. This link-monitoring software shows the rate of clicks on the content of the newsletter (which was high), where and how often the newsletter was opened, what articles were read, and it also helps to alert the communications group to any problems with delivery. Ten issues were sent out during 2015. Thanks to new data collection techniques used by the Department at international conferences and forums, a large number of new people willingly subscribed to the newsletter. he total number of subscribers, who have all "opted in" to receive the newsletter, now stands at 4264, a rise of over 1000 since the end of 2014. Anyone with an interest in the work of the Department can subscribe.

4.4.2.5 Language versions

The Department published45translations of existing Department documents in languages other than English (see Annex B).

4.4.2.6 Web-based communications

(i) WHO Reproductive Health Library (RHL)

The WHO RHL has been published by the Department since 1997. In 2015, the focus was primarily on optimizing the structure, development and publication of new RHL summaries, expanding the RHL collaboration, and better understanding our users and their needs and preferences. We have improved the quality and breadth of RHL, 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. Greater emphasis is now placed on WHO guidelines and recommendations. Translations into official UN languages are updated on an ongoing basis. These efforts have been successful, with numbers of monthly visitors steadily increasing over the 2014–2015 period; RHL now receives over 250 000 visitors each month. Non-English-content accounts for over 40% of RHL's traffic.

In 2015, RHL welcomed eight new volunteer contributors, and posted 37 new summaries (11% of current titles). The Cochrane Collaboration and Wiley have committed to providing free access to the Cochrane Library for all RHL users, which will be implemented with the launch of the new RHL platform in early 2016.

In 2015, the Department engaged a developer to develop a new content management system for RHL, which will operate on the Drupal platform but remain integrated with the WHO information technology infrastructure. It will provide a modern and more sophisticated interface for RHL users. Simultaneously, new RHL apps for mobile and tablet platforms (on iOS and Android) are being developed, as well as a USB-based

RHL platform for offline access. These new products will be released over the first six months of 2016.

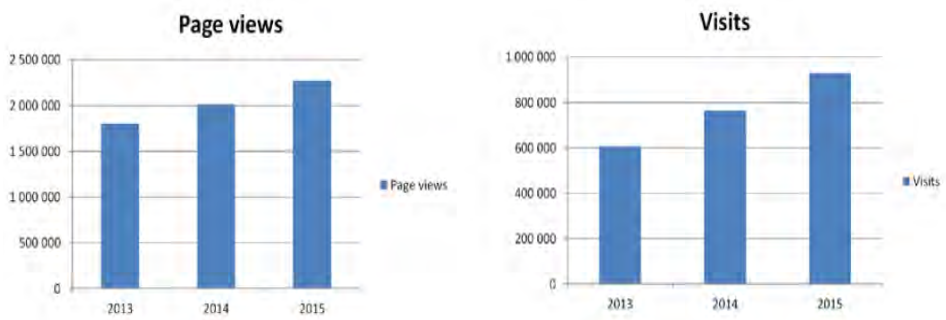
(ii) Departmental website

In addition to the RHL website, the Department maintains a website that includes information and publications on the health topics that make up the area of SRHR. This information is updated daily.

During 2015, the "What's new?" section of the website, which includes the latest publications, research articles, opportunities and events, was regularly promoted in the *HRP News* newsletters. For meetings such as the FIGO World Congress, a day-by-day programme of sessions and speakers was produced with stories updated daily from the conference. New features of the website in 2015 included a new "High-level meetings and advocacy" page which was created to give "bite-sized" updates on the Department's work on the global health stage, and also a section dedicated to providing information about ongoing departmental research projects and key outputs such as guidelines and tools.

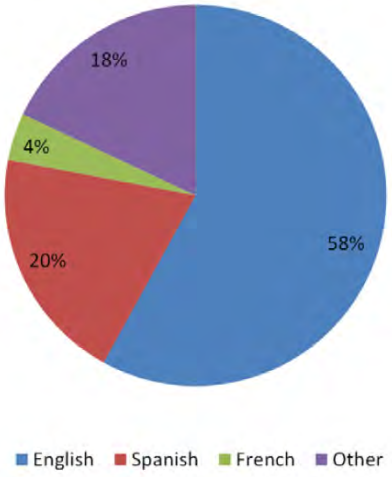
WHO uses Google Analytics to generate and analyse its statistics on website visits and page views. The number of visits rose more than 20% from 766 000 in 2014 to 929 000 in 2015, as shown in Figure 4.4.5. This, in turn, resulted in a higher number of page views, up from 2 million in 2014 to 2.7 million in 2015. These figures exclude RHL, which are reported separately above.

Figure 4.4.5: Number of visits and page views of the departmental website, 2013–2015



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, including Amharic, Bulgarian, Czech, German, Italian, Japanese, Portuguese, Romanian, Slovak, Swahili and Ukrainian (see Figure 4.4.6). In 2014, we reported that 32% of visitors were seeking information in languages other than English. In 2015, the Department continued its efforts to translate more information into multiple languages and as a result, by end 2015 the percentage of non-English-speaking visitors had risen to 40% with Spanish now representing 20% of the total number of web sessions. In light of this information, HRP will continue to translate materials where possible throughout 2016.

Figure 4.4.6: Visitors to the Department's "Reproductive health" website by language, 2015



The RHL and HRP YouTube channels continue to enjoy a large degree of success, with 18 000 video views in 2015. In addition, the Department launched a new HRP Podcast channel in September 2015.

4.4.2.7 Social media

2015 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 sent out 1054 original tweets during 2015. Using a Twitter Analytics programme, it is estimated that these HRP tweets resulted in 725 000 impressions (the number of times tweets are seen by users on Twitter). Notable Twitter events during the year included one tweet on female genital mutilation (FGM) that was retweeted 50 times achieving over 150 000 impressions, similarly one of the tweets about the WHO Statement on caesarean section rates was retweeted 57 times achieving more than 57 000 impressions.

At year end, the HRP Twitter feed had 1100 followers, an increase of almost 800 followers since the end of 2014.

4.4.2.8 International days

A number of international days were marked by the Department in 2015:

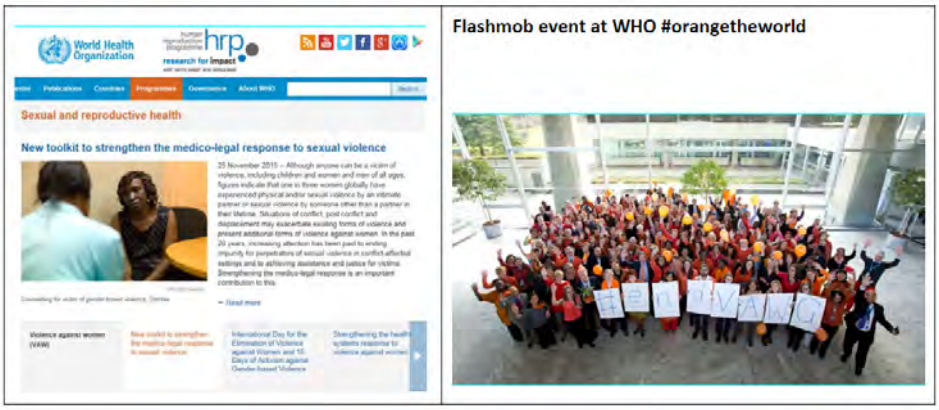
- International Day of Zero Tolerance to Female Genital Mutilation, 6 February
- Obstetric Fistula Day, 23 May
- World Contraception Day, 26 September
- International Day of the Girl Child, 11 October
- World Prematurity Day, 17 November
- International Day for the Elimination of Violence against Women, 25 November
- World AIDS Day, 1 December
- 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.

Case study: Communication activities for the International Day for the Elimination of Violence against Women

Wherever possible, the Department seeks to use recognized international days to launch new information products and guidelines, capitalizing on global interest in the given subject. The 2015 International Day for the Elimination of Violence against Women on 25 November was a case in point. On this occasion, the Department and partners launched a new toolkit aimed at strengthening the medico-legal response to sexual violence. The story about the new toolkit was highlighted on both the departmental website and the main WHO homepage. Twitter messages were sent out both from the HRP account and also from the WHO account, which has close to 3 million followers.

The 25th of November marks the beginning of 16 Days of Activism against gender-based violence, a civil-society originated initiative, which culminates on 10 December, Human Rights Day. In support of the 16 Days, as well as the United Nations Secretary-General's UNiTE to End Violence Against Women and Girls' campaign, which invites all people to "Orange the world to end violence against women and girls", WHO's first ever "flashmob" event was organized and was well supported, including by senior staff.



WHO's Director General joined the campaign by wearing orange alongside the Assistant Director General for the Family, Women's and Children's Health cluster, and also made a strong statement on WHO's condemnation of violence against women and girls.

4.4.2.9 Planned activities

- The Department's work in communications will continue in 2016, as guided by its communications strategy.
- Major new directions identified within the communications strategy include: (i) completing the consolidated web presence for the Department, (ii) continuing to build on successes in social media, including Twitter, and exploring additional new media channels, and (iii) integrating communications within all the work of the Department, including research and development and standard setting.

4.5 Research project review through RP2

4.5.1 Introduction

The Departmentensures 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 Forty-first World Health Assembly in 1988, Resolution 41.9, specific to the field of reproductive health and research. As of the third quarter of 2014, and throughout 2015, the Department used the WHO Ethics Review Committee (WHO-ERC) to provide ethics review.

Major achievements

- Overall, the RP2 conducted 45 successful project reviews during 2015, as either a first submission, a resubmission or for continuing review with or without additional protocol amendments.
- Sixteen projects submitted to the RP2 were new projects generated by Department staff during 2015. All projects submitted to the RP2 were initially reviewed electronically for scientific, technical and budgetary/financial assessment through emailed feedback and/or via teleconference or videoconference when first submitted. Following subsequent reviews to meet final approval, the projects were forwarded to the WHO-ERC for ethical review.
- Fourteen out of the current 19 RP2 members were involved in project review. For continuous and repeat assessments, the RP2 Secretariat ensured that the same members were involved in subsequent committee reviews of a project; this resulted in support from past RP2 members, who kindly provided feedback for ongoing projects.

4.5.2 RP2 membership

The RP2 is an independent body whose members have included multidisciplinary external experts in the field of sexual and reproductive health 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 the five technical specialist panels and the former Scientific and Ethical Review Group (SERG), which were together responsible for strengthening concept notes as well as reviewing research projects. By taking over these roles, the RP2 now reviews projects at various stages of development.

Progress

During 2014, the terms of most RP2 members expired. Out of 53 RP2 members, 10 had their membership renewed for three years, including renewal of the RP2 Chair's position for one year, starting from 1 November 2014. The Vice-Chair's position was also renewed for one year, after which she will act as Chair for three years. In November 2015, the RP2 Chair stepped down and became an RP2 member for the remainder of her three-year term; and at the same time, the Vice-Chair took up her position as Chair. One RP2 member, who was a previous Regional Advisory Panel member from the Pan American Health Organization (PAHO), has stepped down due to conflict with another international review body. Multiple requests for new members were released through the Department's communication channels throughout 2015.

Planned activities

- RP2 membership will be expanded from the current 18 members in 2016.

4.5.3 Project review outcomes

Progress

Throughout 2015, the RP2 reviewed projects for scientific design, technical aspects and financial/ budgetary issues, and did not include formal ethics review or debate. In 2014, the Department decided to defer to the WHO-ERC for full ethics review of all projects.

To accelerate reviews through the Department's processes, all large research projects (where feasible) have formed dedicated research project steering committees or oversight project planning committees, comprising internal staff and external research experts. In 2015, following assessment and approval by senior management at the Department, all research projects were reviewed electronically by RP2 members. New and resubmitted projects continued to follow a procedure that was similar to the previous review format of face-to-face meetings.

In 2015, RP2 adhered to the new terms of reference and rules of procedure which had been drawn up in 2014 to reflect all logistical and procedural changes within the RP2 review process. Sixteen projects submitted to the RP2 during 2015 were new projects not previously assessed by RP2. All projects submitted to RP2 were initially reviewed electronically for scientific, technical and budgetary/financial assessment through emailed feedback and/or via teleconference or videoconference when first submitted. Following a summary assessment, subsequent reviews were undertaken in order to meet final approval. These were then forwarded by responsible project officers in the Department to the WHO-ERC for ethical review. Overall 45 reviews were conducted during 2015, which covered all projects submitted to RP2 as new project submissions, resubmissions, or for continuing reviews, or for an approval of protocol alterations or amendments. All of these 45 reviews were accomplished electronically (see Table 1).

Fourteen out of the current 19 RP2 members were involved in electronic project review during 2015. For continuous multi-year project reviews and repeat assessments, the RP2 Secretariat ensured that the same members were involved in subsequent committee reviews of a project. As a result of changes in membership between 2014 and 2015, past RP2 members, when requested, kindly provided feedback for the ongoing projects for which they had provided an original assessment and had conferred a final approval. Overall, for high-quality projects, the review process – from submission to completion of an RP2 review that resulted in final approval – was completed on average within

four weeks. However, since the electronic (email) review process has been in use, the time commitment and management required for project review from the Chair, Vice-Chair, current RP2 members and RP2 Secretariat has increased significantly. In addition, new and revised research projects now arrive for review at any time, creating the challenge of finding RP2 members who are available to review a project protocol in a timely fashion. With a future expanded RP2 membership, and by observing the requirement in the new terms of reference to begin to appoint additional vice-chairs to support the new Chair who was appointed in late 2015, these challenges should be resolved during 2016.

Table 1. New and multi-year RHR Department and HRP proposals reviewed by the RP2 in 2015

		Outcomes from an RP2 review process			
Type of review	**Number of projects submitted for a review**	**Final approval**	**Conditional approval with recommendations, amendments and clarifications**	**Re-submission**	**Exemption**
RP2 electronic meetings	29	11	13	3	2
Interim/ continuing reviews with or without amendments	16	10	6	-	-
Total	**45**	**21**	**19**	**3**	**2**

5. Research capacity-strengthening, including the HRP Alliance

5.1. Introduction

The Human Reproduction Programme (HRP), which is housed at the WHO Department of Reproductive Health and Research, is the only body within the UN system with a global mandate to lead research in SRHR and to conduct research capacity-strengthening (RCS) as a core activity. Over the past 40 years, HRP has conducted RCS activities in all six WHO regions, contributing to the creation of a critical mass of researchers in low- and middle-income countries. Following the Department restructuring in 2013, the RCS activities were re-organized as a cross-cutting activity. In 2015, HRP focused on maintaining ongoing commitments while going through critical assessment and evaluation of its RCS portfolio. In 2016 RCS activities will be implemented in an integrated manner with the Department's overall research portfolio and strengthening regional networks..

Major achievements

- In 2015, HRP awarded Long-term Institutional Development (LID) grants to 10 institutions, and research training grants to 13 individuals.
- In the WHO Eastern Mediterranean Region, three new institutions in Morocco, Pakistan and in the West Bank and Gaza Strip were awarded LID grants.
- The Institute de Recherché en Science de la Santé (IRSS) in Burkina Faso, in the fifth year of its first cycle, was invited to apply for WHO Collaborating Centre status reflecting its presence as a growing institution in West Africa.
- The Cellule de Recherché en Santé de la Reproduccion en Guinée (CERREGUI), a LID grantee institution in the fourth year of its first LID cycle, has been successfully integrated into the multicountry study on mistreatment of women during childbirth.
- Two HRP Alliance meetings were held successfully, one for the WHO African and Eastern Mediterranean Regions combined, and one for the Region of the Americas.

5.2. The HRP Alliance

The HRP Alliance was conceptualized as a new modality for strengthening regional networks to support the efforts to strengthen research capacity by HRP. The HRP Alliance is composed of WHO Collaborating Centres, HRP grantee institutions, research partners and WHO regional offices.

Progress

In 2015, two HRP Alliance meetings were successfully held for the WHO African and Eastern Mediterranean Regions combined and the Region of the Americas. In both meetings, bringing together WHO Collaborating Centres, research partners and grantees provided a rich discussion and new networking opportunities. It was also important for the grantees to see the common problems and challenges they faced and there were useful suggestions regarding mentorship from experts and mature institutions in the regions.

In February 2015, the first Global Steering Committee of the HRP Alliance was convened. The Committee made some important suggestions regarding how to improve regional networking and suggested the inclusion of policy-makers in the HRP Alliance. It will provide oversight and strategic directions for the activities of the HRP Alliance in coming years.

Planned activities

- Work will continue on regional networking and RCS in SRHR to enable the timely identification of regional priorities and emerging research institutions, and to promote regional collaboration.
- In 2016, HRP will implement HRP Alliance and Regional Research Committee (RRC) meetings in the WHO African Region, Eastern Mediterranean Region and the Region of the Americas.

5.2.1 Integrating RCS with multicountry global research

Progress

In order to strengthen the research capacity of institutional development grantees, the Programme is considering systematically integrating such centres into its centrally coordinated multicountry research projects. In 2015, theCellule de Recherche en Santé de la Reproduction en Guinée(CERREGUI) in Guinea was successfully integrated into the multicountry study on mistreatment of women during childbirth. The LID grantee in Malawi will participate in the Adolescent Health Experience after Abortion or Delivery (AHEAD) trial, which is aimed at preventing rapid, repeat pregnancy.

HRP is collaborating with LID grantees from Burkina Faso (Institut de Recherché 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) for research on postpartum family planning.

5.2.2 Competitive intraregional grants call

Progress

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 were invited as competitive, intra-regional grants with mentor and mentee institutions from the same region. Over 50 applications were received, and five were shortlisted to be developed into full proposals. HRP staff supported the development of the five shortlisted research proposals, which are under review.

Planned activities

- Multicountry global research integration with RCS will continue to be supported.
- The HRP Alliance e-platform will be finalized in 2016.

5.3 Regional activities

5.3.1 WHO African Region

Progress

5.3.1.1 Regional Research Committee (RRC) meeting for Africa and Eastern Mediterranean

The first RRC meeting for Africa and Eastern Mediterranean was held in Nairobi, Kenya on 9–11 June. This meeting was attended by staff from WHO regional offices (Africa and Eastern Mediterranean regions), staff from WHO headquarters, LID grantees, WHO Collaborating Centres, and RRC members. The LID grantees presented their accomplishments, challenges and future work plans. A panel discussion on issues related to strengthening research capacity in SRH ensued, resulting in better understanding of regional challenges and needs. The RRC noted that some centres are facing challenges and took action to support the centres. For example, the United Republic of Tanzania LID proposal was revised following mentorship by the Chair of RRC.

5.3.1.2 Institutional capacity-strengthening

During 2015, LID grants were approved for five institutions:

- Burkina Faso (Institut de Recherche en Sciences de la Santé, Ouagadougou)
- Côte d'Ivoire (Cellule de Recherche en Santé de la Reproduction, Abidjan)
- Guinea (Cellule de Recherche en Santé de la Reproduction, Conakry);
- Pakistan (Health Services Academy)
- The West Bank and Gaza Strip(The Institute of Community and Public Health, Birzeit University).

The institutes in Pakistan and the West Bank and Gaza Stripreceived LID grants for the first time in 2015. The Democratic Republic of the Congo (Université de Kinshasa, Faculté de Medecine Département de Gyneco-Obstetrique, Kinshasa), Malawi (The University of Malawi, College of Medicine/Malawi), Ethiopia (The University of Addis Ababa), and the United Republic of Tanzania (Kilimanjaro Christian Medical Centre, Moshi) were not awarded LID grants in 2015, as the grant applications were either not submitted or not focused on research capacity-strengthening (RCS) respectively. Following RRC recommendations, mentors were identified to support these institutions. The institutions are working with the mentors and will resubmit their grant applications to HRP, by December 2016.

5.3.1.3 Research training grants and research training

Two researchers from the IRSS in Burkina Faso, who had received research-training grants in 2014–2015, completed their master's programme. For the year 2015–2016, two more researchers were awarded grants for their master's programme. As in the previous year, HRP covers 60% of the tuition fee as a scholarship, and the IRSS absorbs the remaining 40% of the cost.

One researcher from Guinea (Cellule de Recherché en Santé de la Reproduction, Conakry) was awarded a grant for a master's programme, which will be completed at the IRSS (a LID grantee) in Burkina Faso.

A grant was awarded to the Witwatersrand Reproductive Health and HIV Research Unit in Johannesburg, South Africa, to fund four participants to attend its "Research methodology course in sexual and reproductive health and gender-based violence", held 17–28 November 2015. The course has been held annually since 1997, and in 2015 was attended by 20 participants from the Democratic Republic of the Congo, Kenya, Nigeria, South Africa, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

In addition, a grant was awarded to Stellenbosch University in South Africa to support a research methods course on systematic reviews and intervention studies, which was attended by 27 young researchers. The main aim of the course is to equip researchers with practical skills to conduct high-quality randomized clinical trials and systematic reviews.

It should be noted that all research-training grants were used for activities within the region.

5.3.1.4 Regional network of research institutions

HRP continued to support ReproNet-Africa, which works for region-specific networking, partnership and advocacy on reproductive health issues. Support included the publication of a newsletter and management of a website for information dissemination.

During 2015, the Zimbabwe University was supported to conduct a study "To assess impact and lessons learnt from the past LID grantees in Africa". The results are under analysis and will be disseminated in the first quarter of 2016.

5.3.1.5 Research projects and related training

The programme often provides training on research design, data collection and analysis to researchers involved in the research projects. In 2015, the following activities were conducted:

- Qualitative data collection training (15 participants) and qualitative data analysis training (20 participants), related to the AHEAD study, were conducted at the University of Ghana School of Public Health.
- As part of the "Maternal morbidity measurement project" pilot study, in conjunction with Jhpiego-Kenya office, the Programme conducted a two-day training (18 participants) on 16–18 September 2015 in Kisumu county. The training covered quantitative data collection methods, including the administration of informed consent; translation/administration of tools in local languages (Swahili and Dholou); and the use of Android tablets for data gathering. Data are being collected for the project from approximately 500 women, and the principal investigator will attend a data analysis meeting in January 2016.
- As part of the "Maternal morbidity measurement project", in conjunction with the University of Malawi, College of Medicine Department of Obstetrics and Gynaecology, HRP conducted a four-day training (10 participants) from 14–17 August 2015. The training covered quantitative data collection methods, including the administration of informed consent, and the use of Android tablets for data gathering. Data are being collected for the project from approximately 500 women, and the principal investigator will attend a data analysis meeting in January 2016.
- In November 2015, a four-day workshop was held with research teams from three countries (Ghana, Guinea and Nigeria) at the University of Ghana, Accra,

Ghana. The participants were researchers, interviewers and data collectors who are participating in the "How women are treated during facility-based childbirth" mixed-methods study led by WHO. The workshop brought together 26 participants from these three countries. It was largely practical, with presentations and guided exercises on the principles and methods of conducting qualitative data analysis. Participants spent two days applying these methods to data collected as part of the study. Research teams were then able to structure plans for continuing qualitative analysis on the remaining data and development of manuscripts beyond the workshop. A similar workshop is planned for February 2016 with participants from the fourth country site (Myanmar).

5.3.1.6 Dissemination of research findings

HRP supported the LID grantee from Burkina Faso (IRSS) to develop a journal supplement entitled "MDG end: maternal and neonatal health in African countries: availability, access to maternal health services and outcomes", and publish it in the International Journal of Gynecology and Obstetrics, the official journal of the International Federation of Gynecology and Obstetrics (FIGO). The supplement will focus on research from the African region and in particular from LID grantees. Publication is expected in the first quarter of 2016.

Planned activities

- Monitor the LID grantees closely with site visits.
- HRP is in discussions with the University of California at San Francisco's Preterm Birth Initiative and Global Health Department on issuing a call for proposals for researchers in Kenya, Rwanda and Uganda.
- There are also plans to collaborate with Society for Maternal Fetal Medicine in the USA on implementing an obstetrics and ultrasound training programme with an RCS component.

5.3.2 WHO Region of the Americas

Progress

5.3.2.1 RRC meeting

The RRC meeting for WHO Region of the Americas was held on 18 November in Lima, Peru, as a back-to-back meeting with the XXIV Biennial Meeting of Asociacion Lationamericana de Investigadores en Reproduccion Humana(ALIRH) (see section 5.3.2.6). The RRC meeting was attended by directors of WHO/HRP/RHR Collaborating Centres in the Americas, past and current RCS (LID and research training) grantees, RRC members, WHO headquarters and regional staff. Progress of RCS grants was reviewed. The meeting discussed the next steps for building regional capacity in SRH.

5.3.2.2 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, completed the first year of the LID grant cycle 2. The Paraguay centre is progressing well with a mentor institution in Argentina and has been contacted by the Ministry of Health to assist in developing a national reproductive health plan. The Centre is working on two multicentre research projects: "Estimation of magnitude of induced abortion in Paraguay", and "Reproductive coercion against women in Encarnacion". The library continued to support researchers in the country.

The Centre for Research in Development Sciences of San Andrés University (CIDES-UMSA) in La Paz, Bolivia, evaluated their master's degree programme on Population and Development (MPD) and developed the MPD-11 curriculum. They admitted 21 students to the programme for the current year. Short-term capacity-building training courses in the use of perinatal clinical records and the Perinatal Information System for generating information for decision-making processes were offered to 18 hospital staff and over 60 health personnel from first-level health-centres. Five students of the first version of the MPD defended their theses and are developing publications. CIDES-UMSA was successful in receiving funds and support from UNFPA and other organizations. They were successful in receiving partial scholarship for 20 students (US$ 15 000 per year) in the master's programme. The Centre has challenges related to implementing research due to scarcity of staff and high turnover of policy-makers and care providers.

The institutional profile of a centre in Ecuador – Kimirina Corporation, a nongovernmental organization (NGO) – was considered for LID grant, but the RRC felt that it did not have enough of a research focus to justify a grant.

5.3.2.3 Research project support

As in the past, in an endeavour to strengthen research skills in Latin America, 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, nine Fellows were awarded grants to attend courses or practical training of six months or less. Of these, two grants were awarded to students to take an online course on research methods in SRH, held by the Geneva Foundation of Medical Education and Research.

5.3.2.4 Research projects and related training

As part of the "Maternal morbidity measurement project" pilot study, in conjunction with University of the West Indies' Department of Community Health and Psychiatry, two separate two-day trainings (a total of 35 participants – in St Ann and Kingston parishes in Jamaica) were conducted on 12–15 May 2015. The training covered quantitative data collection methods, including the administration of informed consent and the use of Android tablets for data gathering. Data have been collected for the project from approximately 500 women, and the principal investigator will attend a data analysis meeting in January 2016.

5.3.2.5 Dissemination of research findings

The HRP Alliance supported the XXIV Biennial Meeting of ALIRH in Lima, Peru, on November 19–21, 2015. ALIRH is an international NGO that aims to promote development of original scientific research applicable to human reproduction and SRH in Latin America, disseminate the results of these scientific investigations, and facilitate the exchange of scientific information among its members. The meeting, with participation of more than 200 scientists, aimed to share research results and their application to SRH in the region. This scientific meeting was preceded by the meeting of the HRP Alliance RRC for the Region of the Americas on 18 November.

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

Together with technical support from HRP, CEPEP developed a manuscript on "Challenges and experiences of strengthening research capacity for sexual and reproductive health: a case study from Latin America". This manuscript is in English and is expected to be published in an international journal in the first quarter of 2016.

Planned activities

- HRP will continue supporting the institutions receiving LID grants.
- HRP will develop plans for aligning the priorities of ALIRH and PLISSER with the Latin America Perinatology Center/Women's and Reproductive Health (El Centro Latinoamericano de Perinatología/Salud de la Mujer y Reproductiva;CLAP/SMR), a regional centre in Uruguay.

5.3.3 WHO Eastern Mediterranean Region

Progress

5.3.3.1 Institutional capacity-strengthening

During 2015, LID grants were disbursed to two new countries: Pakistan (Health Services Academy), and in the West Bank and Gaza Strip (the Institute of Community and Public Health, Birzeit University). For the fourth year, the Afghan Public Health Institute in Kabul, Afghanistan, submitted an application, but the grant was not approved by the RRC as the members were not satisfied with the progress made by the institution and the activities planned. The RRC requested that the institution be linked with a mentor who could facilitate and support RCS activities.

5.3.3.2 Research training grants

No individual training grants were awarded in 2014. Instead, to enlarge the pool of researchers in reproductive health, support was provided to a research methodology workshop in Afghanistan. This involved 28 participants from tertiary hospitals, the majority of whom were from the Maternity, Obstetrics and Gynaecology Department of Kabul Medical University and the Ministry of Public Health.

Planned activities

- Efforts will be directed towards strengthening the two newly identified centres: the Health Service Academy, Pakistan and the Institute of Community and Public Health, Birzeit University, the West Bank and Gaza Strip.
- HRP will continue supporting the institutions receiving LID grants.

5.3.4 WHO European Region

Progress

5.3.4.1 Institutional capacity-strengthening

The Programme is collaborating with the WHO Regional Office for Europe and the Kaunas University in Lithuania to support newly established centres in the region. Support 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 implemented 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 in Dushanbe, Tajikistan". It is expected that the results will be analysed and published in the first quarter of 2016.

Planned activities

- HRP will continue supporting the institutions receiving LID grants.
- There is a need for RCS in the WHO European Region, especially for institutions in Central Asia. Efforts are ongoing to support one centre in Kyrgyzstan for an LID grant.

5.3.5 WHO South-East Asia and Western Pacific Regions

Progress

5.3.5.1 Institutional capacity-strengthening

Support continued to three countries in the region: Bhutan (the Health Research Epidemiology Unit, Ministry of Health); Cambodia (the National Institute of Public Health); and Myanmar (the Department of Medical Research, Pyin Oo Lwin Branch, DMR(POL)).

DMR(POL) is closely collaborating with Myanmar Maternal and Child Welfare Association, a local NGO, to conduct the 8th Asia Pacific Conference on Reproductive Sexual Health and Rights (APCRSHR) from 23–26 February 2016. The APCRSHR is a biennial gathering of civil society, young people, academia, government, media, private sector, and development partners from the region concerned about SRHR.

During the year, the National Institute of Public Health, Cambodia organized four lunch-time seminars in the field of reproductive health to share experience and promote learning among faculty members.

5.3.5.2 Research project support

In Myanmar, DMR(POL) initiated the research project on "Sexual behaviour and contraceptive practices among adolescent university students in Mandalay District". This study will be completed in 2016. The DMR (POL) centre was successful in raising external funds. With support from UNFPA they conducted the multicentre study on "Facility assessment for reproductive health commodities and services".

The National Institute of Public Health, Cambodia submitted the research project "Empowering adolescents towards better reproductive health" to WHO-ERC. The research project had several ethical challenges and was not approved by WHO-ERC. The centre is considering modifications and resubmission of the research project.

5.3.5.3 Research training grants

One candidate from Myanmar completed her post-doctoral training at Asia Health Policy Programme Stanford University, USA and is now working at the DMR(POL) centre to support research in reproductive health. Another student from Myanmar is continuing with the PhD programme at the Faculty of Medicine, Prince of Songkla University, Hat Yai, Thailand, working on "Improvement of the quality of antenatal care and skilled birth delivery in Myanmar by empowering the community and local area service network".

In addition, HRP supported the Health Research Epidemiology Unit, Bhutan, to organize an SPSS workshop to develop capacity of health workers and managers in health research methodologies. The workshop was facilitated by local resource persons from the National Statistical Bureau and Ministry of Health. A total of 42 health workers from all 20 districts across the country were trained on the SPSS software for data analysis. As a result of this training, an increased output of operational research in SRH is anticipated.

5.3.5.4 Dissemination of research findings

One of DMR(POL)'s achievements for this year was disseminating the nationwide representative evidence on reproductive health (RH) commodities and services from the "2014 facility assessment for RH commodities and services". The findings from this study could be utilized for future logistical management systems by local regional health authorities, national and international implementing partners, and programme managers.

5.3.5.5 Research projects and related training

Following the launch of the Cambodian national prevalence study on violence against women using the methodology of the "WHO multi-country study on women's health and domestic violence", a workshop was held with students and researchers at the National Institute of Public Health of Cambodia (an LID grantee). The purpose of the workshop was to build capacity among public health students on carrying out secondary data analysis of the population-based survey dataset. The workshop introduced the issue of violence against women as a public health problem and discussed how to develop research questions, but the main purpose of the workshop was to teach data analysis skills for conducting secondary analysis of large-scale survey data to generate research results that are relevant to policy-makers or institutions working on the issue of violence against women.

Planned activities

- Meeting of RRC for the Asia Pacific region will be held in the first half of 2016 with the specific objective of discussing regional SRHR and RCS priorities.
- Continue support to the institutions receiving LID grants.
- Encourage and support implementation of relevant research in the region.

Key objectives in human reproduction

The activities of the Human Reproduction team of the WHO Department of Reproductive Health and Research including HRP (RHR / HRP) 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.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
Total human reproduction	15 900 000	12 204 444	77%	
Research and development	13 128 315	10 270 004	78%	• In 2015, the Department published 25 scientific papers on family planning and contraception. • To date, 8500 women have been enrolled in ESTAMPA, "Multicentric study of cervical cancer screening and triage with HPV testing", at five study sites: Colombia (2), Honduras (1), Paraguay (1) and Uruguay (1). Over 90% of human papillomavirus (HPV)-positive women have undergone colposcopy procedures. • Through a rigorous review of the latest science addressing contraceptive safety, 14 topics (encompassing more than 575 recommendations) were reviewed as part of the revision process to develop the fifth edition of the Medical Eligibility Criteria. • A comprehensive package of studies to evaluate dual HIV/syphilis rapid diagnostic tests (RDTs) in China, Colombia and Zambia was completed. • Core protocols were developed for an independent laboratory-based and field (clinic-based) validation of point-of-care tests (POCTs) to detect Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis and syphilis.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	*F*inancial implementation rate (%)	Key results
				• A pilot study investigating the persistence of Ebola virus (EBOV) in body fluids in a cohort of Ebola virus disease (EVD) survivors showed that EBOV may be present in semen well beyond six months post-EVD onset. • Two research proposals relating to microbicides and MPT development and introduction were initiated: (i) biomedical measurement of user adherence; and (ii) preclinical development of simple and inexpensive depot injectable formulations for combination contraception and HIV prevention. • Recruitment of study participants in AISHA, "An implementation study on rapid HPV testing in Tanzania", was carried out between May and August 2015. • The Department initiated development of guidance on diagnosis, management and treatment of infertility/subfertility and interventions that provide fertility care. • 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. • 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. • The Department prioritized implementation research on topical pre-exposure prophylaxis as a woman-controlled HIV-prevention method.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	*F*inancial implementation rate (%)	Key results
				• 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.
Norms, standards and guidelines	1 061 012	625 690	59%	• WHO published its eagerly anticipated update of the Medical eligibility criteria for contraceptive use (MEC) guidance and its accompanying job aid for providers of family planning services, the MEC Wheel on 1st June 2015. • The Compendium of WHO recommendations for postpartum family planning guidance – a new user-friendly digital platform to enable easy access to its recommendations – was completed in December 2015. • Updated treatment recommendations were developed for Neisseria gonorrhoeae, Chlamydia trachomatis, herpes simplex virus (HSV) and Treponema pallidum. • The guideline Brief sexuality-related communication: recommendations for a public health approach was published and widely disseminated in 2015. • A report on sexual health, human rights and the law was published in June 2015. • A new chapter in the 11th revision of one of WHO's hallmark publications, The International Classification of Diseases (ICD-11) is dedicated to "Conditions related to sexual health". To accompany this, a publication on the importance and rationale of the new ICD-11 "Sexual health" chapter was published in Reproductive Health Matters in November 2015.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
				• 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. • 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. • *Brief sexuality-related communication: recommendations for a public health approach* – this long-expected guideline was completed.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	*F*inancial implementation rate (%)	Key results
Monitoring and evaluation	461 442	739 840	160%	• Cuba became the first country validated by the Global Validation Advisory Committee (GVAC) for elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. • In a study in Swaziland, 655 women aged 15–49 years were screened with VIA, 14.8% were positive with signs of cervical pre-cancer and all underwent treatment. • To address the need for better STI data, in 2015 the Department published three new global STI estimates on (i) HSV-2 infection, (ii) HSV-1 infection and (iii) curable STIs. • The Department established a global system of STI reporting on 10 core indicators within the Global AIDS Response Progress Reporting System (GARPR).
Partnerships, dissemination, communication, information and advocacy	1 249 232	568 910	46%	• The Department provided technical support to 10 countries in the African region to develop plans postpartum family planning. • The draft Global Health Sector Strategy on sexually transmitted infections, 2016–2021, was developed. • Several articles related to SRHRof women living with HIV, including outcomes of a global community survey, were published in a special supplement to the Journal of the International AIDS Society and launched on World AIDS Day, 1 December 2015.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	*F*inancial implementation rate (%)	Key results
				• WHO, UNFPA, The World Bank, UN Women, UNAIDS, UNICEF, the International Atomic Energy Agency (IAEA), the International Agency for Research on Cancer (IARC) and the United Nations Office on Drugs and Crime (UNODC) have come together with the objectives of reducing morbidity and mortality from cervical cancer, strengthening health-care delivery systems, and detecting, treating and palliating cervical cancer. The primary expected result of the project is to establish a coordinated approach for planning and implementing cervical cancer prevention and control programmes. • A workshop on the fertility intentions of HIV-affected individuals and couples was held with support from the Brocher Foundation. • The first peer-reviewed supplement on multipurpose prevention technologies was published and widely disseminated. • The Implementing Best Practices (IBP) initiative worked with WHO regional and country offices to document best practices and to introduce tools for scaling them up, supporting activities in over 25 countries.

Key objectives in improving maternal and perinatal health

The primary objectives of the work of the Department's Maternal and Perinatal Health team 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 (LMICs). 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.

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	Financial implementation rate (%)	Key results
Total maternal and perinatal health	9 863 000	13 325 263	135%	
Research and development	8 658 248	11 974 127	138%	• The WHO framework on quality of care for pregnant women and newborns around the time of childbirth was published in BJOG. The quality statements and indicators for the eight domains focusing on both provision and experience of care were finalized. • An analysis of changes in caesarean section usage in 21 countries was published inThe Lancet Global Health. By combining data from the WHO Global Survey on Maternal and Perinatal Health and the WHO Multi-Country Survey on Maternal and Newborn Health, the paper demonstrated that the Robson classification can be applied to facility-level data in low- and middle-income countries for standardized comparisons of caesarean section data across countries and time points, and to identify subpopulations driving changes in caesarean section rates.

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	*F*inancial implementation rate (%)	Key results
				• Development began of a WHO technical guidance document related to assessment and prioritization of digital innovations to strengthen health systems, including health information systems. These efforts were initiated in relation to the restoration of health services in Sierra Leone. • The Department conducted formative research across three THRIVE research sites to inform functional and data requirements for multiple RMNCH frontline workforce cadres. This effort also led to the creation of a common RMNCH community-health information system data dictionary. • 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. • 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.

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	*F*inancial implementation rate (%)	Key results
Norms, standards and guidelines	653 179	604 100	92%	• The Department released the WHO statement on caesarean section rates, including information on optimal rates and monitoring of caesarean sections at facilities. This eagerly awaited statement superseded the earlier 1985 statement, which has been widely quoted. The new statement emphasizes that while there seem to be mortality benefits up to national population level rates of 10%, much of the association can be explained by development status of the country. WHO recommends the 10-group Robson classification to monitor caesarean section rates. • WHO recommendations on interventions to improve preterm birth outcomes (for mothers and newborns) were published. This key publication brought much-needed international guidance following the publication of the large multicountry trial that cast doubt on the safety and efficacy of antenatal corticosteroids for women at risk of preterm birth in low and middle-income countries. In addition, the Department secured a grant from the Bill & Melinda Gates Foundation to conduct a randomized clinical trial in sub-Saharan Africa and South Asia to address an important research gap on this topic. • WHO recommendations for prevention and treatment of maternal peripartum infections were launched during the International Federation of Gynecology and Obstetrics World Congress in Vancouver, Canada. The recommendations mainly address preventive interventions and can be seen as a springboard for the maternal and early newborn sepsis initiative that will be launched in 2016. • The MAPS *toolkit: mHealth assessment and planning for scale was launched.* This resource is intended to assist implementers to systematically assess their scale-up efforts, and to plan for corrective actions and next steps.

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	Financial implementation rate (%)	Key results
				• The Department released the WHO practical guide to engaging with mobile network operators for reproductive, maternal, newborn, child and adolescent health, a tool to address the common challenges faced among mHealth implementers in securing partnerships with telecommunications companies. • The WHO *recommendations for augmentation of labour* were published. • In November 2015, estimates of maternal mortality, including trends from 1990 to 2015, were published. Globally, there was a decline of maternal deaths by 44% from 1990.
Partnerships, dissemination, communication, information and advocacy	551 573	747 036	135%	• The mistreatment of women during childbirth in health facilities globally: a mixed-methods systematic review was published in the journal PLoS Medicine, with extensive international media coverage. The review, which was based on data from 34 countries, suggested that mistreatment of women during childbirth is widespread globally. • Estimates of maternal mortality for the period 1990–2015 were published as a peer-reviewed paper in The Lancet and as a full Interagency report. It is estimated that 303 000 maternal deaths occurred during 2015 and that there has been a 44% decline in the maternal mortality ratio (MMR) since 1990, falling short of the Millennium Development Goal (MDG) to reduce it by three quarters. These estimates will serve as the baseline for SDG target 3.1: by 2030 reduce the global MMR to less than 70 per 100 000 live births. • 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..

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
Total preventing unsafe abortion	6 974 000	3 728 647	53%	
Research and development	4 945 411	1 665 694	34%	• As part of the Global Abortion Policies Project (GAPP), preliminary data collection on abortion-related laws and policies was completed for over 190 countries. • Preliminary results from the feasibility study on midwife provision of medical abortion in rural Kyrgyzstan show that this approach is safe, effective and feasible. • The evaluation of the comprehensive abortion care scale-up project in Moldova showed that 72% of all induced abortions are now done using WHO-approved methods. • 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.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
Norms, standards and guidelines	869 395	497 873	57%	• The guideline on *Health worker roles in providing safe abortion care and post-abortion contraception* was launched. • The *Clinical practice handbook for safe abortion* was launched to facilitate the implementation of the 2012 WHO Safe abortion guidelines.
Partnerships, dissemination, communication, information and advocacy	1 159 194	1 565 080	135%	• **A series of briefings and workshops were conducted on the WHO Safe abortion guidance for a broad range of UN treaty monitoring bodies.** • **The** ***Clinical practice handbook on safe abortion*** **(published in 2014) was awarded first prize in the obstetrics and gynaecology category of the British Medical Association's 2015 Medical Book Awards.**

Key objectives in adolescents and at-risk populations

The Department's 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.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
Total adolescents and at-risk populations	12 634 000	14 026 470	111%	
Research and development	7 100 032	7 732 696	109%	• **The Department's three flagship adolescent research studies – ARMADILLO (providing ASRH messages through mobile phones), AHEAD (preventing rapid repeat pregnancy) and GEAS (understanding factors in early adolescence, including gender norms that are precursors to ASRH behaviours) – have completed their formative phases in multiple countries.** • **Country case studies of the policy and programmatic environment have been prepared in 10 countries and six of these were published as peer-reviewed journal articles.** • **The Department committed to carrying out a sexual health research prioritization exercise, using the Child Health and Nutrition Research Initiative (CHNRI) approach.** • **Two research protocols for developing and testing interventions to reduce unintended pregnancy in adolescents were developed and fieldwork was initiated.**

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	Financial implementation rate (%)	Key results
				• 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. • 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 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.

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	Financial implementation rate (%)	Key results
Norms, standards and guidelines	2 231 439	3 998 815	179%	• A set of job aids developed by WHO in collaboration with the United Nations Office on Drugs and Crime and supported by UN Action, entitled *Strengthening the medico-legal response to sexual violence*, was published in November 2015. It is also available in French and will be field tested in Kenya and possibly also in the Democratic Republic of the Congo. • The Department led the development of a draft global plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children. The plan will be submitted to the WHO Executive Board in January 2016. • The Guideline Development Group meeting for the WHO guidelines on the management of health complications from FGM was held in September 2015, during which current, evidence-based recommendations were formulated to improve health care of women and girls living with FGM. The draft guideline is currently being written. • An interagency statement on ending violence and discrimination against lesbian, gay, bisexual, transgender and intersex (LGBTI) people was released with the support of 12 UN agencies on 29 September 2015. • 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 WHO guideline was developed: *Brief sexuality-related communication: recommendations for a public health approach*.

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	Financial implementation rate (%)	Key results
Monitoring and evaluation	1 014 290	978 185	96%	• The survey methodology of the WHO multi-country study on women's health and domestic violence against women was used to conduct Cambodia's national population-based prevalence survey on violence against women. The survey results were published in November 2015. • 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.
Partnerships, dissemination, communication, information and advocacy	2 288 239	1 316 773	58%	• The Department contributed to the establishment of the Working Group on Violence against Women of the International Federation of Gynecology and Obstetrics (FIGO). • 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".

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	FInancial implementation rate (%)	Key results
				• 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. • 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 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.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
Strengthening of research and technical capacity	4 000 000	1 531 953	38%	• 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. • In 2014, 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. • In 2015, HRP awarded Long-term Institutional Development (LID) grants to 10 institutions and research training grants to 13 individuals. • In the WHO Eastern Mediterranean Region, three new institutions in Morocco, Pakistan and in the West Bank and Gaza Strip were awarded LID grants. • The Institute de Recherché en Science de la Santé (IRSS) in Burkina Faso, in the fifth year of its first cycle, was invited to apply for WHO Collaborating Centre status reflecting its presence as a growing institution in West Africa. • The Cellule de Recherché en Santé de la Reproduccion en Guinée (CERREGUI), a LID grantee institution in the fourth year of its first LID cycle, has been successfully integrated into the multicountry study on mistreatment of women during childbirth.

HRP output	2014–2015 budget (US$)	2014–2015 expenditure (US$)	FInancial implementation rate (%)	Key results
				• n 2015, two HRP Alliance meetings were held successfully, one for the WHO African and Eastern Mediterranean Regions combined, and one for the Region of the Americas. • Statistics, data management, research coordination and monitoring support were provided for 23 clinical trials and epidemiological studies during 2015. • The Unit conducted on-site research training on data entry and data management for staff in six collaborating countries participating in projects with the Department: Argentina, Kyrgyzstan, Mozambique (twice), Singapore, South Africa and the United Kingdom. • 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 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 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.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
General technical, advocacy and communications, and research project review and ethics	5 588 000	5 106 923	91%	• The Global Strategy for Women's, Children's and Adolescents' Health was launched at the UN General Assembly, 26 September 2015, in New York. • The Department led advocacy efforts for inclusion of SRHR in the post-2015 sustainable development agenda. • The Department published a landmark report on Sexual health, human rights and the law. • A special supplement to *The BMJ* was issued, entitled "Towards a new Global Strategy for Women's, Children's and Adolescents' Health". • A report of a study on child, early and forced marriage (CEFM) legislation in the Asia-Pacific region was developed in collaboration with the Inter-Parliamentary Union (IPU). • A special series was published in The BMJ on women's, children's and adolescents' health, with a specific focus on SRHR and human rights. • The Department led advocacy efforts for inclusion of SRHR in the post-2015 sustainable development agenda.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
				• The Department led the process for development of the Women and health report for the World Health Assembly, focusing on the unfinished agenda and emerging priorities related to women's health. • In 2015, the Department worked to implement the communications strategy that was developed in 2014 with the participation of partners, funders and staff, and with the guidance of a leading global communications firm. This included a new focus on intensive communications work around a number of key publications and events, including a heightened presence on social media. • In 2015, 32 new WHO publications in English were produced and distributed. • In 2015, the Department began to distribute its publications on USB sticks at conferences in preference to hard copies. During the year, over 4000 USBs were distributed, containing over 120 publications in multiple languages. • The Department produced and distributed 45 translations of existing Department publications. • Research results and knowledge syntheses were published in the scientific press, in 203 peer-reviewed articles. There was a noticeable increase in the number of times these articles were cited by others, including increased relevance and impact. • There were 2.7 million page views of the Department's "Reproductive health" webpage, 3.1 million of the WHO Reproductive Health Library (RHL) website, and 18 000 video views on the RHL and HRP YouTube channels.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
				• In 2015, HRP launched a podcast channel, making available professional-quality podcasts recorded in-house. Five podcasts on with health experts speaking on technical topics and subjects of public interest were produced in 2015. • The Department's outputs were widely disseminated, and SRHR were advocated for, at many different conferences, symposia and international meetings. • A wide range of international days were marked by the Department. Web features were prepared for these days, which were well supported by the WHO central communications services. • The Department's work saw an increased number of highlights on the WHO homepage. • Together with other departments within WHO's Family, Women's and Children's Health cluster, a new website was launched to promote activities and publications that cut across the departments and to provide a space where high-level advocacy efforts can be highlighted. The website is hosted at: http://www.who.int/life-course/ • HRP's Twitter account (@HRPresearch) saw a steady increase in followers during 2015, from approximately 315 at the end of 2014 to approximately 1000 at the end of 2015. The account was used to disseminate information about the Department's work and latest news. • A new format was designed for HRP News, the Department's electronic newsletter, and during 2015, 10 issues were sent out. The number of recipients now stands at 4254, an increase of over 1000 during 2015. • A TEDx Chisinau talk from Moldova entitled "Why we shouldn't shy away from sexual education" was viewed more than 9500 times.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
				• The Compendium of WHO recommendations for postpartum family planning (PPFP) was developed. This is an interactive online tool to search for recommendations specific to PPFP: http://srhr.org/postpartumFP/ • An online tool to search WHO guidelines for recommendations related to SRHR was developed and launched. This tool enables users to search across multiple WHO guidelines to find all recommendations relevant to the search term. The project includes embeddable search features that can be included on any website: http://search.srhr.org/ • A fully interactive website was launched to facilitate access to the recommendations of the WHO guideline entitled Health worker roles in providing safe abortion care and post-abortion contraception. The website allows for recommendations to be filtered by cadre and tasks, and provides access to the clinical, technical and policy guidelines on abortion: http://srhr.org/safeabortion/ • 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. • 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.

HRP output	2014–2015 budget (US$)	2014-2015 expenditure (US$)	Financial implementation rate (%)	Key results
				• 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. • In March 2015, 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. • 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 Department. • The WHO Technical Guidance Note: Strengthening the inclusion of 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 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. • 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. • 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.

Annex B. Indicator report

Summary of indicators for 2014–2015 and achievement values as of 31 December 2015

Output	*Output indicator*	*Target for 31 December 2015*	*Achievement value as of 31 December 2015*
1. New knowledge generated	**HRP Output 1.1** Implementation research and clinical trials on SRH published	(180) scientific articles published	326
	HRP Output 1.2 Global and regional estimates of reproductive, maternal and perinatal conditions published	(4) global/regional estimates published	2
	HRP Output 1.3 Interventions developed, tested and implemented to address unmet needs in sexual and reproductive health (e.g. adolescent interventions)	(3) new interventions developed, tested and disseminated	3
	HRP Output 1.4 New or ongoing research projects funded	(30) research projects approved by HRP Research Project Review Panel (RP2)	24
2. Research evidence synthesized	**HRP Output 2.1** Systematic reviews of key questions in sexual and reproductive health published	(30) systematic reviews published	89
3. Strengthened research and technical capacity	**HRP Output 3.1** National research capacity strengthened	(50) research centres strengthened through HRP grants	50
4. Guidelines, tools, policy statements and other developed, based on a robust assessment of the available evidence	**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)	(6) new or updated guidelines issued	15
5. Strengthened research/policy dialogue	**HRP Output 5.1** Policy options analysed and synthesized, derived from technical and clinical guides	(20) policy briefs/guideline derivatives issued	39
	HRP Output 5.2 National capacity to support and develop evidence-based policies strengthened	(8) regional or international consultations convened or supported for systematic introduction of policy options	74

Output 1.1 Scientific articles published.

HRP 2015 publications list

1. Abalos E, Chamillard M, Diaz V, Tuncalp Ö, Gülmezoglu AM. Antenatal care for healthy pregnant women: a mapping of interventions from existing guidelines to inform the development of new WHO guidance on antenatal care. BJOG. 2015. doi:10.1111/1471-0528.13820. [Epub ahead of print] Review.
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203. Zongo A, Dumont A, Fournier P, Traoré M, Kouanda S, Sondo B. Effect of maternal death review and training on maternal mortality among caesarean delivery: post hoc analysis of a cluster randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2015;185:174-80. doi:10.1016/j.ejogrb.2014.12.023.

Output 1.2 Global and regional estimates of reproductive, maternal and perinatal conditions published

1. Trends in maternal mortality: 1990 to 2015:estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division.

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 health-care facilities, and lower costs, potentially allowing more women to receive clinical care.

2. Dual HIV and syphilis testing

The Department supported the improvement of screening programmes aimed at dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis 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 with contraceptive service delivery: implementation guide. WHO, UNFPA; 2015 (http://apps.who.int/iris/bitstream/10665/158866/1/9789241549103_eng.pdf).

Output 1.4 List of research projects funded

1. A65 – Empowering adolescents towards better reproductive health
2. A65 – Intimate partner violence from the perspective of men in Paraguay
3. A65904 – Persistence of Ebola virus in body fluids of Ebola virus disease survivors in Sierra Leone
4. A65 – Ensuring users values and preferences in WHO guidelines: sexual and reproductive health and human rights of women living with HIV
5. A65 – Financing mechanisms for women's use of new HIV prevention ethods (Microbicide Survey)
6. A65 – Maternal Morbidity Measurement Tool – pilot study
7. A65903 – Clinical evaluation of a temperature logging vaginal ring for measuring user adherence.

Output 2.1 Systematic reviews published.

1. Abalos E, Chamillard M, Diaz V, Tuncalp Ö, Gülmezoglu AM. Antenatal care for healthy pregnant women: a mapping of interventions from existing guidelines to inform the development of new WHO guidance on antenatal care. BJOG. 2015. doi: 10.1111/1471-0528.13820. [Epub ahead of print]
2. Abdulcadir J, Rodriguez MI, Say L. A systematic review of the evidence on clitoral reconstruction after female genital mutilation/cutting. Int J Gynaecol Obstet. 2015;129(2):93-7. doi:10.1016/j.ijgo.2014.11.008.
3. Abdulcadir J, Rodriguez MI, Say L. Research gaps in the care of women with female genital mutilation: an analysis. BJOG. 2015;122(3):294-303. doi:10.1111/1471-0528.13217.
4. Alfirevic Z, Stampalija T, Medley N. Fetal and umbilical Doppler ultrasound in normal pregnancy. Cochrane Database Syst Rev. 2015;(4):CD001450.
5. Andreucci CB, Bussadori JC, Pacagnella RC, Chou D, Filippi V, Say L, Cecatti JG; Brazilian COMMAG Study Group and the WHO Maternal Morbidity Working Group. Sexual life and dysfunction after maternal morbidity:

a systematic review. BMC Pregnancy Childbirth. 2015;15(1):307. doi:10.1186/s12884-015-0742-6.

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7. Bohren MA, Vogel JP, Hunter EC, Lutsiv O, Makh SK, Souza JP et al. The mistreatment of women during childbirth in health facilities globally: amixed-methods systematic review. PLoS Med. 2015;12(6):e1001847; discussion e1001847. doi:10.1371/journal.pmed.1001847.
8. Bricker L, Medley N, Pratt JJ. Routine ultrasound in late pregnancy (after 24 weeks' gestation). Cochrane Database Syst Rev. 2015;(6):CD001451.
9. Buppasiri P, Lumbiganon P, Thinkhamrop J, Ngamjarus C, Laopaiboon M, Medley N. Calcium supplementation (other than for preventing or treating hypertension) for improving pregnancy and infant outcomes. Cochrane Database Syst Rev. 2015;(2):CD007079.
10. Carr SL, Gaffield ME, Dragoman MV, Phillips S. Safety of the progesterone-releasing vaginal ring (PVR) among lactating women: a systematic review. Contraception. 2015;pii: S0010-7824(15)00136-5. doi:10.1016/j.contraception.2015.04.001. [Epub ahead of print]
11. Catling CJ, Medley N, Foureur M, Ryan C, Leap N, Teate A, Homer CS. Group versus conventional antenatal care for women. Cochrane Database Syst Rev. 2015;(2):CD007622. Review.
12. Chandra-Mouli V, Lane C, Wong S. What does not work in adolescent sexual and reproductive health: a review of evidence on interventions commonly accepted as best practices. Glob Health Sci Pract. 2015;3(3):333-40. doi:10.9745/GHSP-D-15-00126.
13. Chibueze EC, Parsons AJ, Ota E, Swa T, Oladapo OT, Mori R. Prophylactic antibiotics for manual removal of retained placenta during vaginal birth: a systematic review of observational studies and meta-analysis. BMC Pregnancy Childbirth. 2015;15:313. doi:10.1186/s12884-015-0752-4.
14. Chou D, Daelmans B, Jolivet RR, Kinney M, Say L; Every Newborn Action Plan (ENAP) and Ending Preventable Maternal Mortality (EPMM) working groups. Ending preventable maternal and newborn mortality and stillbirths. BMJ. 2015;351:h4255. doi:10.1136/bmj.h4255. Review.
15. Colvin CJ, Wainwright M; for the GRADE-CERQual Project Core Group (Noyes J, Munthe-Kaas H, Garside R, Carlsen B, Rashidian A, Booth A et al.). Confidence in the Evidence from Reviews of Qualitative research (CERQual): development and future directions of a novel approach. Cochrane Methods Cochrane Database Syst Rev. 2015;Suppl 1:45-7.
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Output 3.1. Research centres strengthened through issuance of HRP long-term institutional development (LID) or other research capacity-strengthening (RCS) grants

Region of the Americas

1. Instituto de Biología y Medicina Experimental, University of Buenos Aires, Argentina
2. Universidad Mayor de San Andres Post Grado en Ciencias del Desarrollo, Bolivia
3. Asociación Latinoamericana de Investigadores en Reproducción Humana, multicountry
4. The Paraguayan Center for Population Studies, Paraguay
5. Universidad Peruana Cayetano Heredia, Peru

African Region

6. Institut de Recherche en Sciences de la Santé, Burkina Faso
7. Clinique Universitaires de Kinshasa, Département de Gynécologie & Obstétrique, Democratic Republic of the Congo
8. La Cellule de Recherche en Santé de la Reproduction de Côte d'Ivoire, Côte d'Ivoire
9. Addis Ababa University, College of Health Science, Faculty of Medicine, Department of Obstetrics and Gynecology, Ethiopia
10. University of Nairobi, Kenya
11. University of Malawi, Malawi
12. Centre for Evidence based Care, Stellenbosch University, South Africa
13. Wits Reproductive Health and HIV Institute, Johannesburg, South Africa
14. ReproNet-Africa: African Network in Sexual & Reproductive Health & HIV, South Africa

15. Kilimanjaro Christian Medical Centre: An Institute of the Good Samaritan Foundation, Moshi, Tanzania
16. University of Zimbabwe, Zimbabwe

European Region

17. Tajik Scientific Research Institute of Obstetrics and Gynecology of the Ministry of Health of the Republic of Tajikistan, Tajikistan

Eastern Mediterranean Region

18. Public Health Institute, Afghanistan
19. Ecole Nationale de Santé Publique, Morocco
20. Institute of Community and Public Health, Birzeit University, West Bank and Gaza Strip
21. Health Services Academy, Islamabad, Pakistan

South-East Asia and Western Pacific Regions

22. Research and Epidemiology unit, Ministry of Health, Bhutan
23. Department of Medical Research, Upper Myanmar, Myanmar
24. National Institute of Public Health, Cambodia.

Output 4.1 Technical, clinical and policy guidelines issued on sexual and reproductive health

Guidelines

1. Health worker roles in providing safe abortion care and post-abortion contraception
2. Brief sexuality-related communication: recommendations for a public health approach
3. WHO safe childbirth checklist implementation guide
4. WHO recommendations for prevention and treatment of maternal peripartum infections
5. WHO recommendations on interventions to improve preterm birth outcomes
6. Medical eligibility criteria for contraceptive use,fifth edition
7. Medical eligibility criteria for contraceptive use: Wheel
8. Medical eligibility criteria for contraceptive use, fifth edition – Executive summary
9. A practical guide for engaging with mobile operators in mHealth for RMNCH.

Language translations [not included in indicators]

1. Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Global guidance on criteria and processes for validation. French, Spanish
2. Use of cryotherapy for cervical intraepithelial neoplasia. WHO guidelines. French
3. The prevention and elimination of disrespect and abuse during facility-based childbirth. Bulgarian, Croatian, Italian, Japanese, Slovak
4. WHO recommendations for augmentation of labour. Spanish

5. Comprehensive cervical cancer control:a guide to essential practice,second edition. Spanish
6. WHO statement on caesarean section rates. Chinese, French, Italian, Portuguese, Russian, Spanish, Turkish
7. Ending violence and discrimination against lesbian, gay, bisexual, transgender and intersex people. UN statement. Arabic, Chinese, French, Russian, Spanish
8. Health care for women subjected to intimate partner violence or sexual violence: a clinical handbook. French
9. Trends in maternal mortality: 1990 to 2015:estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Russian
10. Trends in maternal mortality: 1990 to 2015:estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Executive summary. Arabic, French, Russian, Spanish
11. WHO guidelines:use of cryotherapy for cervical intraepithelial neoplasia. Chinese, French
12. Strengthening the inclusion of reproductive, maternal, newborn and child (RMNCH) health in concept notes to the Global Fund. WHO Technical Guidance Note. French
13. Comprehensive cervical cancer prevention and control – a healthier future for girls and women. WHO guidance note. Chinese
14. WHO guidelines for treatment of cervical intraepithelial neoplasia 2–3 and adenocarcinoma in situ: cryotherapy, large loop excision of the transformation zone, and cold knife conization. Chinese
15. WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention. Chinese
16. WHO technical specifications. Cryosurgical equipment for the treatment of precancerous cervical lesions and prevention of cervical cancer. Chinese
17. Global guidance on criteria and processes for validation: elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Chinese
18. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Chinese
19. WHO recommendations for prevention and treatment of pre-eclampsia and eclampsia. Chinese
20. WHO recommendations for induction of labour. Chinese
21. Clinical practice handbook for safe abortion. Chinese
22. Safe abortion: technical and policy guidance for health systems, second edition. Chinese
23. Responding to intimate partner violence and sexual violence against women. WHO clinical and policy guidelines. Chinese
24. Guide to fostering change to scale up effective health services. Chinese
25. PCC Report. Twenty-seventh meeting of the Policy and Coordination Committee, HRP. French
26. STAG Report. Thirty-first meeting of the Scientific and Technical Advisory Group, HRP. French

Total 45 language translations.

Strategies and progress reports [not in indicators]

1. H4+ partnership: joint support to improve women's and children's health. Progress report – 2014
2. Strategies toward ending preventable maternal mortality (EPMM)
3. Progress report of the implementation of the global strategy for prevention and control of sexually transmitted infections: 2006–2015
4. Consultation on the UN Secretary-General's Global Strategy for Women's, Children's and Adolescents' Health. Johannesburg, South Africa (6–7 May 2015).

Programme reports [not included in indicators]

1. Annual technical report 2014
2. Highlights of 2014. English, French, Spanish
3. PCC Report. Twenty-seventh meeting of the Policy and Coordination Committee, HRP
4. STAG Report. Thirty-first meeting of the Scientific and Technical Advisory Group, HRP.

Output 5.1 Policy briefs and guideline derivatives issued.

1. Safe abortion: technical and policy guidance for health systems:legal and policy considerations
2. WHO statement on caesarean section rates
3. Ending violence and discrimination against lesbian, gay, bisexual, transgender and intersex people. UN statement
4. Targets and strategies for ending preventable maternal mortality: consensus statement English, French
5. WHO recommendations for augmentation of labour: highlights and key messages from World Health Organization's 2014 Global Recommendations
6. WHO recommendations on interventions to improve preterm birth outcomes: highlights and key messages from the World Health Organization's 2015 Global Recommendations
7. WHO statement on progestogen-only implants:key facts
8. WHO Statement on depot-medroxyprogesterone acetate (DMPA): key facts
9. Sexual health, human rights and the law
10. Ensuring human rights within contraceptive service delivery: implementation guide
11. Strengthening the medico-legal response to sexual violence
12. The MAPS toolkit: mHealth assessment and planning for scale
13. Stakeholder consultation on priority implementation research to inform development of WHO normative guidance on topical pre-exposure prophylaxis
14. A tool for strengthening STI surveillance at the country level
15. Espacement des naissances et choix en matière de méthodes de planification familiale du post-partum. Outil de counseling.

Output 5.2 Regional/international consultations convened or supported for systematic introduction of policy options

1. Stakeholder consultation on the sexual and reproductive health and human rights of women living with HIV, 14–15 January, Geneva, Switzerland
2. Technical consultation on WHO maternal near-miss approach and quality of care: research and implementation, 22–23 January, Istanbul, Turkey
3. Launch of a Special Supplement to the Journal of Adolescent Health, 19 February, Amsterdam, Netherlands
4. Stakeholder consultation on the renewed Global Strategy for Women's, Children's and Adolescents' Health, 26–27 February, New Delhi, India
5. PAHO regional consultations on the draft WHO Global plan of action to strengthen the role of the health systems to address interpersonal violence, in particular against women and girls and against children, 26–27 February, Washington DC, USA
6. Fifty-ninth Commission of the Status of Women, Special Panel to mark the launch of *The Lancet* series on Violence against Women and Girls, 9–20 March, New York, USA
7. 132nd Inter-parliamentary Union General Assembly, 28 March–1 April, Hanoi, Viet Nam
8. "Realizing the future we want": Sexual and Reproductive Health and Rights at the Commission on Population and Development, Forty-eighth session, 13–17 April, New York, USA
9. G7/G20 Parliamentary Meeting for Women's and Children's Health, 16–17 April, Berlin, Germany
10. Family Planning 2020 Reference Group Meeting, 23–24 April, New Delhi, India
11. WHO Western Pacific Region and South-East Asia Region regional consultations on the draft WHO Global plan of action on strengthening the role of the health systems in addressing interpersonal violence, in particular against women and girls, and against children, 23–24 April, Bangkok, Thailand
12. WHO Eastern Mediterranean Region regional consultations on the draft WHO Global plan of action on strengthening the role of the health systems in addressing interpersonal violence, in particular against women and girls, and against children, 28–29 April, Cairo, Egypt
13. Stakeholders' Consultation on the Renewed Global Strategy for Women's, Children's and Adolescents' Health, 5–7 May, Johannesburg, South Africa
14. Africa Regional Meeting on Digital Health for Overcoming Barriers to Ending Preventable Child and Maternal Deaths and Achieving Universal Health Coverage, 12–15 May, Lilongwe, Malawi
15. Technical briefing, "Changing the trajectory of three epidemics: HIV, viral hepatitis and STIs through the development of global health sector strategies", 25 May, Geneva, Switzerland
16. Training curricula meeting on health-care for women subjected to partner violence and sexual violence, 1–2 June, Geneva, Switzerland
17. Global stakeholders consultation on the draft WHO global plan of action on strengthening the role of the health systems in addressing interpersonal violence, in particular against women and girls and against children, Informal

consultation with NGOs, academics, UN Partners and Member States, 3–4 June, Geneva, Switzerland.

18. Accelerating Access to Postpartum Family Planning in Sub-Saharan Africa and Asia, PPFP Global Meeting, 8–11 June, Chiang Mai, Thailand
19. HRP Alliance and Regional Research Committee (RRC) meeting for Africa and Eastern Mediterranean regions and regional consultation on research prioritization in sexual and reproductive health, 9–11 June, Nairobi, Kenya
20. Roadmap for Health Measurement and Accountability, 9–11 June, Washington DC, USA
21. Implementing Best Practices (IBP) Semi-Annual Consortium Meeting, 16–18 June, Addis Ababa, Ethiopia
22. Missions briefing on 2016–2021 Global Health Sector Strategies for HIV, viral hepatitis and STIs, 30 June, Geneva, Switzerland
23. 29th Regular session of the Human Rights Council, 15 June –3 July, Geneva, Switzerland
24. International Council of Nurses Conference, 19–23 June, Seoul, South Korea
25. WHO African Region regional consultations on the draft WHO Global plan of action to strengthen the role of the health systems to address interpersonal violence, in particular against women and girls and against children, 1–2 July, Harare, Zimbabwe
26. WHO and WHO Regional Office for Africa regional meeting to take stock of the progress made in adolescent sexual and reproductive health and rights in the 20 years since the International Conference on Population and Development, 6–7 July, Brazzaville, Republic of Congo
27. Financing for Development: "Time for Global Action", 3rd International Conference, 13–16 July, Addis Ababa, Ethiopia
28. International AIDS Society Conference, 19–22 July, Vancouver, Canada
29. International Confederation of Midwives Asia Pacific Regional Conference, 20–22 July, Yokohama, Japan
30. Site initiation meetings conducted for the UPTAKE Project, 23–31 July, Kenya, South Africa and Zambia
31. 3rd Asian Population Association Conference, 27–30 July, Kuala Lumpur, Malaysia
32. 1st ECOWAS Good Practices Forum in Health, 29–31 July, Ouagadougou, Burkina Faso
33. Technical consultation on companion of choice around the time of childbirth, 11–12 August, Geneva, Switzerland
34. World STI & HIV Congress, 13–16 September, Brisbane, Australia
35. WHO and WHO Regional Ofice for Africa Regional Consultation for accelerating access to family planning in sub-Saharan Africa, 16–17 September, Brazzaville, Congo
36. Sexual Violence Research Initiative (SVRI) Forum, 15–17 September, Stellenbosch, South Africa
37. WHO, USAID and MHTF joint convened meeting on developing a core set of maternal health indicators for global monitoring and reporting, 21–24 September, Washington DC, USA

38. UN General Assembly, 15 September – 2 October, New York, USA
39. The XXI FIGO World Congress, 4–9 October, Vancouver, Canada
40. Global Maternal and Newborn Health conference, 18–21 October, Mexico City, Mexico
41. Reunión sobre Estimación de la Mortalidad Materna, Región de las Américas (1990–2015), 21–22 October, San José, Costa Rica
42. 4th AeHIN General Meeting, 26–30 October, Bali, Indonesia
43. Global stakeholders consultation on the draft WHO global plan of action on strengthening the role of the health systems in addressing interpersonal violence, in particular against women and girls and against children, Formal Consultation with Member States, 2–4 November, Geneva, Switzerland
44. Global mHealth Summit, November 8–11, Washington DC, USA
45. RRC meeting for WHO Region of the Americas, 18 November, Lima, Peru,
46. XXIV Biennial Meeting of Asociacion Lationamericana de Investigadores en Reproduccion Humana(ALIRH), 19–21 November, Lima, Peru
47. Sexual health, human rights and the law, 3–4 December, Geneva, Switzerland
48. IBP Semi-Annual Meeting, 10–11 December, Washington DC, USA
49. Reproductive Health Indicators Strengthening Project: Finalization and regional dissemination meeting, 14–15 December, Accra, Ghana.

Annex C. Donors 2014-2015.

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