Chapter 6
  Strengthening implementation research

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## Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>ANC</td>
<td>antenatal care</td>
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<tr>
<td>AMTSL</td>
<td>Active Management of the Third Stage of Labour (trial)</td>
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<td>CHW</td>
<td>community health worker</td>
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<td>DFID</td>
<td>UK Department for International Development</td>
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<td>EBM</td>
<td>evidence-based medicine</td>
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<td>ERC</td>
<td>Ethics Review Committee</td>
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<td>GP</td>
<td>general practitioner</td>
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<td>GRADE</td>
<td>grades of recommendation, assessment development and evaluation</td>
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<td>GREAT</td>
<td>guideline development, research priorities, evidence synthesis, applicability of evidence, transfer of knowledge</td>
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<tr>
<td>IEC</td>
<td>information, education and communication</td>
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<td>IR</td>
<td>implementation research</td>
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<td>IRP</td>
<td>Implementation Research Platform</td>
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<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>MPH</td>
<td>Improving Maternal and Perinatal Health (team)</td>
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<tr>
<td>NICHD</td>
<td>National Institute of Child Health and Human Development</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<tr>
<td>NORAD</td>
<td>Norwegian Government Agency for Development Cooperation</td>
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<td>PCC</td>
<td>Policy and Coordination Committee</td>
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<tr>
<td>PDRH</td>
<td>Programme Development in Reproductive Health</td>
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<tr>
<td>PFP</td>
<td>Promoting Family Planning (team)</td>
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<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
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<td>PUA</td>
<td>Preventing Unsafe Abortion (team)</td>
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<tr>
<td>RCP</td>
<td>Research, Capacity, Policy and Programme Strengthening</td>
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<td>RCT</td>
<td>randomized controlled trial</td>
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<tr>
<td>RHR</td>
<td>WHO Department of Reproductive Health and Research</td>
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<td>RHL</td>
<td>Reproductive Health Library</td>
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<td>RP2</td>
<td>Research Project Review Panel</td>
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<tr>
<td>SIDA</td>
<td>Swedish International Development Cooperation Agency</td>
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<td>SRH</td>
<td>sexual and reproductive health</td>
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<tr>
<td>STAG</td>
<td>Scientific and Technical Advisory Group</td>
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<tr>
<td>TDR</td>
<td>Special Programme for Research and Training in Tropical Diseases</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNDP</td>
<td>United Nations Development Programme</td>
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<td>UNFPA</td>
<td>United Nations Population Fund</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Abstract

Introduction
The focus of this case-study is work on implementation research (IR) carried out by the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children’s Fund (UNICEF)/World Health Organization (WHO)/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and WHO Department of Reproductive Health and Research (RHR) between 2008 and 2012, and how this work can be strengthened in the future. IR is research aiming to develop strategies for available or new health interventions, in order to improve access to, and the use of, these interventions by the populations in need.

Methods
HRP/RHR staff, members of the Scientific and Technical Advisory Group (STAG) and other WHO staff were interviewed. HRP/RHR research studies that have gone through ethical review since 2008 were reviewed, as well as all HRP publications in the same period, pertinent HRP/RHR governance documents (working plans, reports to STAG, annual internal reports) and the strategic plan for 2010–2015.

Key findings, comments and conclusions
IR has gained attention in recent years, owing to the large underuse of several life-saving interventions in low- and middle-income countries. Since 2009, HRP/RHR has made substantial efforts to raise the priority of IR within the department, and made substantial contributions to include IR as a major topic in funding agencies.

Prioritization of implementation research within the department and the World Health Organization
HRP/RHR assembled the interteam working group that adopted a common definition of IR, and contributed to the conceptual approach that several WHO departments adopted in 2010. IR was prioritized in the HRP/RHR strategic plan for 2010–2015, including products and activities in progress or to be conducted by each HRP/RHR team.

Contribution to implementation research funding
HRP/RHR prioritization of IR contributed to the decisions of funding agencies to allocate funds to IR initiatives and specific projects, specifically the Implementation Research Platform (IRP), funded by the Norwegian Government Agency for Development Cooperation, the Department for International Development of the United Kingdom of Great Britain and Northern Ireland, and the Swedish International Development Cooperation Agency; and the IR study of antenatal care in Mozambique, funded by the Flanders International Cooperation Agency.

The Implementation Research Platform
This initiative has an excellent conceptual approach. It provides funding for IR proposals developed in low- and middle-income countries, with the technical and methodological support of HRP/RHR and the Special Programme for Research and Training in Tropical Diseases (TDR). However, the potential global impact is limited by the relatively low funding and the short time frame, which will only allow small studies at country or subregional level.
**HRP/RHR resources for implementation research**

HRP/RHR has high-quality resources that should facilitate IR studies: the Reproductive Health Library as a source of effective health interventions and implementation strategies in reproductive health; The WHO guidelines system; The Global Survey; the GREAT Project (Guideline development, Research priorities, Evidence synthesis, Applicability of evidence, Transfer of knowledge). All these resources put HRP/RHR in an advantageous position to design and conduct global IR studies effectively and efficiently.

**High-quality implementation research studies**

The eight studies identified are all high-quality IR studies, addressing priority questions. As most of these studies are still ongoing, no impact can be expected at this time. However, the findings of these studies will probably impact public health decision-making in the countries where they are being conducted.

**Collaboration with other global implementation research studies**

Providing support to other relevant initiatives, such as the National Institute of Child Health and Human Development's Global Network Antenatal Corticosteroids Trial, is an efficient way to contribute to answering global IR questions that are being studied by other groups or agencies.

**Lack of large-scale implementation research studies on priority issues**

HRP is still not conducting IR studies addressing reproductive priority questions on a large scale. That means designing implementation interventions that may overcome common barriers in several countries; and evaluating them in large-scale studies in several countries. These studies are essential to gain generalizable knowledge in an efficient way and in a relatively short time.

**Recommendations**

HRP/RHR should design and conduct IR studies addressing reproductive priority questions on a large scale. Large-scale studies should evaluate strategies for scaling up family planning and improving emergency obstetric health care (i.e. scaling up the use of magnesium sulfate for eclampsia treatment, task-shifting in the provision of health care, integration of onsite contraceptive services with abortion and puerperal care, and scaling up the uptake of emergency contraception).

Active participation of HRP/RHR in the IRP should continue. Advocacy to expand future calls for proposals, in order to award larger-scale research projects would be an asset.

HRP/RHR should continue the support and participation in other large-scale research studies focusing on low- and middle-income countries, initiated by other agencies or research groups. These collaborative efforts are an efficient use of resources.

Setting up a transdisciplinary team of scientists in IR may facilitate HRP/RHR activities in IR. This team should ideally include expertise in the design of implementation strategies, design and conduction of implementation intervention studies, qualitative approaches for assessment of barriers, statistical expertise in design and analysis of IR trials, and behavioural sciences. This team, assembled with either existing or new staff, would work with all thematic teams in a cross-cutting way, providing up-to-date standard methods for implementation science.
1 Introduction

The focus of this case-study is work on implementation research (IR) carried out by the United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/United Nations Children’s Fund (UNICEF)/World Health Organization (WHO)/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and WHO Department of Reproductive Health and Research (RHR) between 2008 and 2012, and how this work can be strengthened in the future.

1.1 What is implementation research?

In 2010, several WHO departments, agencies and programmes, including HRP/RHR and the Special Programme for Research and Training in Tropical Diseases (TDR), defined IR as research aiming to develop strategies for available or new health interventions, in order to improve access to, and the use of, these interventions by the populations in need (1). This definition agrees conceptually with most of the numerous definitions that exist, including that of the National Institutes of Health (2) and the Canadian Institutes of Health Research. In 2012, this conceptual approach to implementation research was ratified in a commentary published by representatives of the four United Nations (UN) agencies that work on reproductive health, including HRP (3).

Both position papers (1, 3) made distinctions between IR, operational research and health systems research. Although the three domains have overlapping areas, the types of questions addressed are different. Operational research aims to develop solutions to current operational problems of specific health programmes, and is very context specific. IR aims to develop strategies for health interventions, in order to improve the use of these interventions by the populations in need. As such, it intends to create generalizable knowledge that can be applied across settings and contexts. Health systems research addresses health system and policy questions that are not disease specific but concern systems problems as a whole (1–3). The three research types require a multidisciplinary approach involving both quantitative and qualitative methods.

These distinctions were appropriate and timely, as many definitions for these types of research exist, creating confusion among scientists and decision-makers about the scope, nature, methodologies and issues to be addressed by the research involved (1). We believe that this situation may also be applicable internally to WHO and HRP/RHR more specifically.

This chapter will focus on examining what HRP has done since 2008 on IR specifically, and how this can be strengthened in the future. That means reviewing HRP research activities aiming to create generalizable knowledge about strategies to improve the use of effective health interventions by the populations in need.

2 Rationale

2.1 The problem: underuse of life-saving interventions in low- and middle-income countries

There is still a large underuse of many well-known life-saving interventions for women and children, particularly in low- and middle-income countries (4). Several of the research studies demonstrating the efficacy of these interventions have been generated by HRP/RHR, or with the collaboration of HRP/RHR. The demand for family planning methods is currently satisfied in only 55% of eligible women; similar rates are shown for an antenatal care (ANC) package in four visits, and skilled birth attendance at birth. It is worth mentioning that these last two are
actually strategies to provide evidence-based interventions for ANC and childbirth. The rates of use of specific interventions for preventing or treating some emergency obstetric complications are even lower, like the use of magnesium sulfate for preventing or treating eclampsia, or the availability and use of blood products to treat severe obstetric haemorrhage – which, in low-income countries, are only used in tertiary referral hospitals. The use of antenatal steroids in preterm babies, to reduce mortality, shows rates below 10%, and the proportion of children sleeping under insecticide-treated nets to prevent malaria does not exceed 35% (5–8). The body of evidence supporting the use of these interventions has been available for 10–30 years. This gap between knowledge and practice can largely be explained by two factors: weak health systems, with constraints in infrastructure, equipment, supplies and personnel; and lack of effective evidence-based implementation strategies.

Regarding the latter, as HRP/RHR and representatives of other UN agencies recently acknowledged, “historically we have placed the overwhelming majority of our scientific emphasis and funding on the ‘what to do,’ – i.e., the development of highly effective interventions for preventing maternal and newborn deaths – and not on the ‘how to do it’” (3). As Richard Grol said 15 years ago, “most approaches to changing health care practices are more often based on beliefs than on scientific evidence. Evidence based practice should be complemented by evidence based implementation” (9).

2.2 Scaling up life-saving interventions

There is a wide international agreement on the urgent need for scaling up life-saving interventions as a way to reduce maternal and infant mortality and morbidity. The accomplishment of Millennium Development Goals (MDGs) 4 and 5 largely depends on these efforts, but the concept clearly exceeds the importance of reaching the goals in 2015 and should be sustained in the future as a main objective.

Basically (and perhaps a bit schematically), there are two ways of doing this that should be supported in parallel. One is strengthening the health systems; increasing and improving health infrastructure, personnel, supplies and equipment will increase the use of effective interventions and improve the health status of the population. This has been observed in South Asia and some Latin American countries in the last 25 years (10). While there is no doubt that this is a sustainable way, it is worth acknowledging that it is a long-term process. In general, the low-income countries in the most need have the weakest systems; thus, it would take decades to have solid health systems in such countries, while thousands of women and children unnecessarily die during the process.

A second way for scaling up is through implementing disease-specific vertical interventions. These interventions can be superimposed on ineffectual health systems, or can bypass them, and achieve improvements in the coverage of beneficial practices and health status in short periods. Examples of such vertical interventions are vitamin A fortification of sugar, polio immunization, child health, conditional cash transfers in Mexico, and the West African Onchocerciasis Control Programme (11, 12). As countries and their health systems improve and develop, these vertical interventions are absorbed and mainstreamed into the regular health system (12).

Methodologically, it appears that IR is necessary to develop and evaluate such effective implementation strategies.

2.3 Why has this topic has been included in this evaluation?

IR was included in the HRP/RHR agenda only recently, and, consistently with that, it was not previously included in HRP/RHR external evaluations as a separate topic. The 2003–2007 external evaluation included some aspects of implementation research within the chapters
dedicated to knowledge synthesis and transfer, and maternal and perinatal care. In mid-2008, the Policy and Coordination Committee (PCC) proposed the follow-up action to the 2003–2007 external evaluation of HRP, which included recommendations and proposed action to address the conclusions of the external evaluation.

The main overall recommendations related to IR include:

- accelerating removal of the remaining barriers for translating evidence from research into practice;
- reviewing and strengthening strategies at the interface with the rest of RHR for better knowledge transfer and exchange;
- developing strategies to feed the evidence obtained more systematically into the work of cosponsors, donors and partner countries, to maximize efforts to bridge the gap between research and practice;
- identifying operational barriers or facilitators to uptake of evidence;
- strengthening translational research and capacity building for country partners in this field.

IR gained more attention as an independent and growing field in which HRP/RHR showed willingness to invest human and financial resources. As already mentioned, IR was recognized as a component of the strategy to narrow the gap between the MDGs and the slow uptake of clinical research findings into routine care (1, 3).

3 Methods

To conduct this external evaluation, the reviewer visited the HRP/RHR offices at WHO Geneva and interviewed staff involved in IR projects. Staff suggestions and shared experiences were incorporated in this document. Experts in IR were also interviewed.

The HRP list of projects was revised to identify projects related to IR. Lead officers for each of these projects were contact by e-mail and asked to share relevant information: the final approved protocol, actual state of the project, intermediate and final evaluations, published manuscripts and any additional information that would be useful to get a better understanding of the project. The HRP/RHR web site was used as a source of information to identify activities related to the Implementation Research Platform (IRP).

The reviewer also received a list of all HRP/RHR manuscripts published in a peer-reviewed journal from 2008 to 2012. The reviewer examined the list in sequential steps, in order to highlight only those publications that referred to IR.

Reviewers were provided with a file containing all HRP/RHR peer-reviewed publications published between 2008 and 2012. The following methodology was applied to obtain only those publications related to IR. First, duplicated titles were deleted. Second, titles related to basic science research, literature reviews, global trends and systematic reviews/meta-analysis were deleted. Third, titles that were clearly not related to IR were deleted. Fourth, abstracts and/or full text from publications potentially related to IR were read. Finally, IR projects and reviews related to this topic were identified.

Overall, the main limitations found during the production of this case-study were:

- the lack of a clear distinction between HRP IR activities and HRP technical cooperation activities regarding implementation;
- difficulty in measuring the outcomes and impact of various projects that are still ongoing;
- difficulty in contacting some of the lead investigators by e-mail.
4 Key findings

4.1 Research governance milestones at HRP related to implementation research

As a follow-up to the recommendations of the 2003–2007 HRP/RHR External Evaluation Report (12), and the follow-up actions to these recommendations proposed by PCC in mid-2008, HRP/RHR took several actions in order to prioritize and enable conduction of IR activities.

4.1.1 Interteam working group on implementation research.

In 2009, HRP/RHR established the Interteam Working Group on Implementation Research coordinated by Dr Eduardo Bergel (System and Information Service). The working group served as a forum for the development of a collective vision for the department, and facilitation of the mapping and expansion of the work in IR.

Although several groups within the department were working on implementation activities, it seems clear that, at that time, there was still no agreement about the scope and focus of implementation, operational, and health systems research. Nevertheless, the working group adopted a definition of implementation, which is one of the most accepted and cited in the literature:

Implementation Research is the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care. It includes the study of influences on healthcare professional and organizational behaviour (13).

The working group also posed several crucial questions to the Scientific and Technical Advisory Group (STAG), in order to get recommendations to guide IR activities:

- can STAG identify one or more evidenced-based interventions that should be prioritized for the development and evaluation of implementation/scaling-up strategies?
- are there any major issues not addressed by the group?
- does STAG agree with the working definition of IR proposed?
- which areas of work within IR should be prioritized?

The main answers and recommendations from STAG included:

- endorsing the working definition of IR, but STAG noted that it ignored other dimensions of health systems (this shows that even inside STAG, the focus of IR was not clear);
- recommending raising the profile of IR as a key component for improving reproductive health;
- stressing that vertical interventions might improve some outcomes at the expense of other aspects of the health system (again, this showed that a focus on IR was seen as competing with health system research and not complementing it);
- merging efforts with other groups like the Knowledge Synthesis and Exchange group.

In 2010, following this last recommendation, the Implementation Research and the Knowledge Synthesis and Exchange working groups merged into a single entity. This entity further developed into the GREAT project (see Section 5.2).
4.2 Implementation research within the HRP strategic plan for 2010–2015

The HRP/RHR strategic plan for 2010–2015 (14) recognized the need for IR to reveal barriers in reproductive health care and its utility to develop appropriate delivery systems for innovative technologies and knowledge. It was proposed to use IR to develop new technologies for the translation of research findings into practice. However, this topic was not considered separately within the cross-cutting areas in the budget description.

The Reproductive Health Research budget for 2012–2013 notably highlights several endeavours and projects involving IR. Moreover, in this latest report (14), IR is considered as a cross-cutting area. Having said that, it is difficult to find the exact budget for IR projects, given that several teams within HRP/RHR finance most of them, and the overall IR budget is split into different budget sections. Nevertheless, it is worth mentioning that, according to a graph presented in this report, HRP/RHR will devote approximately U$S 18–19 million and the Programme Development in Reproductive Health (PDRH) will devote approximately U$S 4–5 million in IR projects. In addition, the same report specifically refers to those IR aspects that are planned for implementation in 2012–2013. Those projects clearly involving IR, and their level of priority, are discussed next.

Approximately 16 products and activities within the HRP strategic plan for 2010–2015 (14) are related to IR. Among these, seven are considered vital, six essential and two important. The vital products and activities are related to the following areas:

- IR research in maternal and perinatal health:
  - improving community-level maternal and perinatal care;
  - integration of maternal and newborn health with HIV/malaria and other health system issues in Mozambique;
- IR to expand access to medical abortion;
- IR to address, in ANC, violence against women;
- IR to establish a model and best practice for integrating gender and gender-based violence interventions into national AIDS plans/strategies;
- conducting studies of implementation of assessment tools for reproductive morbidity;
- IR: support and monitoring of projects funded by the IRP.

In addition, to activities categorized as vital, essential activities include: IR to address infertility in health-care settings; IR to increase the use of antenatal corticosteroids for prevention of neonatal mortality; IR on midlevel provision of safe abortion care; and IR to improve reproductive health programmes in different regions across the globe.

5 Special initiatives and projects

5.1 The Implementation Research Platform

One of the most innovative initiatives of WHO is the IRP, which is supported by the Government of Norway (Norwegian Government Agency for Development Cooperation, NORAD), the Swedish International Development Cooperation Agency (Sida) and the Department for International Development (DFID) of the United Kingdom of Great Britain and Northern Ireland. The IRP was created to address issues related to health-care delivery and to explore challenges related to the scale-up of effective interventions. Specifically, the IRP supports research that:
identifies common implementation problems and their main determinants that hinder effective access to interventions;

- develops and tests practical solutions to these problems that are either specific to particular health systems and environments or that address a problem common to several countries in a region;

- determines the best way of introducing these practical solutions into the health system and facilitates their full-scale implementation, evaluation and modification as required.

In 2010, the IRP launched its first calls for proposals orientated towards the development of partnerships in low- and middle-income countries that are country led and linked to national strategies; involve policy-makers and implementers; build capacity to undertake and lead such research; and establish networks and multicountry collaborations.

Seven research projects from Burkina Faso, Guatemala, India, Kenya, the Middle East (Egypt, Lebanon, Occupied Palestinian Territories, Syria), Nepal and Uganda were funded. The addressed topics were: malaria, HIV, emergency obstetrics care, and maternal and child health care. More details can be accessed on the IRP web site (15).

Three of the projects are managed in collaboration with HRP/RHR (Guatemala, Middle East, Uganda). They are described in Section 6. A second call for applications was released in July 2012.

It is worth mentioning that, although the conceptual and methodological approach is very appropriate, the short time frame and the limited amount of funds (2 funded years; US$ 350,000 per project) do not allow research studies to be designed and conducted across several settings. Moreover, the proposals are generated at country level, which may, in some cases, imply that the problems or solutions addressed have a local or regional nature rather than global implication.

5.2 The GREAT project (guideline development, research priorities, evidence synthesis, applicability of evidence, transfer of knowledge)

This new project propose an approach to tackle the knowledge-to-action gap, which includes an integrated process of identification of priority problems, guidelines development and implementation activities. The project is based on the “Knowledge to Action Framework” proposed by Graham in 2006 (16), which is an appropriate platform to consider the intricate process of creation and application of knowledge. The project relies on two solid WHO resources and initiatives: the WHO Reproductive Health Library (RHL), and the WHO guidelines production system.

The RHL provides free access to high-quality systematic reviews on sexual and reproductive health (SRH), mainly Cochrane reviews. It is without doubt a reference tool to allow practitioners and policy-makers in low- and middle-income countries to assess the evidence-based interventions that have proven effectiveness to improve reproductive, maternal and perinatal health. In addition, the RHL now also includes systematic reviews of dissemination and implementation strategies, developed by the Cochrane Effective Practice and Organisation of Care Group.

The WHO guidelines production system started in 2007 and HRP/RHR is developing evidence-based guidelines in SRH using the GRADE (grades of recommendation, assessment development and evaluation) approach for appraising the quality of evidence and determining the strength of recommendations and following the WHO Guidelines Review Committee standards. Guidelines for the prevention and treatment of postpartum haemorrhage (17) and
pre-eclampsia/eclampsia were already developed (18). WHO guidance is a unique mandate for setting standards internationally, and low- and middle-income countries very much rely on these standards.

Therefore, the GREAT project is a strong resource for providing evidence on which are the best interventions, how priority problems should be managed, and what is known about strategies to effectively implement them in routine practice. However, it is yet not clear how the proposed process will lead to defining global implementation research questions and prioritizing and converting them into research protocols. Neither is it clear how the process will be linked with the funding decisions within HRP/RHR.

5.2 Global survey on maternal and perinatal health

This is a research project implemented by WHO periodically in a global network of health facilities. The Global survey 2010 was implemented in 377 facilities from 29 countries (19, 20). This is the largest study ever conducted looking at the prevalence of pregnancy-related complications and severe maternal outcomes using standardized definitions across countries. One of its objectives is to provide information on the rate of use of evidence-based interventions in low- and middle-income countries.

One of the current major problems for scaling up effective interventions is that in low-income and some middle-income countries, there are no good information systems that routinely or periodically report the use of key evidence-based interventions using similar definitions. The survey allows researchers to gather data on more than 314,000 pregnant women, 312,000 infants born alive and 4000 stillbirths. The 2010 survey showed that, despite the high coverage of essential interventions, there are variations in terms of health outcomes and indicators of health performance of care. The information coming from the global survey will allow detection global or regionally of underused interventions, and will provide a system to monitor the trends and allow an evaluation of implementation strategies.

A series of activities are planned to disseminate the results of the study. Two main manuscripts have been submitted to a peer-reviewed journal and the first 10 secondary analyses are being prepared.

5.3 The WHO Strategic Approach to strengthening sexual and reproductive health policies and programmes

This HRP/RHR initiative started more than 15 years ago, to assist countries to undertake a systematic, evidence-based approach to develop, test and scale up a wide range of different complex interventions to improve the reproductive health of communities and individuals (21).

The Strategic Approach is a three-stage process. Stage I is a strategic assessment to identify community and programme needs and priorities. Stage II involves investigating, through pilot studies and research, the recommendations for policy change and the community and programmatic interventions to improve access, utilization and quality of care in service delivery. In the third stage of the Strategic Approach, the findings and results from the first two stages are used to scale up interventions for wider impact. The Strategic Approach has today been used by over 35 countries, to address a variety of different reproductive health issues, and in 10 of these the process has been used two or more times to address additional reproductive health issues. Two examples of the Strategic Approach that were carried out in Zambia and Malawi are discussed next.

In 2008, a strategic assessment was conducted in Zambia to facilitate the Ministry of Health to build national consensus about strategies and interventions to reduce unwanted pregnancy and unsafe abortion. A qualitative approach was used to interview over 400 persons in urban
and rural areas. The strategic assessment generated recommendations for improving access and comprehensive care of unintended pregnancies and abortion. Specifically, it is mentioned in the report that the recommendations of the strategic assessment should be implemented on two fronts: addressing the causes of unintended pregnancies; and addressing the barriers to safe abortion.

In 2009, a strategic assessment was conducted in Malawi to address the issue of unsafe abortion. This strategic assessment showed that one important barrier in access to abortion services is the restrictive abortion law. The restrictive law does not prevent women from procuring abortions but instead it forces them to seek abortion service clandestinely. While post-abortion care services were available, the assessment showed that the stigmatization of abortion was an important barrier for both the user and the provider. Another finding was that adolescents were particularly compromised with respect to post-abortion care services and other reproductive health services in general. The main barriers and weaknesses identified in the strategic assessment were: inadequate legal framework to address unsafe abortion; weak implementation of recommendations related to unsafe abortion and the prevention of unplanned pregnancies; cultural practices and gender inequities; and unavailability and inaccessibility of adequate family planning commodities and services. In addition, the assessment showed some opportunities, such as: Malawi has demonstrated some level of political will by putting in place several policies and action plans to address maternal mortality rates; generation of tangible evidence on unsafe abortion by the Ministry of Health; and unsafe abortion is easily preventable and would involve relatively inexpensive methods and procedures (complications of unsafe abortions are more expensive to treat). The strategic assessment portrayed a series of recommendations taking into consideration the barriers and weaknesses, as well as the opportunities in Malawi to address the issue of unsafe abortion.

It should be mentioned that some activities of the Strategic Approach do not fall under the definition of IR, as they intend to demonstrate a process rather than to answer a research question involving implementation aspects.

In addition, a new endeavour was created called ExpandNet. ExpandNet is a global network of public health professionals and scientists seeking to advance the practice and science of scaling up successful health innovations tested in experimental, pilot and demonstration projects. More details can be accessed on the ExpandNet web site (22).

6 Research projects

A total of 160 studies between 2008 and 2012 have been identified that were approved by the Ethics Review Committee (ERC) or Research Project Review Panel (RP2) and thus can be considered research studies. Among them, 25 studies (16%) were identified as having a focus on implementation – either operational or implementation research. The HRP groups involved in the majority of these projects are: Research, Capacity, Policy and Programme Strengthening (RCP; \( n = 13 \)); Improving Maternal and Perinatal Health (MPH; \( n = 4 \)); Preventing Unsafe Abortion (PUA; \( n = 3 \)); and Promoting Family Planning (PFP, \( n = 1 \)). Thematic areas are distributed in: unsafe abortion, family planning, pre-eclampsia, prenatal care, obstetric emergencies and sexually transmitted infections. More details of these projects are shown in Annex 1.

Based on their focus, research questions and methods, it was considered that 8 (5%) studies were actual IR studies. The analysis that follows focuses on these studies.

The study areas are maternal and perinatal care and safe abortion. The main aims include increasing skilled birth attendance; improving the quality of maternal, neonatal and emergency obstetric care; improving ANC and antenatal screening of syphilis; and task-shifting for medical abortion. Six are single-country studies conducted in Guatemala, Mongolia,
Mozambique, Nepal, the United Republic of Tanzania and Uganda and two are multicountry studies conducted in the Middle East region (Egypt, Lebanon, Occupied Palestinian Territories, Syria), and in Latin America (Argentina, Brazil), Africa (Democratic Republic of the Congo, South Africa) and Asia (India, the Philippines, Thailand). Most of the interventions under study are multifaceted, mainly including components orientated toward health-care workers’ capacity building or knowledge transfer, but also involving different models of organization of care and community-level interventions. The design of the interventions has been based on, or refined by, formative research in five of them. All are prospective intervention studies, most of them with experimental designs: cluster randomized controlled trial (RCT; 4); individual randomized trial (1); stepwedge design (1); interrupted time series (1); and a non-randomized intervention study (1).

HRP/RHR has different grades of involvement in the studies. There are some projects awarded by the IRP in 2010, in which the principal investigators are from different countries and HRP has provided methodological support and management. In other studies, the original idea was developed at HRP, and the studies were designed in collaboration with country investigators, or vice versa. Two studies are already completed, while six are still ongoing.

Each of these eight studies are described next.

6.1 A matched pair cluster-randomized implementation study to measure the effectiveness of an intervention package aiming to decrease perinatal mortality and increase institution-based obstetric care among indigenous populations in Guatemala

This is a matched pair cluster randomized trial aiming to evaluate the effectiveness of a package of interventions to increase the prevalence of institution-based care and reduce perinatal mortality in the four districts with the highest maternal mortality ratio in Guatemala. Specifically, the package includes three interventions: (1) to train health-care professionals in emergency obstetric and perinatal care using a high-fidelity, low-tech, in situ, multidisciplinary simulation training curriculum; (2) to design and implement a social marketing strategy that promotes institution-based delivery; and (3) to integrate the role of an obstetric nurse and professional midwife in intervention communities to act as liaisons between traditional birth attendants and public health units.

6.2 A demonstration project for the implementation of the WHO antenatal care model in Mozambique

This is a stepwedge design intervention study. The goal of this project is to determine the effect of an intervention designed to increase the use of evidence-based practices included in the ANC (package by midwives and other health professionals) in prenatal clinics in Mozambique. The intervention consists of four different components: (1) a seminar for health-care providers and distribution of printed materials to clinics to increase awareness of the WHO ANC recommendations, the package of interventions included in the Mozambique ANC model and the project objectives; (2) identification of midwives or other health-care professionals interested in participating as project facilitators; (3) a planning workshop on how to implement the ANC package and other training activities; and (4) implementation of the programme at ANC clinics, including the use of reminders for midwives or other health-care providers and patients.
6.3 Assessing the acceptability, feasibility and effectiveness of a strategy for improving the quality and safety of maternal/neonatal health care in the health system contexts of four Middle East countries

This has a quasi-experimental design using a longitudinal prospective interrupted time series (pre–post intervention design with no control). The study has two primary objectives: (1) to test the acceptability, feasibility and effectiveness of a multifaceted quality-improvement strategy combining clinical audit, feedback and engaging opinion leaders with a focus on the management of maternal/neonatal near-misses; and (2) to investigate how differences in the health system context across four Middle Eastern countries identified in public hospitals in Egypt, Lebanon, Occupied Palestinian Territories and Syria, affect the acceptability and feasibility of this quality-improvement strategy. The intervention encompasses different aspects: (1) audit and feedback of maternal/neonatal near-miss cases by collecting information on a prospective basis at equal time intervals; (2) interactive workshops to train health-care providers and hospital administrators on how to conduct criterion-based audit – (a) establishing standards of good practice; (b) measuring current practice; (c) identifying gaps in current practice and feedback concerning these gaps to health professionals; (d) implementing recommendations for change; and (e) re-evaluating practice and making recommendations; (3) training would also standardize the audit and feedback procedures across hospitals; and (4) focus group discussions with junior doctors in each hospital at the conclusion of the intervention.

6.4 Innovations for increasing access to integrated safe delivery, PMTCT and newborn care in rural Uganda

This is a community-based, three-arm, non-randomized trial (quasi-experimental study). The primary objectives of the study are: (1) to develop and implement an integrated intervention that includes vouchers for institutional deliveries and care of complications, and home visits by community health-care providers in pregnancy and the postnatal period in four health subdistricts in rural Uganda; (2) to understand the implementation and learning processes used to deal with challenges encountered during the implementation of the intervention; (3) to assess the intervention effects on the proportion of deliveries occurring in health facilities and on the uptake of prevention of mother-to-child transmission (PMTCT) of HIV; (4) to assess the effects of implementation of the intervention on the health system; and (5) to engage stakeholders and disseminate implementation experiences and findings in order to inform policy and scale-up in Uganda. The intervention has three components: (1) use of community health workers (CHWs) for community-based maternal, newborn and PMTCT promotion – (a) CHWs will register women of childbearing age, identify pregnant women and make home visits (before and after delivery to promote proper care for mothers and newborn babies; and (b) CHWs will carry out community mobilization and dialogue to promote community-wide behaviour change; they will also encourage mothers to test for HIV/AIDS during ANC, and for those who disclose their status, they will encourage adherence to the antiretroviral treatment for mothers and babies; (2) provision of vouchers for maternity services and transport to access institutional delivery, and care for maternal postpartum complications and for sick newborn babies; and (3) training, provision of basic drugs and supplies, and integrated support supervision to strengthen health-care facilities.

6.5 A cluster randomized controlled trial to evaluate the effectiveness of the clinically integrated RHL evidence-based medicine course

This is a multicentre cluster randomized trial. The main objective is to evaluate whether the RHL-evidence-based medicine (EBM) course is effective in improving knowledge, skills and competencies as compared to passive dissemination of resource materials. The main outcome
is to assess the gain in EBM knowledge and change in attitudes and skills competence. 
Participants are training institutions in obstetrics and gynaecology in the participating 
countries. (1) The RHL-EBM course, which is a clinically integrated e-learning course, will be the 
experimental intervention; and (2) the second intervention is self-directed learning (passive 
dissemination of EBM teaching materials. The RHL-EBM course will be compared to passively 
disseminated EBM resources from the WHO RHL workshop-based course that has the same 
learning objectives. The study is ongoing in Latin America (Argentina, Brazil), Africa 
(Democratic Republic of the Congo, South Africa) and Asia (India, Philippines, Thailand) (23).

6.6 Comparison of the safety, efficacy, and feasibility of medical abortion by 
physicians or non-physicians in Nepal
This is a multicentre randomized controlled equivalence trial conducted in five rural districts. It 
is actually an effectiveness study with a focus on implementation issues (who can provide 
effective care instead of doctors). The primary objective is to compare the safety, effectiveness 
and feasibility of medical abortions provided by a physician-led team with those provided by 
teams of midlevel providers with a referral system. The main outcome was to assess the 
proportion of complete abortions without manual vacuum aspiration within 30 days of 
treatment. This project is completed. Findings from this study showed no differences between 
the proportion of complete abortions assisted by midlevel providers or physician-led teams. 
One paper has already been published in *The Lancet* (24).

6.7 The effectiveness of antenatal birth plans in increasing skilled care at delivery 
and after delivery in rural Tanzania
This is a cluster randomized trial conducted in 18 health units in rural areas of the United 
Republic of Tanzania. The primary objective of the project was to determine the effectiveness 
of birth plans in increasing skilled care at delivery and after delivery. Intervention units 
provided ANC with renewed emphasis in birth plans provided by care providers. Control units 
continued offering ANC as currently provided. Women were interviewed twice, at first 
encounter and one month after delivery. The main outcome is the proportion of women who 
sought delivery at the available health units. The project is completed. Two manuscripts have 
already been published (25, 26) and one is under review. No specific findings were reported to 
the reviewer prior to the finalization of this case-study.

6.8 Comparison of “one-stop” versus “conventional” service on antenatal syphilis 
screening in Ulaanbaatar, Mongolia
This is a cluster randomized trial at 14 ANC clinics in Mongolia’s capital city. The objectives of 
the study were: (1) to compare the effectiveness of “one-stop” versus “conventional” service; 
and (2) to compare the coverage of antenatal syphilis screening between “one-stop” and 
“conventional” service. In the intervention clinics, the first 2-day workshop was held for ANC 
providers. The second 2-day workshop was also held for obstetricians and gynaecologists and 
covered specific knowledge on maternal and congenital syphilis. The intervention clinics were 
supplied with the necessary materials and supplies. In the control clinics, ANC providers 
participated in a 2-day training workshop on the project overview, logistics of the project and 
case-reporting. The obstetricians and gynaecologists received refresher training on the same 
topics as the intervention group. Treatment of individuals with syphilis and their partners was 
given free of charge in all facilities. The primary outcomes of the study are (1) utilization of 
antenatal syphilis screening at the first antenatal visit and at the third trimester of gestation; 
(2) detected syphilis cases; and (3) the number of congenital syphilis cases. The project was 
completed but no specific findings were reported to the reviewer prior to the finalization of 
this case-study (27).
It is important to note in relation to these studies that, although they are a small proportion of all HRP projects, all are high-quality IR studies. The designs of the interventions have been based or refined by formative research in most studies, and the study designs are rigorous. The focuses of the studies are related to high priority-areas and problems. On the other hand, it is worth mentioning that there are no studies dealing with family planning issues, a high-priority area with unmet needs. Additionally, most of the interventions and studies were designed for single countries. It is likely that the interventions were developed or adapted more for the country context than for a global context. This may prevent easy generalization of the findings, thus limiting the impact of the interventions.

6.9 Collaboration with other agencies or research groups on implementation research initiatives

Since 2007 the MPH group of HRP/RHR has supported the Antenatal Corticosteroids Trial designed and conducted by the National Institute of Child Health and Human Development (NICHD) Global Network for Women’s and Children’s Health Research. This study is a cluster randomized trial conducted in 102 health districts in six countries (Argentina, Guatemala, India, Kenya, Pakistan and Zambia), to evaluate whether a complex intervention facilitating the identification of women at high risk for preterm birth and the administration of antenatal corticosteroids increases the use of steroids in preterm babies and reduces neonatal mortality.

The support provided by HRP/RHR facilitated the implementation of the trial at country level.

7 HRP peer-reviewed publications 2008–2012

Reviewers were provided with a file containing all HRP peer-reviewed publications published between 2008 and 2012. Over a total of 417 titles, 34 were eligible for full-text review. From these, eight were considered directly related to HRP IR projects (see Annex 2 for more detail).

In addition, one more publication was found (26), related to a birth plan IR project in the United Republic of Tanzania, that was not included in the original files.

Three papers reported studies started before 2008. Six papers were protocols, preparatory activities or part of the formative research of some of the projects described above. One paper (24), reports the results of the RCT comparing midlevel health-care workers with doctors providing medical abortion services in Nepal.

8 Conclusions

IR has gained attention in recent years, due to the large underuse of several life-saving interventions in low- and middle-income countries. Since 2009, HRP/RHR has made substantial efforts to raise the priority of IR within the department, and made substantial contributions to include IR as a major topic in funding agencies. For the future, HRP/RHR has all the capacities to design and conduct large-scale IR projects that will provide answers to scale up priority reproductive interventions at a global level. The main positive findings and some pending issues are presented next.

8.1 Positive findings

- *Prioritization of IR within the department and at WHO*: HRP/RHR assembled the interteam working group that adopted a common definition of IR, and contributed to the conceptual approach that several WHO departments adopted in 2010. IR was prioritized in the HRP/RHR strategic plan for 2010–2015 (14), including products and activities that are ongoing or will be conducted by each HRP/RHR team.
Contribution to IR funding: HRP/RHR prioritization of IR contributed to the decisions of funding agencies to allocate funds to IR initiatives and specific projects. The consultation with Norway in 2009 made possible the founding of the IRP, coordinated by the Alliance for Health Policies and Systems Research, TDR and HRP, and funded by NORAD, DFID and Sida. The collaborative work with the Flanders International Cooperation Agency made possible the IR study of ANC in Mozambique.

The IRP: this initiative has an excellent conceptual approach. It provides funding for IR proposals developed in low- and middle-income countries, with the technical and methodological support of HRP/RHR and TDR. The knowledge created through this initiative will be very relevant for the countries or regions included in the funded studies. The potential global impact, however, is limited by the relatively low funding and the short time frame, which will only allow small studies at country or subregional level.

HRP/RHR resources for IR: the department has high-quality resources that should facilitate IR studies. The RHL is a source of effective health interventions and implementation strategies in reproductive health; the WHO guidelines system, which produces high-quality evidence-based guidelines that facilitate scaling up of health interventions in low- and middle-income countries; the Global survey (19), which facilitates a comparable assessment of the use of interventions, and provides a system to monitor trends; and the GREAT project, which provides a conceptual approach to IR challenges. All these resources put HRP/RHR in an advantageous position to design and conduct global IR studies effectively and efficiently.

High-quality IR studies: the eight studies identified in this chapter are all high-quality IR studies, addressing priority questions. As most of these studies are still ongoing, no impact evaluation can be addressed at this time. However, it is expected that the findings from these studies will probably impact public health decision-making in the countries where they are being conducted. One of these studies may have direct implications on regional policies in the Middle East, as it is ongoing in four countries.

Collaboration with other global IR studies: providing support to other relevant initiatives, like the NICHD’s Global Network Antenatal Corticosteroids Trial, is an efficient way to contribute to answering global IR questions that are being studied by other groups or agencies.

8.2 Pending issues

HRP/RHR is not conducting IR studies addressing reproductive priority questions on a large scale yet. Although, some of the HRP/RHR projects took place in different countries of the same region (mainly Asia), HRP/RHR work is primarily orientated towards specific countries’ needs and there is still much work to do regarding interventions that may be useful to overcome common barriers in several countries. Studies that use a global approach are extremely necessary to gain generalizable knowledge in an efficient way and in relatively short periods. HRP/RHR has extensive experience in conducting large-scale studies investigating new interventions in maternal health, family planning, and methods for safe abortion. HRP/RHR have done a good job in creating generalizable knowledge regarding interventions to improve health (such as the AMTSL (Active Management of the Third Stage of Labour) trial (28)), but in the same period they have not done anything comparable regarding IR. Studies of this magnitude and potential impact are much needed and HRP/RHR has the knowledge and resources to lead them.
HRP/RHR health specialists were asked to list the main interventions that they believe should be scaled up and that should be prioritized in IR studies. The topics considered as priorities to scale up are listed next.

8.2.1 Preventing unsafe abortion

- Conducting IR on a large scale to demonstrate the health-systems feasibility of task-shifting in provision of safe abortion care and post-abortion care: HRP/RHR research has shown that nurses, midwives and auxiliary nurses can provide early medical abortion and manual vacuum aspiration as safely and effectively as physicians and that this is acceptable to women. IR can be useful to translate these findings into programmatic action. The role of other cadres of workers like CHWs in playing a supporting role in the provision of safe care also needs research on a larger scale.

- IR that looks at ability to simplify protocols for the provision of abortion care (e.g. eliminating the need for routine follow-up care, allowing part of the drugs regimen required for medical abortion (i.e. the misoprostol) to be taken at home after an initial visit to the facility, eliminating routine ultrasound use) are also important in making care more adaptable to women's needs. All of these have been included as recommendations in the new WHO guidance on safe abortion (29).

- Larger-scale research to look at programmatic interventions that integrate onsite contraceptive services to abortion and post-abortion care.

- IR into financing mechanisms to ensure access for poorer women can also be helpful if overall universal access to safe care is to be achieved.

8.2.2 Family planning

- HRP/RHR research has elaborated safe and efficacious regimens for emergency contraception and facilitated more product registration. However, uptake of emergency contraception remains very limited. IR could inform the integration and expanded use of emergency contraception to prevent unplanned pregnancies.

- IR for the systematic and universal introduction of contraception during the postpartum or post-abortion period, and under-fives child-care clinics.

8.2.3 Maternal/reproductive care

- In addition to the AMTSL trial, the maternal severe morbidity and mortality approach or near-miss that HRP/RHR used in the multicountry survey (19) are amenable to IR. As mentioned by health leaders, some countries are already adopting this strategy (China implemented a sentinel site system based on our form and Peru is also planning a national scale-up).

- IR can also be deployed as a follow-up to the systematic reviews on task-sharing/shifting, to help expand family planning coverage and address human resource shortages for other reproductive health-care interventions.

9 Recommendations

HRP/RHR should design and conduct IR studies addressing reproductive priority questions on a large scale. Large-scale studies should evaluate strategies for scaling up family planning, safe abortion and improving emergency obstetric health care (i.e. scaling up the use of magnesium sulfate for eclampsia treatment, task-shifting in provision of healthcare, integration of onsite contraceptive services to abortion and puerperal care, and scaling up the uptake of emergency
contraception). It would be an asset to have at least three ongoing studies in 2015 covering these issues.

HRP/RHR should continue to have an active participation in the IRP. Advocacy to expand future calls for proposals in order to award larger-scale research projects would be an asset.

HRP/RHR should continue the support and participation in other large-scale research studies focused on low- and middle-income countries, initiated by other agencies or research groups. These collaborative efforts are an efficient use of resources.

Setting up a transdisciplinary team of scientists in IR may facilitate HRP/RHR activities in IR. This team should ideally include expertise in the design of implementation strategies, design and conduction of implementation intervention studies, qualitative approaches for assessment of barriers, statistical expertise in design and analysis of IR trials, and behavioural sciences. This team, assembled with either existing or new staff, would work with all thematic teams in a cross-cutting way to provide up-to-date implementation science standard methods.
References


Annex 1: Implementation research projects undertaken by HRP/RHR between 2008 and 2012

These projects were approved by the Ethics Review Committee (ERC) or the Research Project Review Panel (RP2) and thus can be considered research studies.

<table>
<thead>
<tr>
<th>Project title</th>
<th>HRP team</th>
<th>Country</th>
<th>Design</th>
<th>Primary objective</th>
<th>Intervention</th>
<th>Main outcome</th>
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<tbody>
<tr>
<td>A cluster randomized controlled trial to evaluate the effectiveness of the clinically integrated RHL evidence-based medicine course (23)</td>
<td>RCP/MPH</td>
<td>Argentina, Brazil, Democratic Republic of the Congo, India, Philippines, South Africa, Thailand</td>
<td>Cluster randomized design</td>
<td>The main objective is to evaluate whether the Reproductive Health Library evidence-based medicine (RHL-EBM) course is effective in improving knowledge, skills and competencies as compared to passive dissemination of resource materials</td>
<td>Participants are training institutions in obstetrics and gynaecology in the participating countries. Intervention 1: RHL-EBM course, which is a clinically integrated e-learning course, will be the experimental intervention. Teaching takes place in the clinical environment and the postgraduate trainee obtains the theoretical knowledge from the interactive e-learning materials, completes assignments and interacts with her/his facilitator throughout the process. There should be one facilitator per group of 5–10 postgraduate trainees. Intervention 2: self-directed learning (passive dissemination of EBM teaching materials).</td>
<td>Gain in EBM knowledge, change in attitudes, skills competence</td>
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<td>Comparison of the safety, efficacy, and feasibility of medical abortion by physicians or non-physicians in Nepal (25)</td>
<td>PUA</td>
<td>Nepal</td>
<td>Multicentre randomized controlled equivalence trial (five rural districts)</td>
<td>To compare the safety, effectiveness and feasibility of medical abortions provided by a physician-led team with those provided by teams of midlevel providers with a referral system.</td>
<td>Women were randomly assigned to a doctor or a midlevel provider for oral administration of 200 mg mifepristone followed by 800 μg misoprostol vaginally 2 days later, and followed up 10–14 days later.</td>
<td>Complete abortion without manual vacuum aspiration within 30 days of treatment</td>
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<td>A matched pair cluster-randomized implementation study to measure the effectiveness of an intervention package aiming to decrease perinatal mortality and increase institution-based obstetric care among indigenous populations in Guatemala</td>
<td>MPH</td>
<td>Guatemala</td>
<td>Matched pair cluster randomized trial</td>
<td>To evaluate the effectiveness of a package of interventions to increase the prevalence of institution-based care and reduce perinatal mortality in the four districts with the highest maternal mortality ratio in Guatemala</td>
<td>The package includes three interventions: (1) to train health-care professionals in emergency obstetric and perinatal care using a high-fidelity, low-tech, in situ, multidisciplinary simulation training curriculum (PRONTO); (2) to design and implement a social marketing strategy that promotes institution-based delivery; and (3) to integrate the role of the obstetric nurse and professional midwife in intervention communities to act as liaisons between traditional birth attendants and public health units.</td>
<td>Decrease in the perinatal death rate in intervention versus control clinics</td>
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<td>A demonstration project for the implementation of the WHO antenatal care model in Mozambique: a cluster randomized controlled trial</td>
<td>MPH</td>
<td>Mozambique</td>
<td>Two-arm, parallel cluster randomized controlled trial</td>
<td>To determine the effect of an intervention designed to increase the use of evidence-based practices included in the ANC package by midwives (and other health-care professionals) in prenatal clinics in Mozambique</td>
<td>(1) A seminar for health-care providers and distribution of printed materials to clinics to increase awareness of the WHO ANC recommendations, the package of interventions included in the Mozambique ANC model and the project objectives; (2) identification of midwives or other health-care professionals interested in participating as project facilitators; (3) planning workshop on how to implement the ANC package and other training activities; and (4) implementation of the programme at the ANC clinics, including the use of reminders for midwives or other health-care providers and patients.</td>
<td>The delivery of selected health-care practices to women attending prenatal care. Selected screening practices: frequency of women receiving screening for: (a) syphilis at least once during pregnancy; (b) HIV at the first ANC visit; (c) HIV at subsequent visits; (d) anaemia; and (e) hypertension. Selected preventive practices: frequency of women receiving: (a) tetanus toxoid; (b) intermittent preventive malaria treatment; (c) iron supplementation; and (d) antiparasitic treatment for anaemia prevention</td>
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<td>Project title</td>
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<td>Assessing the acceptability, feasibility and effectiveness of a strategy for improving the quality and safety of maternal/neonatal health care in the health system contexts of four Middle East countries</td>
<td>MPH</td>
<td>Egypt, Lebanon, Occupied Palestinian Territories and Syria</td>
<td>Two-phased study; phase 1: formative research; phase 2: quasi-experimental design using a longitudinal prospective interrupted time-series design (pre-post intervention design with no control)</td>
<td>(1) To test the acceptability, feasibility and effectiveness of a multifaceted quality-improvement strategy combining clinical audit, feedback and engaging opinion leaders with a focus on the management of maternal/neonatal near-misses; (2) to investigate how differences in the health-system context across four Middle Eastern countries identified in public hospitals in Egypt, Lebanon, Occupied Palestinian Territories and Syria affect the acceptability and feasibility of this quality-improvement strategy</td>
<td>The intervention encompasses different aspects: audit and feedback of maternal/neonatal near-miss cases by collecting information on a prospective basis at equal time intervals; interactive workshops to train health-care providers and hospital administrators on how to conduct criterion-based audit; focus group discussions with junior doctors in each hospital at the conclusion of the intervention.</td>
<td>Proportion of cases of maternal and neonatal near-misses that were inappropriately managed using the WHO-developed tool on maternal and neonatal near-miss (29)</td>
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<td>Project title</td>
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<td>Innovations for increasing access to integrated safe delivery, PMTCT and newborn care in rural Uganda</td>
<td>RCP</td>
<td>Uganda</td>
<td>Community-based, three-arm non-randomized trial</td>
<td>Primary objectives: (1) to develop and implement an integrated intervention that includes vouchers for institutional deliveries and care of complications, and home visits by CHWs in pregnancy and the postnatal period in four health subdistricts in rural Uganda; (2) to understand the implementation and learning processes used to deal with challenges encountered during the implementation of the intervention; (3) to assess the intervention effects on the proportion of deliveries occurring in health-care facilities and on uptake of prevention of mother-to-child transmission (PMTCT) of HIV; (4) to assess the effects of implementation of the intervention on the health system; and (5) to engage stakeholders and disseminate implementation experiences and findings in order to inform policy and scale-up in Uganda</td>
<td>The intervention has three components: (1) use of CHWs for community-based maternal, newborn and PMTCT promotion – (a) CHWs will register women of childbearing age, identify pregnant women and make home visits (before and after delivery to promote proper care for mothers and newborn babies; (b) CHWs will carry out community mobilization and dialogue to promote community-wide behaviour change. They will also encourage mothers to test for HIV/AIDS during ANC, and for those who disclose their status, they will encourage adherence to the antiretroviral treatment for mothers and babies; (2) provision of vouchers for maternity services and transport to access institutional delivery and care for maternal postpartum complications and for sick newborn babies; and (3) training, provision of basic drugs and supplies, and integrated support supervision to strengthen the health-care facility.</td>
<td>Service delivery: (1) health-care facility utilization for ANC, deliveries and newborn care; (2) quality of ANC and delivery care; (3) rates of testing for HIV in pregnancy; and (4) number of visits by CHWs per mother/baby pair. Health workforce: (1) abstinence rates; (2) attitude; (3) motivation; (4) satisfaction; and (5) performance. Information: (1) completeness of records; (2) use of data for decision-making; (3) workload; and (4) validity of voucher-related records. Medical technology: (1) availability of drugs and supplies and equipment. Financing: (1) effect on allocations to maternity unit from voucher incomes; (2) effect on availability of resources for the unit; (3) incremental cost per supervised delivery; (4) incremental cost effectiveness of the two packages; (5) the proportion of deliveries occurring in health-care facilities; and (6) uptake of HIV testing during ANC.</td>
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<td>The effectiveness of antenatal birth plans in increasing skilled care at delivery and after delivery in rural Tanzania (25, 26)*</td>
<td>The United Republic of Tanzania</td>
<td>The United Republic of Tanzania</td>
<td>Cluster randomized trial conducted in 18 health-care units in rural settings in the United Republic of Tanzania</td>
<td>To determine the effectiveness of birth plans in increasing skilled care at delivery and after delivery</td>
<td>Intervention units provided ANC with renewed emphasis in birth plans provided by care providers. Control units continued offering antenatal care as currently provided. Women were interviewed twice, at first encounter and 1 month after delivery.</td>
<td>Proportion of women who sought delivery at the available health units</td>
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<tr>
<td>Project title</td>
<td>HRP team</td>
<td>Country</td>
<td>Design</td>
<td>Primary objective</td>
<td>Intervention</td>
<td>Main outcome</td>
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<tr>
<td>Comparison of &quot;one-stop&quot; versus &quot;conventional&quot; service on antenatal syphilis screening in Ulaanbaatar, Mongolia (27, 31)</td>
<td>PFP</td>
<td>Mongolia</td>
<td>Cluster-randomized trial</td>
<td>The objectives of the study are: (1) to compare the effectiveness of &quot;one-stop&quot; versus &quot;conventional&quot; service on antenatal syphilis screening in Ulaanbaatar; and (2) to compare the coverage of antenatal syphilis screening between &quot;one-stop&quot; and &quot;conventional&quot; service on antenatal syphilis screening in Ulaanbaatar</td>
<td>In the intervention clinics, the first 2-day workshop was held for ANC providers. The second two-day workshop was also held for obstetricians and gynaecologists and covered the specific knowledge on maternal and congenital syphilis. The intervention clinics were supplied with the necessary materials and supplies. ANC providers in the control clinics participated in a 2-day training workshop on the project overview, logistics of the project and case reporting. As with the intervention group, treatment of syphilis cases and their partners was given free of charge. Benzathine benzylpenicillin was supplied for treatment but not facilities for serological tests.</td>
<td>The primary outcomes of the study were (1) utilization of antenatal syphilis screening at the first antenatal visit and at the third trimester of gestation; (2) detected syphilis cases; and (3) number of congenital syphilis cases</td>
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<tr>
<td>An intervention to improve knowledge on reproductive health and access to services of migrant youth in Ho Chi Minh City, Vietnam</td>
<td>RCP</td>
<td>Viet Nam</td>
<td>Pretest/post-test design</td>
<td>To determine if the level of reproductive health knowledge and access to services of migrant youth can be improved through peer education and mobile clinics</td>
<td>Peer education carried out as group discussion sessions, each session involving with 10–15 migrant youths. An education cycle consisted of four sessions at weekly intervals, then another cycle would be carried out on other migrant youths throughout the intervention period of 18 months. Mobile clinics from Hung Vuong Hospital made routine visits every 6 weeks to each factory or commune health centre where the study factory was located, when young migrants were informed and encouraged to attend for counselling, examination and treatment.</td>
<td>Increase in knowledge on sexual and reproductive health (SRH) of young migrants, and increase in access to reproductive health services. Comparison of pre- versus post-intervention will be made in terms of the percentage of those who have adequate SRH knowledge, and the percentage of those who have good access to reproductive health services</td>
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<tr>
<td>Reproductive health promotion for young migrant factory workers in four main districts in Vientiane Capital, Laos</td>
<td>RCP</td>
<td>The Lao People’s Democratic Republic</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Project title</td>
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<tr>
<td>Mejorar la atención a las mujeres en riesgo de aborto inseguro mediante la capacitación y sensibilización de los profesionales y equipos de salud en la frontera Uruguayo-Brasilena (32)</td>
<td>PUA</td>
<td>Uruguay</td>
<td>(1) Before–after design for the hospital that received the intervention; (2) comparison between the hospital that received the intervention and the control hospital</td>
<td>(1) To raise awareness of, and to train, health professionals and other support staff about the need to care for women who undergo an abortion; (2) to empower women</td>
<td>Two main interventions: (1) to raise the awareness of, and then train, health-care professionals and other support staff about the need to care for women who may want or who have just had an abortion; and (2) to implement, the programme that Iniciativas Sanitarias had successfully deployed in Montevideo and provide an assessment of its impact at that level.</td>
<td>Near-misses cases; women admitted to intensive care unit and/or hysterectomies</td>
</tr>
<tr>
<td>Improving quality of reproductive health services by strengthening linkages with STI/RTI service</td>
<td>RCP</td>
<td>Viet Nam</td>
<td>Pretest/post-test design</td>
<td>(1) To improve the capacity of primary health care and reproductive health-care providers in provision of quality reproductive tract/sexually transmitted infection (RTI/STI) services through training and supervision and monitoring; (2) to ensure availability of information, education and communication (IEC) materials and STI supplies; (3) to evaluate the outcomes of programme interventions on improving the quality of reproductive health-care care services</td>
<td>Three intervention components: (1) training of health-care staff at the commune and district levels on the provision of quality RTI/STI services; (2) ensuring the availability of supplies (drugs and condoms) and IEC materials at the district and commune level; and (3) strengthening supervision and monitoring the provision of quality care.</td>
<td>(1) Proportion of health-care providers who are able to provide RTI/STI services; (2) proportion of clients coming for antenatal care (ANC), family planning services or gynaecological examination who receive essential information on STI prevention, risk assessment and required services related to RTI/STI; and (3) client satisfaction with RTI/STI services</td>
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<tr>
<td>Project title</td>
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<td>A quasi-experimental operations research project to provide life-skills-based training and youth-friendly services on SRH among unmarried youth</td>
<td>RCP</td>
<td>China</td>
<td>Quasi-experimental design</td>
<td>To improve the SRH of unmarried migrant youth by providing life-skills-based education and youth-friendly SRH services, to provide policy-makers with a cost-effective, practical and sustainable approach for improving the SRH of unmarried migrant youth, and promoting safe sexual behaviour</td>
<td>Unmarried migrant youth in the intervention group will receive life-skills-based training and education together with youth-friendly SRH service (if required) for 6 months. Prior to the intervention to unmarried migrant youth, preparatory work will be conducted: (1) a 1-day advocacy meeting; (2) building up institutional capacity for youth-friendly services; (3) training 12–16 community health workers (CHWs) and family planning service providers; (4) education: preparing training materials; training of trainers on life-skills-based education; and (5) providing youth-friendly services.</td>
<td>Regarding service providers: increase of their understanding of providing SRH education and services to unmarried migrant youth; improvement of their working performance. Regarding unmarried youth: percentage of migrant youth using the service provided by the project; increased knowledge about SRH; increased ability to make decisions or protect themselves; increased contraceptive use among sexually active subjects</td>
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<tr>
<td>The effectiveness of a patient education programme, a direct referral system – improving contraceptive uptake by patients suffering from medical illnesses</td>
<td>PUA, PFP</td>
<td>Sri Lanka</td>
<td>Two experimental arms in a pretest and post-test quasi-experimental design</td>
<td>To introduce a referral system or a patient-education programme at the medical clinic to improve uptake of modern methods of contraception by women suffering from medical illnesses</td>
<td>Group 1: referral to the specialist in the family planning clinic of the institution in the form of a referral card. Group 2: displaying of posters highlighting the conditions that require family planning and the importance of it. Such posters will be displayed at the patient waiting areas of the medical clinics. These interventions would be carried out for a 6-month period</td>
<td>Uptake of family planning methods by the client</td>
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<td>Promoting antenatal care services to improve early detection of pre-eclampsia, urban health centres, Mandalay, Myanmar</td>
<td>RCP</td>
<td>Myanmar</td>
<td>Pretest/post-test quasi-experimental design will be applied in this operations research study</td>
<td>To determine if training on pre-eclampsia using the updated training modules based on pregnancy, childbirth, postpartum and newborn care would improve the detection and referral of pre-eclampsia by midwives at the urban health-care centres to the tertiary hospital, thereby reducing the complications and consequences of pre-eclampsia.</td>
<td>The intervention will be provision of training to midwives and lady health visitors using the updated training modules based on the World Health Organization (WHO) guideline, <em>Pregnancy, childbirth, postpartum and newborn care</em> (33) to improve their skills on detection and referral of pre-eclampsia. The training lasted for 2 days. The training activity included lectures, discussions, demonstration and role play. Each training workshop was planned to be conducted for approximately 20 participants.</td>
<td>Proportion of pre-eclampsia cases diagnosed by midwives among pregnant women attending ANC; proportion of pre-eclampsia cases among pregnant women attending ANC referred by midwives. It was expected that at the end of the training, the midwives were able to: (1) assess the pregnant women for pre-eclampsia, develop a birth and emergency plan and advise on danger signs; (2) identify risk factors such as first pregnancy, multiple pregnancy; mention common maternal complications and serious fetal outcomes of pre-eclampsia; when to refer a case of pre-eclampsia; (3) measure blood pressure accurately; and (4) check urine protein accurately.</td>
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<tr>
<td>Promotion of reproductive health of adolescent migrants in Mandalay City</td>
<td>RCP</td>
<td>Myanmar</td>
<td>Pretest/post-test design without a control population</td>
<td>(1) To assess the baseline level of knowledge, perception and practices about reproductive health in adolescent and youth migrant factory workers; (2) to provide reproductive health information and referral information for reproductive health problems, to adolescent and youth migrant factory workers; (3) To reassess the level of knowledge, perception and practices about reproductive health in adolescent and youth migrant factory workers after 12 months of selected interventions; (4) to identify the factors that facilitate and the factors that hinder the success of the intervention; and (5) to contribute to the evidence base related to the intervention model for promotion of reproductive health among adolescent and youth migrants</td>
<td>Twenty youths from Red Cross Society will be given a 10-day training on adolescent reproductive health education and counselling and 10 general practitioners (GPs) from the project township will be given a 7-day training on management of common reproductive health problems and adolescent reproductive health counselling. Trained youth health communicators from the Red Cross Society will give three rounds of small-group health communication sessions about reproductive health to youth aged 15 and 24 years, in each of 11 participating factories in 18 months. Participating GPs will provide diagnosis, treatment, counselling and referral for adolescent reproductive health problems of youth migrant factory workers at their clinics.</td>
<td>The significance of change in knowledge, perception and practice and access to reproductive health information and services from the baseline to the end-line of the intervention.</td>
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<td>Expanding access to sexual and reproductive health information and services for factory migrant youth in Bangkok, Thailand</td>
<td>RCP</td>
<td>Thailand</td>
<td>Pretest/post-test design</td>
<td>To test a model of migrant youth peer educators in communicating and providing SRH information, skills, and counselling services in the community. To provide knowledge and access to SRH information and services to migrant youth.</td>
<td>Seven-day training workshop for peer educators that comprised both theoretical and practical sessions, covering knowledge on reproductive health physiology, pregnancy, abortion, contraception, STIs including HIV/AIDS, life-skill development, and communication skills. Training planned to be conducted every 6 months for the trained peer educators and new recruited educators involved in the project. Altogether, there will be three training workshops held during the 18 months of intervention. A 5-day training workshop for health staff including topics on adolescent reproductive health.</td>
<td>Outcomes: (1) increased knowledge on SRH of migrant youth; (2) increased skills in negotiating desired sexual outcomes; (3) increased access to reproductive health services; and (4) improvement of reproductive health behaviour</td>
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<td>Pharmacy provision of misoprostol for post-abortion care and other reproductive services</td>
<td>PUA</td>
<td>Kenya</td>
<td>Controlled randomized trial</td>
<td>(1) To determine whether training of pharmacists and pharmacy workers leads to improved information provision and/or referral of misoprostol users; (2) to determine whether training of pharmacists and pharmacy workers leads to improved information provision and referral for post-abortion care services; (3) to determine whether linking pharmacists and pharmacy workers and reproductive-health-care providers at the community level leads to an increase in referrals for treatment of incomplete abortion and other reproductive health services; and (4) to utilize the intervention findings to mobilize the Ministry of Health, Pharmacy Board and other partners to develop a policy on the role of pharmacies in the provision of information on misoprostol for post-abortion care and reproductive health services.</td>
<td>Pharmacists and pharmacy workers in the intervention group will participate in an 8-hour training (including the legality of post-abortion care and abortion in Kenya and information on misoprostol for post-abortion care, particularly the correct usage of misoprostol and contraceptive service provision, information, and referral); receive IEC materials and follow-up supportive supervision visits. Pharmacists and pharmacy workers in the control group will not receive this training. Trained simulated clients will be used to complement data collected by pharmacists and pharmacy workers post-intervention. All participants will be fully trained after the data-collection phase. The training of the control group will, however, be advised by the success of the study – if the intervention is effective, then the investigators will provide training to the control group.</td>
<td>Increase information/education on post-abortion care misoprostol; increased referrals for post-abortion care; and increased post-abortion contraceptive use</td>
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<td>Project title</td>
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<td>Improving early medical abortion service delivery: is a take-home checklist and pregnancy test a safe and acceptable alternative to a routine follow-up visit?</td>
<td>PUA</td>
<td>Ghana and Zambia</td>
<td>Non-inferiority active-controlled randomized clinical trial</td>
<td>Overall objective: to obtain evidence on the safety, feasibility and acceptability of a simplified medical abortion protocol consisting of a pregnancy test and checklist for self-referral for follow-up care. Primary objective: to compare the safety of a pregnancy test and checklist for self-referral follow-up care in place of a routine follow-up visit for all women</td>
<td>The intervention consists of replacing the follow-up visit at 10–14 days with a follow-up system consisting of a checklist of questions and a pregnancy test to assess the outcome of the abortion and to screen for ongoing pregnancies.</td>
<td>Primary end-point: safety. Women will be classified as: complete abortion, ongoing pregnancy, continuing excessive bleeding or other problem (incomplete abortion)</td>
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<tr>
<td>Increasing usage and correct application of the partograph in three maternity hospitals in Kabul, Afghanistan</td>
<td>RCP</td>
<td>Afghanistan</td>
<td>Pretest/post-test design</td>
<td>(1) To assess the current situation regarding the percentage prevalence and correct usage of the partograph; (2) to determine whether an intervention package addressing the gaps and limitations found in the baseline study will result in increased and correct application of the partograph; (3) to assess the skills of staff</td>
<td>Completed partograph training for all staff of all three sites. Regular external supervision and monitoring from the research department</td>
<td>The partograph was attached in the patient's record in 87% of cases, but only 20% were used correctly; 24% of the staff expressed the opinion that although the partograph is a good tool, it is impossible to use because they do not have time to fill it in. Doctors stated that most decisions are made based on clinical findings and examination and the midwives said that they are made in consultation with the physician, based on clinical findings, rarely based on the partograph. Most mentioned there is a rush of patients, limited number of staff, insufficient time and staff not trained in the use of the partograph. The following recommendations were made: training, supervision and monitoring of midwives and junior doctors; maternity hospitals should have three shifts with an equal number of staffs in each shift; logistical problems identified should be addressed; patronage and advocacy at the policy-makers' level; develop good record-keeping practice, possibly computerized</td>
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</table>

NA, no information available.

* WHO teams: MPH, Maternal and Perinatal Health; PFP, Promoting Family Planning; PUA, Preventing Unsafe Abortion; RCP, Research, Capacity, Policy and Programme Strengthening.

The project “A quasi-experimental operations research study to provide life-skills based training and youth-friendly service on SRH among unmarried migrant youth in Shanghai” is the same project as “A quasi-experimental operations research project to provide life-skills based training and youth-friendly services on SRH among unmarried youth”.

The project “Expanding access to sexual and reproductive health information and services for factory migrant youth in the Greater Mekong subregion” is the same project as “Expanding access to sexual and reproductive health information and services for factory migrant youth in Bangkok, Thailand”.

Other notes

No information was sent to reviewers regarding the project “Evaluation of the impact of continuous education programme for health providers and for the community, on quality of care and utilization of reproductive health services in Paraguay”.

The project “Training midwives in Kyrgyzstan to provide safe abortion care with mifepristone and misoprostol” is being revised for possible resubmission to the Research Project Review Panel (RP2). Is not yet even approved by RP2 and hence reviewers did not have access to the protocol.

The project “Challenges and opportunities for integration of sexual and reproductive health and HIV/AIDS services: operations and implementation research on the cooperation of programmes and services in Peru” was approved by RP2 but there is not enough funding to implement it yet.
Annex 2: Publications in peer-reviewed journals related to implementation research projects

This table was created using a file containing all HRP/RHR peer-reviewed publications published between 2008 and 2012 that was provided to reviewers.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of publications</th>
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<tbody>
<tr>
<td>Total number of publication in the files sent to reviewers</td>
<td>417</td>
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<tr>
<td>Number of publication after deleting duplicates</td>
<td>388</td>
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<tr>
<td>Number of publication after deleting titles related to basic science research, literature reviews, global trends and systematic reviews/meta-analysis</td>
<td>145</td>
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<tr>
<td>Number of publications after deleting titles clearly not related to IR</td>
<td>34</td>
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<tr>
<td>IR projects</td>
<td>8</td>
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</tbody>
</table>

Publications in peer-reviewed journals relating directly to HRP implementation research projects


* This publication was sent separately from the list of publications but was included as it is related to a project included in this case-study.