Innovations in Global Health Research and Development (R&D):

An Agenda for the Sexual and Reproductive Health and Rights (SRHR) Community.

DSW

"Governments, assisted by the international community and donor agencies, the private sector, non-governmental organizations and the academic community, should increase support for basic and applied biomedical, technological, clinical, epidemiological and social science research."

International Conference on Population and Development Program of Action (ICPD PoA), Cairo, 1994.

Overview

The purpose of this paper is to describe the linkages between SRHR and Global Health R&D, with a view to outlining a common advocacy agenda that advocates in the field of SRHR and Global Health R&D can utilise.

Although there is no universally established definition of Global Health R&D, the term commonly refers to the research and development of new or adapted tools, technologies and products that are designed to meet the health needs of the developing world, specifically, poverty-related and neglected diseases (PRNDs).

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Advocates for SRHR and advocates for Global Health R&D share the same goals: poverty reduction, universal access to health, and reductions in mortality and morbidity. Both groups are working towards the attainment of the three health-related Millennium Development Goals (MDGs): MDG 4, 5 and 6.

However, as a general rule, SRHR advocates tend to focus on pushing for access to existing medication, supplies and services, while Global Health R&D advocates tend to focus on meeting gaps that are not met by these, through the improvement of existing products, or the creation of new ones. Very few actors bridge both arenas.

This paper argues that there has never been a more important time for SRHR and Global Health R&D advocates to join forces, on the basis of four main premises:

1. **Global Health R&D and SRHR share the same goals, specifically the attainment of poverty reduction and the three health-related MDGs.**
2. **Global Health R&D efforts seek to provide solutions to health problems that are a major cause of ill-health among women and newborns in the global South,** these include diseases that have a disproportionate impact on pregnant women, such as malaria and hookworm.
3. **The need for increased investment in research and development is enshrined in the key international agreements on sexual and reproductive health and rights, and women's empowerment,** including the Cairo Program of Action, and the Beijing Platform for Action.
4. **The Global Health R&D effort already includes research directly related to the advancement of sexual and reproductive health.** This includes the prevention and treatment of HIV and other sexually transmitted infections (STIs), new contraceptive options and maternal health technologies.

The Links between Poverty, Disease, and SRHR

SRHR is defined in the Programme of Action from the UN Conference on Population and Development (ICPD PoA) in Cairo in 1994 as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capacity to reproduce and the freedom to decide if, when and how often to do so."

Further, the definition states: "Implicit in this last condition are the right of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods

of their choice for regulation of fertility which are not against the law, and the right of access to appropriate health-care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant."

Helping people to prevent unwanted pregnancies by promoting access to sexual and reproductive health information and services, including voluntary family planning, improves the health and well-being of women, men, and young people.

Poor health, inequities in income, and population dynamics are major obstacles to poverty reduction. Meeting the sexual and reproductive health needs of individuals benefits the health and well-being of the wider population in multiple ways. Helping people to prevent unwanted pregnancies by promoting access to sexual and reproductive health information and services, including voluntary family planning, improves the health and well-being of women, men, and young people. At the same time, it helps to increase educational and employment opportunities, particularly for women and girls. Ultimately, it helps countries make savings and gains that enable them to reduce poverty and to reach their development goals.

Solely addressing reproductive health needs, however, is insufficient to meet the MDGs. SRHR in low- and middle-income countries is heavily impaired by PRNDs. Taken together, poverty-related diseases and neglected tropical diseases are among the leading indirect causes of maternal mortality[1].

1 Poverty-related diseases and neglected tropical diseases are significant causes of indirect maternal mortality, which represent 20 per cent of all maternal deaths globally. WHO, 2005.

Poverty-Related Diseases and SRHR

The three biggest killers in low- and middle-income countries are HIV, tuberculosis (TB), and malaria. These are also known as 'poverty-related diseases'. The linkages between HIV and SRHR are well-known since the majority of HIV infections are sexually transmitted or associated with pregnancy, childbirth, and breastfeeding. In addition, sexual and reproductive ill-health and HIV share root causes, including poverty, gender inequality and social marginalisation of the most vulnerable populations. In South Africa, HIV has been the leading contributor to maternal mortality since 1998 and the maternal death rate has been found to be up to six times higher in women living with HIV[2].

In Africa, malaria in pregnancy is responsible for 400,000 cases of severe maternal anaemia and 200,000 newborn deaths each year.

Malaria is one of the leading indirect causes of maternal mortality, with pregnant women twice as likely to die from malaria than other adults[3]. In Africa, malaria in pregnancy is responsible for 400,000 cases of severe maternal anaemia and 200,000 newborn deaths each year[4]. Despite considerable advancements in recent years through the distribution and usage of long lasting insecticidal nets (LLINs), malaria is seriously hindering the achievement of MDG Goals 4 and 5. TB meanwhile is the third leading cause of death globally among women in their reproductive years[5]. Mother-to-child transmission of TB is estimated to be 15 per cent within three weeks of birth[6].

2 Black et al, Effect of Human Immunodeficiency Virus Treatment on Maternal Mortality at a Tertiary Center in South Africa: A 5-Year Audit, Obstetrics & Gynecology: August 2009 – Volume 114 – Issue 2, Part 1 – pp 292–299.

3 Malaria Consortium: The Challenges, 2012.

4 Ibid.

5 Maternal and Child Health: Potential Role of New TB Vaccines, AERAS, 2012.

6 Global Coalition on Women and AIDS, Tackling TB and HIV in Women: An Urgent Agenda, July 2010.

Neglected Tropical Diseases and SRHR

Almost every woman or girl living in Africa, Asia, and the Americas is infected by one or more of the 17 NTDs listed by WHO.

Neglected tropical diseases (NTDs) are parasitic and bacterial infections so-named because they thrive only in parts of the world with unsafe water, poor sanitation and limited access to basic healthcare. The seven most prevalent NDTs, of which include ascariasis, hookworm, lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma, and trichuriasis, affect over one billion individuals, or one sixth of the world population[7]. Almost every woman or girl living in Africa, Asia, and the Americas is infected by one or more of the 17 NTDs listed by WHO[8]. Three are known to be closely linked to SRHR: hookworm, schistosomiasis, and Chagas disease.

Hookworm is one of the most important parasitic maternal health problems around the world. This intestinal parasitic infection is a major cause of anaemia in pregnant women, which in turn is a major indirect cause of maternal mortality. In total, almost 40 million African women of reproductive age are infected with hookworms, and seven million of these women are pregnant[9].

More than 100 million women and girls in sub-Saharan Africa suffer from female genital schistosomiasis, a waterborne parasitic worm whose eggs affect the urinary and genital system. Research in Zimbabwe has shown that women with urinary schistosomiasis have as much as a three-fold increased risk of acquiring HIV[10]. In Latin America, Chagas disease causes thousands of miscarriages and congenital infections[11]. Links have also recently been established between Chagas disease and HIV transmission and disease progression in Uganda and Brazil[12].

7 Schistosomiasis Control Initiative, Imperial College, 2012.

8 Buruli ulcer, Chagas disease, cholera and diarrhoea epidemics, dengue fever, Guinea-worm, endemic infectious diseases (e.g. endemic syphilis), sleeping sickness, leishmaniasis (kala-azar, black fever), leprosy, elephantiasis, river blindness, rabies, schistosomiasis (bilharzias), hookworm, trachoma, and yaws.

9 Brooker S, Hotez PJ, Bundy DAP (2008) Hookworm-Related Anaemia among Pregnant Women: A Systematic Review. PLoS Negl Trop Dis 2(9).

10 Kjetland EF, Ndhlovu PD, Gomo E, et al. Association between genital schistosomiasis and HIV in rural Zimbabwean women. AIDS2006; 20: 594.

11 Inspiring a Generation of Women to Fight Neglected Tropical Diseases, Peter Hotez, Huffington Post Blog Posting, 3rd March 2012: http://www.huffingtonpost.com/peter-hotez-md-phd/maternal-health-ntds_b_1318335.html.

12 Global Network for Neglected Tropical Diseases, 2012.

The Need for Global Health R&D

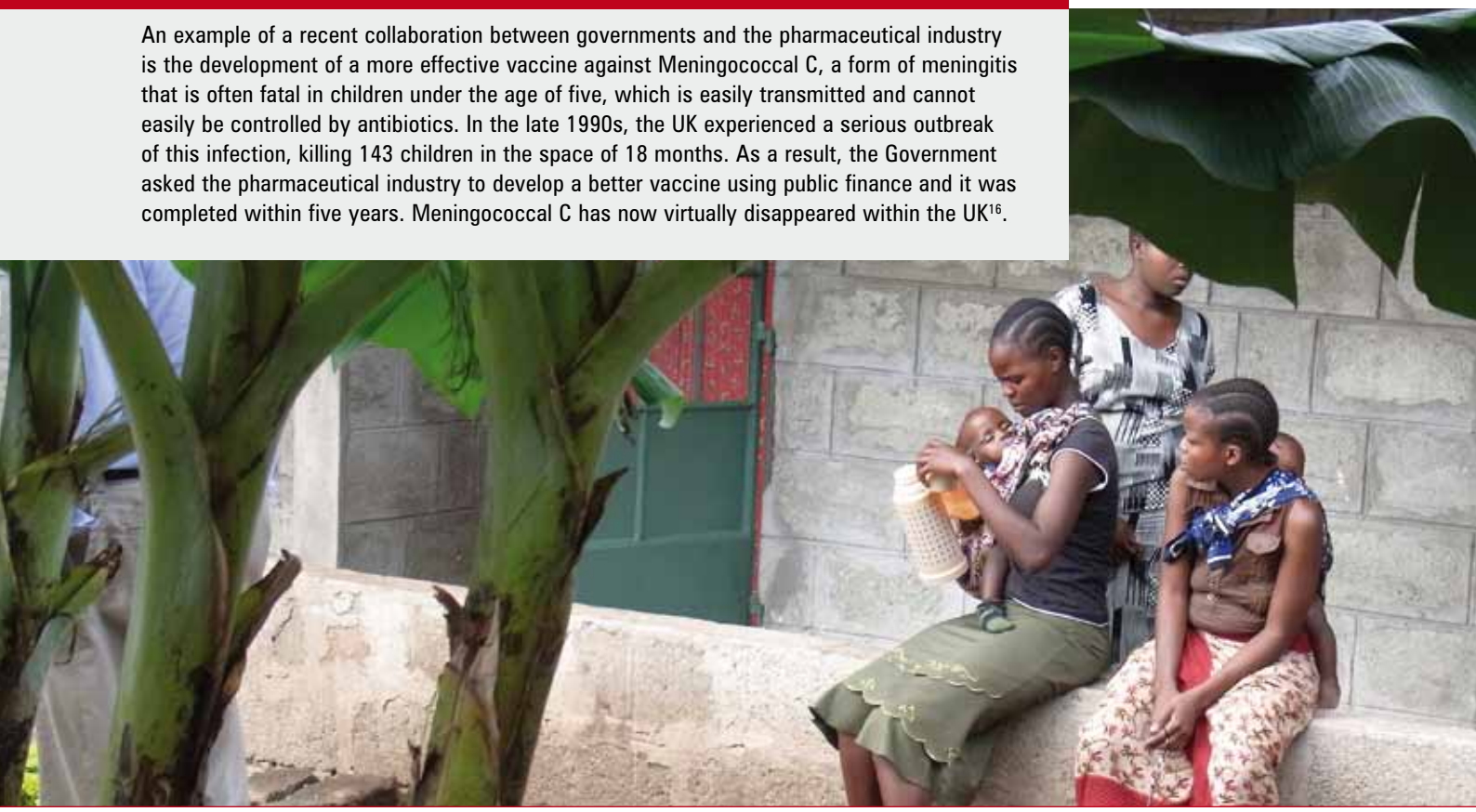
Most medical research and health-related R&D today is carried out by the private industry. In both the global North and global South, governments, to a lesser or greater extent have passed on the responsibility of developing solutions to health problems to pharmaceutical companies. Pharmaceuticals recover their costs for developing these new drugs and treatments by selling them on the open market. As a result, they predominantly focus on developing products that affect populations that can afford to buy them, or where a government will reimburse them. In addition, health technologies are usually designed for environments with high spending on health, reliable energy supply and large numbers of trained healthcare professionals[13].

Only 10 per cent of the world's resources for health research are applied to diseases that affect the poorest 90 per cent of the world's population.

Overall, only 10 per cent of the world's resources for health research are applied to diseases that affect the poorest 90 per cent of the world's population. This is known as the 10/90 gap[14]. The vast majority of funding for Global Health R&D comes from public sources, including governments and foundations[15].

The Power of Vaccines

An example of a recent collaboration between governments and the pharmaceutical industry is the development of a more effective vaccine against Meningococcal C, a form of meningitis that is often fatal in children under the age of five, which is easily transmitted and cannot easily be controlled by antibiotics. In the late 1990s, the UK experienced a serious outbreak of this infection, killing 143 children in the space of 18 months. As a result, the Government asked the pharmaceutical industry to develop a better vaccine using public finance and it was completed within five years. Meningococcal C has now virtually disappeared within the UK[16].



13 Howitt P. et al, Technologies for Global Health. The Lancet, 2012, 380:507-35.

14 The Global Forum for Health Research, 1998.

15 Research and Development to meet health needs in developing countries: Strengthening Global Financing and Coordination, Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, WHO, April 2012.

16 Professor Salisbury:The Power of Vaccines, oral presentation on 18th May 2012, London; The Meningitis Research Foundation.

Product development partnerships (PDPs) are non-profit organisations that have emerged in the past 12–15 years to specifically address the 10/90 gap. These organisations combine industrial expertise with public financing to deliver health products that meet the needs of developing countries. Currently there are over 26 PDPs around the world with different product portfolios[17]. Some specialise in developing a specific intervention, while others pursue R&D for several diseases. PDPs accelerate the development of products that would otherwise never come to exist. Prior to their creation, only 16 of 1,393 medical tools developed between 1975 and 2000, related to the needs of developing countries[18]. PDPs accounted for over 40 per cent of new global health products registered between 2000 and 2010[19].

PDPs accelerate the development of products that would otherwise never come to exist.

In addition, PDPs are making substantial efforts to build sustainable research capacity in low- and middle-income countries and invest in local health infrastructure. This includes the establishment of state of the art laboratories and clinics, as well as training healthcare professionals in good clinical practices and counselling techniques[20].

R&D in International Commitments: Cairo and Beijing

Governments are called upon to increase support for research to improve existing methods and develop new ones for regulation of fertility that meet users' needs and are acceptable, easy to use, safe, free of side-effects, effective, and affordable.

Both the ICPD and the Beijing Declaration refer to the importance of investing in R&D to address global sexual and reproductive health needs. In Cairo, governments recognised the need to bring new, safe, affordable, and effective methods of contraception and HIV prevention to fruition and pledged to pay particular attention to vaccines and microbicides.

Chapter 14 of the ICPD Programme of Action is dedicated to Technology, Research and Development. In this chapter, governments are called upon to increase support for research to improve existing methods and develop new ones for regulation of fertility that meet users' needs and are acceptable, easy to use, safe, free of side-effects, effective, and affordable[21].

17 Innovative Product Development Partnerships, Policy Brief 26, IAVI, September 2010.

18 Chirac P, Torreele E. Global framework on essential health R&D. The Lancet, 2006; 367(9522):1560–1561.

19 Global Health Technologies Coalition & Policy Cures, Saving Lives and Creating Impact: Why Investing in Global Health Research Works, Policy Cures, 2012.

20 See for example, Microbicides Research: Hope for the Future, Benefits for Today, IPM, 2010 and How IAVI builds scientific capacity in developing countries, IAVI, February 2012.

21 http://www.unfpa.org/public/home/sitemap/icpd/International-Conference-on-Population-and-Development/ICPD-Summary.

The Development of the Pill

Many people may not be aware that the Pill was not the brainchild of the pharmaceutical industry, but as a result of the commitment of two women, Margaret Sanger and heiress Katherine McCormick, who persuaded and funded scientists to develop something that women could take orally to prevent pregnancy. The mechanisms of action discovered during the contraceptive revolution that followed McCormick's investment are the basis for most of today's modern methods of contraception.

Publicly-funded research has been essential in the development of new female condoms, second generation contraceptives like the vaginal ring, implants, the patch, and the cervical cancer vaccine. These, it is argued, have taken much longer than predicted to arrive on the market because contraceptive development has failed to sustain the financial support it enjoyed during the initial period of innovation. After 50 years of modern contraception, we are still struggling to provide appropriate products of assured quality at an affordable price to people throughout the world.

The document highlights promising developments in contraceptive research and that "a significant increase in support from governments and industry is needed to bring a number of potential new, safe and affordable methods of contraception to fruition."

At the Beijing conference in 1995, the international community recognised that barriers to women's health include inequality as well as inadequate responsiveness to women's needs.

At the Beijing conference in 1995, the international community recognised that barriers to women's health include inequality as well as inadequate responsiveness to women's needs. The Beijing Declaration also called for financial and institutional support for research on methods and technologies for the reproductive and sexual health of women and men, including the regulation of fertility, protection against HIV & AIDS and other STIs [22]. Later, in the United Nations General Assembly Special Session (UNGASS) Declaration in 2000, governments agreed to empower women to have control over their sexual lives and increase their ability to protect themselves from HIV infection. The 2003 UNAIDS International Guidelines on HIV & AIDS and Human Rights also require countries to ensure access to affordable medications and preventive technologies [23]. They further note that this duty is shared among nations, and that wealthy nations have an obligation to assist less wealthy nations in realising the right to health.

22 Beijing Platform for Action, 1995.

23 International Guidelines on HIV & AIDS & Human Rights Revised Guideline 6: Access to Prevention, Treatment, Care and Support, UNAIDS, 2003.

Recent Innovations in R&D for SRHR: Selected Case Studies

Global Health R&D is not just concerned with the eradication of PRNDs. Within this field today are a wide range of research initiatives that directly address maternal health and family planning, such as new contraceptive options that can be used on demand, the development of vaccines for sexually transmitted infections, and tools to prevent postpartum haemorrhage (PPH) in resource-poor and non-clinical settings. Some of these are described in more detail as follows:

Oxytocin in Uniject

Excessive bleeding after childbirth, or postpartum haemorrhage (PPH), accounts for about a quarter of all maternal deaths. Nine out of ten of pregnancy- and birth-related mortalities occur in the global South where healthcare facilities and staff are often not equipped to handle obstetric emergencies. Moreover, the re-use of syringes and needles increases the risks of transmission of HIV and hepatitis C. To address this, Instituto Biologico Argentino, an Argentine pharmaceutical manufacturer collaborating with, PATH, launched oxytocin in Uniject in 2009. The Uniject device is a prefilled, non-reusable syringe that offers delivery of the life-saving benefits of oxytocin to women in peripheral healthcare settings, and homes. These benefits can improve the ability of midwives and village health workers to administer oxytocin outside of health care facilities and in emergency situations or remote locations.

Anti-Shock Suit[24]

Another new tool designed to reduce maternal deaths from PPH in non-clinical settings is a low-cost neoprene covering resembling a wetsuit. PATH has developed a low-tech anti-shock garment that applies pressure to the lower part of a women's body, forcing blood to key organs including the heart, lungs, and brain. When fitted correctly, it can keep a mother alive until she receives treatment at an emergency obstetric care facility.

24 http://www.path.org/projects/antishock-garment.php

Still in the Development Pipeline:

HIV Vaccines

The search for a vaccine against HIV has been underway since the mid-1990s, with slow progress. However, results from a trial held in Thailand in 2009 were promising. Though the protection the vaccine provided was too modest to support licensure, subsequent analysis of the immune responses induced by the vaccine has provided information that will be applied to the design and clinical evaluation of future HIV vaccine candidates.

Recent modelling studies by the, International AIDS Vaccine Initiative (IAVI), suggest that even a partially effective vaccine could significantly reduce the number of new HIV infections among women within the context of a comprehensive programme of treatment and prevention. For example, a vaccine with 50 per cent efficacy given to 30 per cent of the adult population in low- and middle-income countries from 2020 to 2030 would prevent 2.8 million infections in women[25]. Under current trends in HIV & AIDS programming, an AIDS vaccine could save between 36–75 billion USD in averted costs of ART provision alone[26].

Dual-Purpose Vaginal Ring

High rates of HIV and unintended pregnancy are significant causes of health complications and death for women worldwide. A dual-purpose product that is able to protect against HIV and provide reliable contraception would offer significant health benefits for women, particularly in areas where the HIV epidemic is highest. Researchers at organisations such as the, International Partnership for Microbicides (IPM), and the, Population Council, are currently working on developing a dual-purpose contraceptive, HIV prevention vaginal ring containing a microbicide that could remain in place for two months.

Several versions of the vaginal ring are already available for contraception, including the Nuva-Ring. IPM's Ring Study, currently enrolling 1,650 women ages 18–45 across six sites in South Africa, Rwanda, and Malawi, will examine the effectiveness of the anti-retroviral microbicide dapivirine in preventing HIV infection in a similar vaginal ring. This ring could form the basis of the dual-purpose version if it is found to be effective.

The Pericoital Pill[27]

About 20 per cent of women in sub-Saharan Africa, and South and Southeast Asia cite infrequent sex as the reason for an unmet need for family planning. There is increasing evidence that women are interested in a contraceptive pill that they could take 'on the day' rather than every day. It is hoped that the morning-after, or emergency contraceptive pill, could be the basis for this pericoital, or on demand option.

Large scale clinical trials will be needed to gather more data on effectiveness and secure stringent regulatory approval for widespread use. The non-governmental organisation (NGO), Gynuity Health Projects, has secured funding to plan for such trials and other steps in the product development process for this new method.

25 Spotlight on Women: Modeling the Impact of a Future AIDS Vaccine, Policy Note, IAVI, May 2012.

26 AIDS Vaccines: Exploring the Potential Cost/Benefit, Policy Brief 30, IAVI, May 2012.

27 A new type of oral contraceptive pill: http://sites.path.org/rh recent-reproductive-health-projects/a-new-type-of-oral-contraceptive-pill/.

Bridging the Divide

There is a perception that we already have all the methods we need for family planning and maternal health.

To date there has been no joint call for greater investment in R&D coming from SRHR and Global Health R&D advocates beyond the need to find additional HIV prevention options. This has partly to do with the difficulties in ensuring that even the most basic health services reach women. For this reason SRHR advocates tend to focus on increasing the availability of existing and proven interventions. There is a perception that we already have all the methods we need for family planning and maternal health, or it is taken for granted that new improved options will be researched and made available by the pharmaceutical industry. Another contributing factor is that R&D advocacy is often regarded by SRHR advocates as beyond their expertise. Finally, and more recently in the current economic context, R&D is thought to be incredibly expensive in comparison to other global health interventions.

Meanwhile, the field of Global Health R&D is usually talked about in terms of the eradication of disease, and rarely references research already ongoing into new tools for sexual and reproductive health. The most prominent definitions of Global Health R&D tend to describe diseases that primarily affect the global poor and for which patents provide insufficient market incentives[28].

In this context, awareness of the wide range of existing R&D efforts in the field of SRHR, such as the pericoital pill, anti-shock suit, and oxytocin in Uniject remains low. Recently, however there has been increasing attention to the need for new tools that meet the sexual and reproductive health needs of women in resource-poor settings. R&D advocates are also starting to highlight the disproportionate impact of malaria, TB, and neglected tropical diseases felt by women and children in in low- and middle-income countries.

We can't save lives from one cause, only for them to be taken by another.

All of the new health products currently being explored in research have the potential to lower the cost of delivering health outcomes, particularly if they are combined effectively with existing options.

Both SRHR and Global Health R&D are inadequately resourced. In the context of increasingly constrained resources it is all too easy to see funding as a zero-sum game. Investment in R&D can appear to be 'too expensive' or a 'luxury we cannot afford' when equivalent sums can be spent on existing interventions that have been proven to save lives. However, the costs of continuing down the same road are likely to be even greater without new or adapted interventions specifically designed to address the health needs of the developing world. We can't save lives from one cause, only for them to be taken by another. All of the new tools currently being explored in research have the potential to lower the cost of delivering health outcomes, particularly if they are combined effectively with existing options. In addition, continued contraceptive and other reproductive health R&D will benefit women's reproductive rights and choices by increasing the range of options available to them.

28 Røttingen J-A, Chamas C (2012) A New Deal for Global Health R&D? The Recommendations of the Consultative Expert Working Group on Research and Development (CEWG). PLoS Med 9(5).

Towards a Shared SRHR and Global Health R&D Agenda

SRHR and global health advocates need to work more closely together to achieve mutual goals. This can start by integrating R&D asks into ongoing SRHR and wider global health advocacy. Likewise, R&D advocates can increase awareness of how R&D has delivered, and is continuing to deliver, new tools that can bring about universal access to sexual and reproductive health.

There is a clear need for greater consensus on the research needs within SRHR as we move beyond the MDGs and enter the post-MDG process. Using the ICPD framework as a basis, the outline of a common R&D agenda might look like this:

1. **Safe motherhood:** measures to address the leading causes of maternal mortality in low- and middle-income countries, such as new or adapted tools that prevent severe postpartum haemorrhage (PPH) and hypertension in non-clinical settings, vaccines and other prevention options against all PRNDs, in particular HIV, TB, malaria, hookworm, Chagas disease, and schistosomiasis.
2. **Family planning:** new methods of contraception that are long-acting, can be self-administered, do not cause systemic side-effects, can be used on demand, and do not require partner participation or knowledge.
3. **HIV and other STIs:** new prevention options against HIV and other STIs including vaccines, microbicides, pre-exposure prophylaxis (PrEP), cervical barriers, multi-purpose technologies that combine HIV and STI protection with contraception.
4. **Research and development capacity in low- and middle-income countries:** fostering the ability to create and use beneficial technologies in all countries, building research and development capacity including state of the art research facilities and training of healthcare workers where health needs are greatest.

Advocates in both the SRHR and Global Health R&D areas can join forces by calling for continued, long-term, and flexible R&D funding for new or adapted cost-effective interventions that support all of the above.

Recommendations

In Germany, DSW calls for:

- Increased German financial commitment for the European and Developing Countries Clinical Trial Partnership (EDCTP).
- A second call for PDP core funding with multi-annual funding totalling 100 million Euro.
- Better synergy of GH R&D and German official development assistance (ODA).

At the EU level, DSW calls for:

- To substantially increase funding for R&D into PRND in Horizon 2020 in comparison with the previous Framework Programme. This includes a budget for PRND R&D of **500 million Euro** and the **commitment of at least 500 million Euro towards EDCTP** (European and Developing Countries Clinical Trials Partnership) to continue and extend its successful work in Sub-Saharan Africa beyond its current focus on HIV & AIDS, malaria, and tuberculosis to also cover other neglected tropical diseases and all clinical trial phases.

End note: The paper is drawn from a range of sources, including the DSW Strategic Plan 2011–2016, recent DSW annual reports and other internal documentation, plus factsheets and material produced by leading NGOs in Global Health R&D such as IAVI, IPM and PATH. In addition, interviews were conducted with selected representatives of PDPs and other NGOs in the field of Global Health R&D, as well as DSW project officers based in Eastern Africa.

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