Concept Foundation

Annual Report

2020
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### Abbreviations

- **AIM** – Accelerating Innovation for Mothers
- **BPG** – Benzathine Penicillin G
- **API** – Active Pharmaceutical Ingredient
- **CEDES** – Centro de Estudios de Estado y Sociedad
- **E-MOTIVE** – Early detection of PPH and treatment using the WHO MOTIVE 'first response' bundle
- **EC** – Emergency Contraception
- **ECOWAS** – Economic Community of West African States
- **EMI** – Early menstrual induction
- **EAC** – East African Community
- **ECDES** – Centro de Estudios de Estado y Sociedad
- **EML** – Essential medicines list
- **E-MOTIVE** – Early detection of PPH and treatment using the WHO MOTIVE 'first response' bundle
- **EC** – Emergency Contraception
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- **EC** – Emergency Contraception
- **ECOWAS** – Economic Community of West African States
- **EMI** – Early menstrual induction
- **HSC** – Heat-stable carbetocin
- **IPPF** – International Planned Parenthood Federation
- **IRB** – Institutional Review Board
- **M&D** – Manufacturing and Development
- **MDG** – Millennium Development Goals
- **NMRA** – National Medicines Regulatory Authority
- **OXY** – Oxytocin
- **PPH** – Postpartum haemorrhage
- **R&I** – Research and Innovation
- **RH** – Reproductive Health
- **SDG** – Sustainable Development goals
- **SRHR** – Sexual and Reproductive Health Rights
- **TXA** – Tranexamic acid
- **UNFPA** – United Nations Population Fund
- **UoB** – University of Birmingham
- **WAHO** – West African Health Organization
- **ZNFPC** – Zimbabwe National Family Planning Council

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Photo credit: Joni Kabana, Paul Joseph Brown for Concept Foundation
From the Executive Director

Concept Foundation adopted a 5-year strategy to implement in 2020-2025. The strategy is based on the experience and expertise that we have accumulated over the last decade. It also articulates our vision for the future work of Concept Foundation in the global sexual and reproductive health and rights (SRHR) field.

As we set out to implement our new strategy, the COVID-19 pandemic entered our lives disrupting our daily functioning and programme implementation. We immediately developed risk assessment and mitigation plans for the organization and individual projects. As with other organizations in the field, our capacity to conduct visits to manufacturing sites was severely impacted. We developed remote monitoring protocols which alleviated the impact of this disruption. Another project that was impacted was our advocacy project with WACI Health in East and West Africa to update normative policies for prevention and management of postpartum haemorrhage (PPH). Although regional and country in-person workshops had been planned for this project, our partner WACI Health could switch to virtual meetings and the project could be implemented without major disruptions. For most of our other projects, we could progress with remote working.

While most of 2020 was disrupted by the COVID-19 pandemic, we were able to generate new projects and grants towards the end of the year. Our maternal health portfolio expanded significantly in 2020 while we continued with our contraception and safe abortion projects. An important addition to our portfolio is the self-care activities. Following the publication of the WHO 2019 guideline, we undertook a review of regulatory processes in selected countries of the WHO Eastern Mediterranean region initially and then continued with the other five regions. Self-care is hugely important for access to SRHR, and we have also joined the Self-Care Trailblazer Group.

I am happy to report that we published several peer-reviewed journal articles in 2020. The comprehensive cost-of-goods analysis of co-packaged mifepristone and misoprostol was clearly the highlight which we presented and discussed in a dedicated Reproductive Health Supplies Coalition (RHSC) webinar as well.

Through various collaborative projects, we have established some strong partnerships. Our collaboration with the E-MOTIVE (Early detection of PPH and treatment using the WHO MOTIVE 'first response' bundle) trial group has strengthened our links with University of Birmingham and Monash Institute of Pharmaceutical Sciences. Our Accelerating Innovation for Mothers (AIM) project focusing new product development and introduction for five pregnancy-specific conditions, funded by the Bill and Melinda Gates Foundation, allowed us to partner with the Burnet Institute Maternal, Child and Adolescent Health team and Policy Cures Research. We value these global health partnerships greatly and strongly believe that they increase the impact of our projects.

Concept Foundation will continue to seek and implement projects and partnerships that will support the attainment of key global targets and improve SRHR of women and girls globally.
The 2020-2025 strategy

The world is going through a technological shift that has never been seen before. Precision medicine, smart devices and artificial intelligence have become everyday terms that impact health care significantly. The concept of self care is gaining increasing popularity with the development of subcutaneous injectable contraception, the increasing choices of diagnostic tests that can be carried out at home as well as remote care options for emergency contraception, medical abortion and antenatal care.

It is with this background that the Foundation staff discussed and developed a five-year strategy that is guiding Concept Foundation’s priority areas of work.

The strategy is based on the following vision and mission statements that guide our work and personal commitments.
OUR VISION

Concept Foundation envisions a world where all people have access to quality-assured sexual and reproductive health medicines and technologies.

OUR MISSION

Concept Foundation identifies, innovates, and enables equitable access to quality-assured, affordable, essential sexual and reproductive health medicines and technologies.
Our strategic plan aims to build on our existing portfolio of support to manufacturers for ensuring the development of quality assured technologies that will be available, accessible, and affordable in low-and middle-income countries (LMIC); prequalification and in-country support for registration of WHO-recommended commodities, their inclusion in country policies; and start a new area of work on research and evaluation of promising and recommended technologies. The latter is an area where Concept Foundation has conducted work in the past, such as evaluation of the quality of essential SRH medicines and expanding into the area of early phase research and development for product development and assessment for readiness for large scale evaluations of promising technologies. The research portfolio will also include basic technology development, including manufacturing technologies as well as pharmacological bioequivalence assessments for generic medicines.

An aspect of our work that is often not visible but critical to our portfolio is our due diligence expertise in assessing pharmaceutical market partners such as pharmaceutical companies, quality testing laboratories, distribution companies and local agent assessment in preparing for regulatory submissions. We have developed this expertise over years of working in the regions and countries that are often not easily accessible and we intend to strengthen this expertise in coming years in concordance with our programme portfolio.

Concept Foundation, in accordance with its mission and statutes, will provide services to generate income for its operations to secure its sustainability. Such activities will be within its thematic area of SRH, limited to evidence-based recommended technologies and where the work will contribute to the availability of quality-assured, affordable technologies in LMIC.
Research and Innovation

Introduction

The year 2020 has been the first functional year for the Research and Innovation (R&I) team since its initiation in 2019. With the arrival of a Research Manager, the R&I team has been formally established, several projects are ongoing and new projects have started. The aim of the R&I team is to identify, develop and evaluate new and neglected high potential SRH medicines and technologies. Our projects include among others, clinical studies for potential new medicines, implementation studies of existing therapies, pipeline and landscape studies to investigate the current need in maternal health, studies on self-care and self-care interventions and analytical testing of medicines.

COVID-19 has made 2020 a challenging year, which has impacted some of the R&I projects. Although, it has also provided an opportunity to engage and connect with many different individuals, organizations and partners through virtual meetings for discussing our current activities, new ideas and explore possible future collaborations.

Projects and activities in 2020

E-MOTIVE – PPH-Bundle

In many LMIC, PPH is often not detected early, thus life-saving treatment is not promptly initiated. In addition, there is a delayed or inconsistent use of interventions for PPH management. As a result, every six minutes a mother dies from PPH in low-resource countries, in the prime of her life and often leaving behind a young family.

Since November 2019, Concept Foundation is part of an implementation research project led by the University of Birmingham (UoB), to evaluate the impact of a first response PPH treatment bundle on substantive health outcomes. The PPH first response bundle includes the administration of oxytocin (OXY), tranexamic acid (TXA), uterine massage and fluids. The study is taking place in numerous health facilities in Kenya, Nigeria, Tanzania, South Africa and Sri Lanka.

The role of Concept Foundation is to evaluate the quality of the OXY and TXA products that the participating health facilities are using. Examining product quality ensures that the study is performed under optimal conditions. By identifying the presence of low-quality products within facilities, advice can be provided on alternatives and/or alternative products can be provided. If replacing low-quality products is not an option, due to access or price, this factor can be considered during the evaluation of the study outcome. The quality assessment of OXY and TXA will be performed by the HMSTrust Analytical Laboratory, a translational research facility located in the Monash Institute of Pharmaceutical Sciences (Melbourne, Australia). Before we could commence collection and shipment of the samples used in the facilities, country approvals and site selection were required. After some delays because of COVID-19, UoB shifted to virtual site selection in identifying and assessing of facilities to participate in the study. However, this did not fully mitigate the delay and as a result, site selection and country approval were extended to 2021.
In 2020, Concept Foundation organized the analysis of samples collected from facilities in Nigeria and South-Africa. In Nigeria, seven unique OXY products and four unique TXA samples were identified. Of these seven OXY products, only two products met the specification of >95% active ingredient. The remaining five products ranged between 70-87%. Three of the four TXA products met specification, the fourth contained a large unknown related substance. In South-Africa, only one OXY and one TXA product were analyzed, with both meeting specification. Sample collection in Tanzania, Kenya and Sri Lanka will take place in early 2021, with additional sites also being selected in Nigeria.

AIM – Accelerating Innovation for Mothers
Maternal health was first prioritized as a global public health issue at a meeting in Nairobi in 1987 which led to the establishment of the Safe Motherhood movement. In 1994, at the International Conference on Population and Development (ICPD) in Cairo, a comprehensive definition of SRH which included the pregnancy and childbirth period was agreed upon. At the Millennium Summit in 2000, improving maternal health was included as Goal 5 of the Millennium Development Goals (MDG) with reducing maternal mortality as the key target. Reducing maternal mortality and universal access to SRH care was again prioritized as a target in Sustainable Development Goal (SDG) 3. In between, the UN Secretary General launched the Global Strategy for Women’s, Children’s and Adolescents’ Health (2016-2030) to help further the SDGs. In summary, it is fair to say that improving maternal health has been a global health priority since the 1990s.

We believe that under-investment in developing innovative pharmaceutical medicines has hindered progress towards the attainment of the key SDG3 target of ‘reducing the global maternal mortality ratio to less than 70 per 100,000 live births by 2030’. Although overall maternal death numbers are reducing, hypertensive disorders of pregnancy and obstetric haemorrhage continue to cause preventable deaths.
THE NEED = More safe, effective, affordable products

Most of the maternal health medicines currently available for use in the field were developed more than half a century ago (e.g., magnesium sulfate, OXY, misoprostol etc.) and have critical shortcomings such as difficulty in administration, transportation and storage, monitoring and recurrent quality issues. There is no effective medical management for prevention and treatment of impaired foetal growth. The knowledge accumulated in the past two decades around the mechanism of placenta-related pregnancy morbidities and advances in bio-pharmaceutical developments should allow new innovations to be developed for pregnancy specific conditions such as preeclampsia/eclampsia and impaired foetal growth and improvements in technologies for PPH.

Since the early 2000s there have been only a handful of ‘new’ pharmaceuticals either in the form of new prostaglandins or oxytocin analogues or antagonists. Fisk and Atun highlighted this lack of pharmaceutical R&D in maternal health in their 2008 analysis and Chappell and David highlighted the same in 2016. Authors of both papers highlighted the need for a partnership approach to guide the development of new medicines for pregnancy-specific conditions.

Our ambition is to develop a mechanism that enables and fosters greater investment to develop medicines for pregnancy specific conditions

In partnership and with support from the Bill & Melinda Gates Foundation, Concept Foundation is engaging with key stakeholders in the pharmaceutical industry and public health fields to assess interest in establishing a consortium including donors, manufacturers, procurers, academia and consumer organization towards the establishment of a strategic product development partnership (PDP) for new innovations in maternal health.

Preparation phase

Concept Foundation will establish an understanding of the current status of maternal health medicine development for five pregnancy specific conditions through reviewing literature and interviewing key individuals and opinion-leaders from different stakeholder groups. Policy Cures Research, known for their G-FINDER analysis, will conduct a comprehensive pipeline analysis on the history of maternal health medicine development over the past 15-20 years. The five conditions in scope of the preparation phase are the following:

Preterm labour/birth, pre-eclampsia/eclampsia, impaired foetal growth, intrapartum foetal distress, and PPH.

The 12-month planning and preparation phase (November 2020 – October 2021) period will result in:

• A clear understanding of the current landscape in maternal health medicines and the barriers and challenges restricting R&D investments
• The selection of priority pipeline medicines, including three developed target product profiles (TPP)
• A mechanism to operationalize a partnership structure

If it is established, AIM will be a long-term multi-stakeholder initiative, consisting of academia, research institutions, pharmaceutical manufactures, UN agencies, professional organizations and donors, and inspired by existing successful PDPs, such as Medicines for Malaria Venture (MMV), Drugs for Neglected Diseases Initiative (DNDi), and the TB Alliance.

Novel treatment research for early menstrual induction (EMI)

Emergency contraception (EC) offers an effective solution in cases of unprotected intercourse. Emergency contraceptive pills and intrauterine devices (IUD) provide a reliable option when taken within 3-5 days. However, after missing this 3-5-day window, women need to wait for expected menses and must take a pregnancy test to confirm pregnancy before being able to take the appropriate course of action from the options available.

In 2020, in collaboration with Chulalongkorn University (Bangkok, Thailand), CEMAG Care (Paris, France) and WHO, we developed a study proposal to investigate the effect of a novel treatment which can be used between...
five days after intercourse and the day before expected menstruation. In the planned proof-of-concept study, 80 women who are pregnant, because they have missed the current EC window, will be given progesterone followed by an anti-progesterone 48 hours later to induce menstruation, and thereby preventing pregnancy. If effective, this intervention will increase options available to women, filling an important gap in the efforts to prevent unwanted pregnancies and potentially unsafe abortions. The duration of the study will be 20 months, of which 12 months will be needed for the recruitment of women at the Chulalongkorn University Hospital in Bangkok, Thailand.

The first meeting with the EMI expert advisory group took place in early 2020, after which the clinical protocol was developed, and the full proposal was written. Concept Foundation received input from a statistician on the study design, success rate and sample size, and several rounds of feedback from the advisory group and WHO. The final proposal was submitted to WHO-HRP review panel and is currently under review. In collaboration with Chulalongkorn University, we are preparing the submission of the proposal to the Thai Institutional Review Board (IRB) in early 2021.

Mifepristone and misoprostol laboratory analysis from selected LMIC

In 2020, we issued a request for proposal (RFP) for selecting a qualified laboratory for the analytical testing of mifepristone and misoprostol samples collected as part of a collaborative project between Concept Foundation and International Planned Parenthood Federation (IPPF). Proposals from four laboratories were assessed and a laboratory was engaged for development of the testing protocols and subsequent analytical testing of samples. Analytical method verification was completed in December 2020. In parallel, Concept Foundation and IPPF developed a standard operating procedure for sample collection and disseminated to IPPF Member Associations in the initial target countries - Bangladesh, Cambodia, Ethiopia, Democratic Republic of the Congo, India, Nepal, Nigeria, Pakistan, Uganda and Vietnam. Sample collection and laboratory testing will be ongoing during 2021 with findings expected to be published in the final quarter of 2021. This activity is part of a broad range of activities supported by the WHO Prevention of Unsafe Abortion (PUA) unit aimed at improving the availability of co-packaged mifepristone and misoprostol for safe medical abortion in LMIC.
Self-care - regulatory standards and processes for SRH products

We received two grants from the WHO in 2020 to undertake research, and report on the regulatory situation and availability of products for self-care focusing on regular contraceptives, emergency contraception and selected fertility products. In June 2020, a three-month pilot project started with five countries from the Eastern Mediterranean Region (Egypt, Jordan, Morocco, Lebanon and Tunisia). The second project started in September 2020 and will be completed in February 2021. It will cover selected countries from the remaining five WHO regions: Africa (Burkina Faso, Ethiopia, Kenya, Nigeria, Senegal, Uganda, Zambia and Zimbabwe), Americas (Argentina, Brazil, Canada, Panama and Uruguay), Europe (France, Georgia, Kazakhstan and the United Kingdom), South-East Asia (Bangladesh, India and Thailand), and Western Pacific (Australia, China, Laos, the Philippines and Papua New Guinea). In this project, the scope was expanded to include diagnostic tests (pregnancy, ovulation & Human Papilloma Virus) in some of the selected countries.

For both projects, Concept Foundation activities included: i) Researching the current regulatory procedures related to over-the-counter (OTC)/self-care products, ii) Preparing an overview of products available in the countries and where available, establish those licensed for OTC/self-care use, iii) Using local experts to validate the information and provide ‘real life’ scenarios related to SRH medicines, iv) Compiling a report and a manuscript highlighting the findings and potential recommendations to improve regulatory standards and processes of self-care interventions. The projects were undertaken by a cross-functional Concept Foundation team comprising research, regulatory affairs and country support experts.

In November 2020, a manuscript with our findings ‘Regulatory standards and processes for over-the-counter availability of hormonal contraception and drugs for medical abortion in five countries in the Eastern Mediterranean Region’ was accepted for publication in Health Research Policy and Systems. In February 2021, a report will be submitted to WHO with our findings from the other five WHO regions and overall recommendations. In addition to this report, a further manuscript will be prepared.

**Highlights**

- The start of a new research line on SRH self-care interventions, including their regulatory standards and processes, together with the Country Support team.
- Finalization and submission of a proof-of-concept study for WHO funding for a novel post-coital intervention.
- Obtaining funding from the Bill and Melinda Gates Foundation to investigate the interest, potential and ideal structure for a multi-stakeholder initiative (PDP) to accelerate innovation for maternal health conditions.
Manufacturing and Development

Introduction
Concept Foundation has been collaborating with the generic SRH medicines industry for the past three decades since the organization was founded in 1989. Our work with manufacturers has historically centered around quality assured manufacturing and supply of SRH products in LMIC, including establishment of commercial strategies and north to south technology transfer of essential SRH medicines to increase the availability of low cost, safe and effective SRH medicines in low resource settings. To date, approximately 50% of all reproductive health (RH) medicines approved under the WHO prequalification programme have done so with technical support from Concept Foundation experts.

Today, the Manufacturing and Development (M&D) programme has the primary goal of facilitating the availability of quality assured, affordable SRH and technologies worldwide. To meet this goal, Concept Foundation is working with both manufacturers of active pharmaceutical ingredients (API) as well as those manufacturing finished pharmaceutical products (FPP) manufacturers, which depend upon having access to quality-assured and affordable API, to be able to manufacture high-quality products and supply them at affordable prices – an approach which lies at the center of our mission. Our work with manufacturers continues to focus on capacity strengthening through providing remote and on-site technical support towards meeting international quality assurance standards, development of data and compilation of regulatory documentation that meet the requirements of the WHO prequalification (PQ) programme and other stringent regulatory authorities. We are also identifying opportunities for reformulating and/or repurposing SRH technologies to improve their safety and efficacy and reduce production costs, as well as developing and scaling up of new generic medicines and products through direct technical support or conduct of technology transfer to industry partners.

We do this by offering our unique knowledge, know-how and expertise in SRH medicines, through a variety of donor funded projects and commercial partnerships with industry.

Projects and activities in 2020
Development of a lower cost, subcutaneous 3-month injectable contraceptive in Uniject
This collaboration, supported by the Bill and Melinda Gates Foundation and Children’s Investment Fund Foundation, in partnership with a manufacturer in Bangladesh, entered its third year in 2020 following the successful completion of product development activities in 2018 and 2019. The project goal, since its initiation is to develop, in partnership with the selected manufacturer, a lower cost, subcutaneous three-month injectable contraceptive in the Uniject device, a device that allows for self-administration. The focus in 2020 was the finalization of documentation for the technology transfer package and initiation of its transfer to the manufacturer, both of which were successfully implemented during the year. A pilot bioavailability study planned for the first half of 2020, was delayed to August due to the COVID-19 pandemic, with a successful outcome demonstrating comparative pharmacokinetic profiles between the comparator and test product, a major milestone for the project.

OUR MANUFACTURING & DEVELOPMENT IMPACT

- COMPLETED SUCCESSFUL TECHNOLOGY TRANSFER OF SUB-C DMPA ENABLING THE MANUFACTURER TO START THE BIOAVAILABILITY STUDY
- PUBLISHED THE COST OF GOODS ANALYSIS OF MIFE-MISO COMBIPACK
In addition, continuous support was provided to a medroxyprogesterone acetate API manufacturer located in China, resulting in submission to the WHO PQ programme at the end of 2020. With the current limited options for procurement of this API, it is expected that prequalification of this material will make a substantial contribution to the sustainable supply of injectable contraception.

Technical support to manufacturers
In 2020, the M&D team provided technical support and strategic advice, under its commercial partnerships programme to an Indonesian manufacturer of three-monthly injectable contraception towards prequalification by WHO and identifying forward strategies for increasing their footprint and portfolio in LMIC and provided good manufacturing practice (GMP) expertise to a manufacturer of an influenza vaccines in Russia.

2020 was also the year in which the three-monthly injectable contraceptive manufactured by Incepta Pharmaceuticals was formally prequalified by WHO, an outcome of a long-term technical collaboration supported by the Bill and Melinda Gates Foundation.

Increasing the availability of mifepristone and misoprostol active pharmaceutical ingredients (API) for medical abortion drugs
Since 2019, Concept Foundation has been supported by WHO PUA to undertake a range of activities to improve the availability of co-packaged mifepristone and misoprostol medical abortion drugs (commonly known as combipacks) across LMIC, working with both manufacturers and country-level stakeholders to increase access to quality-assured, affordable medical abortion products in selected countries. As part of this broad focused project, the M&D team is providing technical assistance to manufacturers of medical abortion FPP and manufacturers of the API needed for those products.

Our recently published cost of goods sold analysis and accompanying recommendations identified that the cost of mifepristone API, is a key barrier to the development and supply of quality-assured combipacks in LMIC. In
2020, with an overall aim to have at least one additional misoprostol, and one additional quality-assured source of mifepristone API, Concept Foundation identified and selected candidate manufacturers to receive technical support towards achieving WHO prequalification. Companies were selected following an Expression of Interest invitation, technical questionnaire evaluation process and indicative price commitments, resulting in two candidates for each API, located in Europe and Asia. To support decision-making processes and forward planning, Concept Foundation is also developing a business case that will include estimates of global demand, an activity that commenced in late 2020.

Provision of technical support to manufacturers of Benzathine Penicillin G (BPG)

Concept Foundation continued to play an active role in the WHO convened Technical Working Group for BPG, convened by WHO and the World Heart Federation (WHF) to address systemic market failures – stock-outs, supply chain issues and product quality of this essential antibiotic used for the treatment of syphilis during pregnancy and congenital syphilis in newborns. In 2020, the M&D team continued to provide technical assistance to two manufacturers of BPG located in China. This support during the year has focused primarily on the development of analytical testing methods specifically, a dissolution method feasibility study to establish a baseline and support both manufacturers in their broader method development. Following on-site technical assessments of both manufacturers in 2019, access to a correctly developed and validated dissolution method was identified as a key barrier towards the broader objective of achieving WHO prequalification.

**Highlights**

- Development of a technology transfer package and successful transfer to the manufacturing partner - subcutaneous three-month injectable contraceptive.
- Conduct of a successful pilot bioavailability study demonstrating comparable pharmacokinetic profile with the innovator product.
- Identification and selection of manufacturing partners of misoprostol and mifepristone API for supporting towards dossier submission to the WHO prequalification programme.
- Engagement and forward planning with two new manufacturers of misoprostol-mifepristone medical abortion drugs interested in developing quality-assured products targeted toward LMIC.
Country Support and Market Access

Introduction

The country support and market access programme goal is to facilitate access to quality assured SRH medicines and technologies in LMIC and the establishment and implementation of international and national normative guidelines, policies, and processes for SRH technologies. Our current market access related activities range from large-scale regulatory support and identification of local representation/distribution partners to conducting due diligence, cost of goods analysis, supply strategies and a variety of market assessment activities.

During the year, Concept Foundation has further strengthened its country support, regulatory and market access functions with the addition of new staff and strategic partnerships to meet increasing demand and convened cross-functional dedicated expert teams to effectively develop and implement multifaceted and interrelated country and market access activities across three focus areas - family planning, maternal health and medical abortion.

Projects and activities in 2020

Implementing normative guidelines and policies for SRH technologies

Improving access to essential medicines to reduce PPH morbidity and mortality

Implemented by the Country Support team and funded by MSD for Mothers over the past few years, as part of Project CHAMPION, a specific two-year project for 2019-2020 was successfully completed in December 2020. The goal of the project was to achieve the update of national PPH guidelines and Essential Medicines Lists (EML) to reflect the most recent WHO recommendations on uterotonics, to include heat-stable carbetocin (HSC) for prevention and TXA for treatment of PPH in ten countries by end 2020. The target countries were all within the East African Community (EAC) and Economic Community of West African States (ECOWAS).

Working in partnership with WACI Health, an African regional advocacy organization, Concept Foundation engaged with national governments, regional initiatives and other key stakeholders in South Sudan, Rwanda, Uganda, Ethiopia, Burkina Faso, Liberia, Ghana, Sierra Leone, Senegal and Ivory Coast, conducting country focused and regional meetings throughout the project to i) Identify and benchmark existing policies across the two Regional Economic Communities (RECs), levels of awareness and propose solutions (WHO Recommendations, new evidence on stability and effectiveness of uterotonics, alternatives to current options, etc.), ii) Engage the health secretariats of the two RECs – EAC Health Secretariat, West African Health Organization (WAHO) for ECOWAS, and reach agreement to work collaboratively and use the REC Health Secretariat as partner to reach country stakeholders, iii) Conduct a series of regional workshops and country engagement activities in order to support achievement of the project goals. Two regional workshops were conducted in Nairobi, Kenya for the EAC region in December 2019 and Accra, Ghana for the ECOWAS region in March 2020. The workshops were advocacy focused on informing the countries of changes to the WHO Recommendations on uterotonics for prevention and treatment of PPH and the updated WHO EML and supporting materials, explaining the new recommendations, and demonstrating the need for policy change. Following the workshops, we monitored and provided technical guidance to each country to ensure the
implementation of agreed regional/national level actions and mobilized technical resources for in-country follow-up workshops.

Establishing these strong relationships with the countries has provided opportunity for continuous engagement and impact. In our current 2021-2022 MSD for Mothers project, Concept Foundation is expanding activities to connect the policy change with practice in selected countries and extend our impact into Universal Health Coverage which is the current global health priority articulated by WHO and endorsed by its Member States.

Strengthening national and regional policies and guidelines for Medical Abortion services and commodities in three countries – Kyrgyzstan, Uzbekistan and Zimbabwe

As part of the grant awarded to Concept Foundation from WHO PUA for 2019-2020, we conducted country level activities in 2020 to support normative guidelines and processes for accessing medical abortion products and services in Kyrgyzstan, Uzbekistan and Zimbabwe.

In Kyrgyzstan, significant progress was made in 2020 through updating of Order 618, issued by the Ministry of Health (MoH) detailing the regulations and updating critical aspects of the procedure for provision of medical abortion services in the country. These regulations were created in 2009 and had not been updated since, despite several efforts. The updated order has been renamed Order 931 and was published on the MoH’s website at the end of 2020.

In Uzbekistan, activities focused on inclusion of co-packaged mifepristone and misoprostol for the management of medical abortion into the national EML. These activities were coordinated with the WHO Country Office. Based on progress at the end of 2020, it is expected that co-packaged mifepristone and misoprostol will be included on the EML in 2021.

In both Kyrgyzstan and Uzbekistan, working groups were created to review and update training materials for abortion being used by institutions that provide training for providers of medical abortion services, including the National Medical College and Academies, OBGYN association, association of Midwives and National Medical
Institutes. In both countries, Concept Foundation worked with regional experts to coordinate working groups of local experts to develop and revise training modules based on the most recent WHO recommendations. These revisions were successfully completed in both countries and will be translated, finalized, and disseminated to the relevant stakeholders in each country in 2021.

In Zimbabwe, Concept Foundation worked with Zimbabwe National Family Planning Council (ZNFPC) and successfully organized the first National Safe Abortion Roundtable in December 2019 in Mazowe, Zimbabwe. Based on the recommendations from the meeting, in 2020, an initial country plan draft was established by the different stakeholders including the MoH delegation. Concept Foundation and ZNFPC drafted the safe abortion workplan which was presented to the Director of Family Health for its validation as part of the national safe abortion strategy in February 2020. In September 2020, the acting Director of Family Health validated the workplan and forward activities to be implemented.
Regulatory support for registration of SRH medicines and technologies

Facilitating the availability of a novel uterotonic in LMIC

Under a long-standing partnership with industry, Concept Foundation is playing a pivotal role in facilitating the global LMIC availability of an essential new medicines for PPH – from providing strategic advice through to compilation of regulatory dossiers and supporting submissions, as well as identifying and conducting due diligence on national representatives as part of the registration process. In 2020, we prepared regulatory submissions for five countries and conducted due diligence on six local entities in four countries.

Regulatory guidance on oxytocin storage

In 2020, Concept Foundation regulatory experts developed an oxytocin regulatory guidance document (Guidance for Regulators on the Assessment and Management of Oxytocin) on behalf of WHO HRP. The guidance was developed with participation from regulatory authorities and international experts and included an Oxytocin Virtual Expert Consultative Meeting on 15 and 17 September convened and hosted by Concept Foundation. This meeting brought together nearly 40 oxytocin quality and regulatory experts from around the world to provide inputs into the document. Pharmaceutical regulators are at the forefront of ensuring that only safe and effective medicines are authorized and available in the market. The document builds upon previous recommendations and was prepared to specifically assist National Medicines Regulatory Authorities (NMRA) in understanding the nature and extent of oxytocin quality issues and to provide key technical information and quality requirements for an oxytocin product needed for dossier assessment to ensure that only quality-assured oxytocin products are authorised.

Whilst the primary target audience is pharmaceutical regulators in NMRA, the information contained may also assist manufacturers in the development of quality oxytocin, and similarly assist procurers involved in identifying or selecting oxytocin products for procurement.

Regulatory support for medical abortion combipack in Zimbabwe

Concept Foundation has been supporting the registration of a quality-assured co-packaged mifepristone and misoprostol medical abortion product in Zimbabwe, providing key information and guidance to ensure compliance with Medicines Control Authority of Zimbabwe (MCAZ) requirements. We were also able to identify and conduct initial due diligence on a local distributor, who as a result has been contracted by the manufacturer. This activity was part of a broad range of activities supported by WHO PUA aimed at improving the availability of co-packaged mifepristone and misoprostol for safe medical abortion in LMIC.
Supporting access to safe medical abortion in Argentina
In anticipation of a change in the abortion law, Concept Foundation, under a grant from the RHSC Innovation Fund began a market assessment of the potential Argentinian market for medical abortion drugs, partnering with Centro de Estudios de Estado y Sociedad (CEDES), a national non-governmental organization. In December 2020, the law was changed to allow access to abortion up to 14 weeks and the market assessment report will be an important resource for the country as it prepares to implement the legislation in terms of ensuring the availability of products and forecasting demand. The report is scheduled for completion during the first half of 2021.

Highlights
- While progress toward updating national PPH guidelines and EML varied between countries, all the target countries had drafted updated guidelines and EML to include HSC and TXA at the end of 2020. In most countries, the guidelines and EMLs are being finalized and we are confident they will be signed and published in early 2021.
- Update of Order 618 by the Ministry of Health in Kyrgyzstan detailing critical procedures for provision of medical abortion services in the country.
- Identification of national representatives for a novel uterotonic in four LMIC.
- Development of OXY guidance document (Guidance for Regulators on the Assessment and Management of OXY) for WHO HRP.
- Publication of our cost of goods sold analysis and recommendations to reduce costs of co-packaged mifepristone-misoprostol for medical abortion.

Outreach


ECOWAS regional workshop updates, March 30/31, 2020 in Accra, Ghana (work plan drafted, and joint activities were agreed upon by WACI Health and WAHO).
Partners and Donors

Key partners
Concept Foundation works with many partners in both the reproductive health commodity and the broader sexual and reproductive health constituencies.

HRP (the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction), WHO and UNFPA
HRP/RHR/WHO is one of our main partners. Concept Foundation has a long-standing collaboration agreement with HRP based on its earlier work on Cyclofem® and safe medical abortion commodities, mifepristone and misoprostol (Medabon®). The WHO collaboration agreement allows Concept Foundation to work closely WHO on all sexual and reproductive health technologies. Concept Foundation also works closely with the WHO prequalification and medicines departments, POA unit and collaborative registration programme. These partnerships have been built over the last 30 years and have resulted in a close and unique relationship with the WHO.

Concept Foundation works closely with UNFPA, specifically its Supplies Division based in Copenhagen, Denmark co-convening and participating in its technical meetings and providing support and advice as needed.

Reproductive Health Supplies Coalition (RHSC)
RHSC is the only platform where pharmaceutical manufacturers, donors, NGOs, SMOs and academic institutions come together. Over the years, Concept Foundation staff have played leading roles in RHSC and continue to work collaboratively with RHSC, actively participating in conferences and activities.

Manufacturers
As a policy position, Concept Foundation is manufacturer agnostic regarding its engagement with manufacturers of SRH technologies. We conduct both technical and non-technical ‘due diligence’ on all of the manufacturers that we work with in order to and assess capability and compliance and provide a broad range of ‘industry standard’ technical expertise from product development through to registration. As part of our collaboration agreement with WHO HRP, we partner with PT Tunggal for the manufacturer of Cyclofem® and Sun Pharma for Medabon®. Under these arrangements, Concept Foundation has licensing agreements in place with both companies which generates modest royalty income to support our operations.

Our long-standing engagement with industry has enabled us to have a comprehensive knowledge of the SRH manufacturing landscape, globally and especially for and in LMIC. More recently in 2020, Concept Foundation signed a memorandum of understanding with CEMAG Care a small company based in Paris, France to collaborate on safe medical abortion and other reproductive health technologies.

During the year, either as part of a donor funded project or through a direct service contract, we provided technical support and conducted activities with 15 pharmaceutical companies in Bangladesh (two), China (five), European Union (four), India, Indonesia, Russia and Taiwan.

Nongovernmental, not for profit and social marketing organizations
Concept Foundation has close links with nongovernmental, not for profit and social marketing organizations working in the field of sexual and reproductive health. In 2020, we have collaborated with IPPF, a long-standing partner, on sample collection of medical abortion products, Monash Institute of Pharmaceutical Sciences on analytical testing of maternal health medicines, Policy Cures Research and Burnet Institute under the AIM initiative for pregnancy specific conditions, CEDES to develop a market assessment for medical abortion in Argentina and WACI Health on normative guideline updates across sub-Saharan Africa.

Donors
Concept Foundation is grateful to its donor partners for supporting the work presented in the annual report.
Financial summary (2020)

INCOME

10% Royalties
39% Country Support
49% Manufacturing & Development
2% Research & Innovation

INCOME

Grants 3,225,094
Contracts 546,775
Royalties 435,667
Other 11,193
Total Income $ 4,218,729

EXPENSES

22% Operations and General
78% Programmes

EXPENSES

Programmes 3,223,918
Operations and General 913,166
Total Expenses $ 4,137,084
Publications


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