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In 2021, although COVID-19 disruptions continued, we managed to develop resilience and a new approach to work. As the travel restrictions slowly decreased, we started thinking more carefully about taking on trips that we used to consider routine. We started planning our tele-working and virtual meetings more strategically.

Our collaboration with Asian and Australian institutions and North American partners increased which means that we are now working across most time zones.

One of our main projects in 2021 was ‘Accelerating Innovation for Mothers’ or AIM project supported by the Bill and Melinda Gates Foundation and implemented with Burnet Institute and Policy Cures Research. Together, we identified 444 products that have been or are being researched for five pregnancy-specific conditions since 2000. We completed four target product profiles for the first time for maternal health products, and we conducted a thorough market analysis. Our AIM work has been catalytic to several other organizations and partners.

The challenges that make the development of new products for pregnancy-specific conditions in the AIM project were put on global display through the COVID-19 vaccine and drug trials. Pregnant women were excluded especially from the vaccine trials and when evidence about increased vulnerability of pregnant women to COVID-19 emerged, vaccines were recommended for pregnant women because of possible benefits over potential harms without trial-based evidence.

COVID-19 research and development is a current example of the prevailing gender inequalities and bias that disadvantages women globally. Without understanding and directly addressing the individual and societal determinants of these gender biases, progress in sexual and reproductive health and rights will not be possible. We will complement our work on enabling access to quality-assured medicines and technologies with advocacy and collaboration with like-minded partners to reduce gender biases in global health. Being one of the sponsors of the Geneva Health Forum conference, we are partnering with GENDRO, a nongovernmental organization focusing on gender-related issues in research, to organize a workshop entitled Swiss Women’s Health Alliance to discuss these matters at the 2022 conference.

I am also happy to report that our project on improving access to postpartum haemorrhage medicines in partnership with FIGO/ICM and WACI Health is slowly gaining momentum. Updating national normative policies in line with WHO recommendations takes time and is challenging. I am proud to see that even though the progress has been uneven, the majority of the fourteen sub-Saharan African countries participating in the project updated their policies to include heat stable carbetocin and tranexamic acid since our project began. The policy change is necessary but insufficient and these efforts need to be complemented by other key access activities. Our work on safe medical abortion brought important policy changes in Kyrgyzstan and Uzbekistan as well.

Finally, we have continued to play a key role in quality assessment of several reproductive health commodities in 2021. Through our work with WHO, we assessed the quality of mifepristone, misoprostol, and combi-pack products in 11 countries and with the University of Birmingham E-Motive collaboration studied oxytocin and tranexamic acid quality in four countries. These studies will be published in peer-reviewed journals soon.

We have been active in large conferences and conducted several webinars to highlight the issues of concern to us and our work. I am pleased to see that Concept Foundation is increasing its visibility and standing in the global sexual and reproductive health and rights field.
i. Introduction

During 2021, we initiated and supported innovations across a number of projects covering both medicines and devices. The broad and diverse range of project activities included development of improved contraceptive injectable formulations, extensive research into medicines for pregnancy-specific conditions, post-partum haemorrhage (PPH) devices and early clinical research for a novel menstrual induction combination regimen.

ii. Accelerating Innovation for Mothers (AIM)

The goal of the AIM project is to define and implement pathways for accelerating development and introduction of innovative products for pregnancy-specific conditions through global partnerships. AIM started in October 2020 with an initial one-year grant from the Bill and Melinda Gates Foundation (BMGF).

In 2021, we conducted three main activities. Firstly, a stakeholder analysis with over 50 interviews with researchers, donors, academics, pharmaceutical companies and others. We established an understanding of the current state of the field of maternal health medicine development including the most recent progress and key market drivers and failures that limit the introduction of effective maternal medicines at scale, including issues of trial and product liability barriers. Secondly, a comprehensive pipeline analysis was completed and published on a dedicated internet portal for five priority conditions; PPH, pre-eclampsia/eclampsia (PE/E), intrauterine growth restriction (IUGR), preterm labour/birth (PTL/PTB) and fetal distress. The pipeline contains all medicines (drugs, biologics, and dietary supplements) investigated since 2000 for each pregnancy-specific condition. A total of 444 candidates were identified, 178 for PTL/PTB, 153 for PE/E, 63 for IUGR, 39 for PPH, and 11 for fetal distress. The third activity was the development of Target Product Profiles (TPP) for preeclampsia prevention and treatment, tocolytics for preterm labour and prevention of spontaneous preterm labour and birth in women at high risk. These TPPs represent the first set of TPPs for maternal health conditions in the literature and are compatible with WHO TPP methodology.

IMPACT

• AIM is changing the way maternal health R&D is organized and executed
• CF has been instrumental in increasing quality-assured options for injectable contraception
• We are developing new technologies relevant to women and girls in resource-limited settings
The findings of AIM are captured in two reports: 'Medicines for Pregnancy-specific Conditions: Research, Development and Market Analysis' and 'Market Challenges and Potential Solutions for the Development and Introduction of Medicines for Pregnancy Specific Conditions'.

Overview of Maternal Health Medicines Pipeline findings

We consider AIM as a ground-breaking gender transformative initiative and are planning to scale-up and expand the project during 2022.
We initiated a campaign to raise awareness among women, families, and professionals about the need for more innovation and the inclusion of pregnant women in clinical trials. We launched a Public Service Announcement (PSA) video, which was picked up by several news agencies who published articles on their website. Via social media advertisement, we reached 1.8 million people and we continue to spread the message via our social media channels.

Highlights

The first comprehensive pipeline analysis for five major pregnancy conditions was completed and published, containing 444 candidates.

Four TPPs were developed on pre-eclampsia prevention, pre-eclampsia treatment, preterm labour prevention and preterm labour management.

A global advocacy campaign to raise awareness of the issues relating to the lack of medicines for pregnancy-specific conditions was launched.

The exclusion of pregnant women from COVID-19 vaccine and treatment intervention research has been noted and highlighted as a major issue. A similar reluctance exists to test and evaluate new compounds for pregnancy-specific conditions despite clear guidance and encouragement from stringent regulatory agencies.
iii. Subcutaneous DMPA product development

In 2021 Concept Foundation entered its 4th year of a project supporting global efforts for making affordable, quality-assured subcutaneous (SC) depot medroxyprogesterone acetate (DMPA) for self-administration more widely available in low and middle-income countries (LMIC). As the use of injectables continues to rise year on year, the ability of country health systems to meet this growing demand is dependent on the availability of affordable, high-quality products, the ability of the supply chain to get them where they are required and the availability of accessible services and products. This project aims to support country health systems in meeting this growing demand by introducing a generic, self-injectable DMPA product to LMIC markets.

The project is co-funded (BMGF-CIFF) and we collaborate with manufacturers of raw material and finished product in the People’s Republic of China and Bangladesh. With the majority of the formulation development and technology transfer completed in 2020; our focus in 2021 has been on ensuring that a second source of quality-assured active pharmaceutical ingredient (API) is available for sustaining supply for emerging products. To achieve this, throughout 2021 we have been providing technical assistance in GMP and dossier preparation to the manufacturer towards achieving WHO Prequalification of Medicines Programme (PQP).

During the year, we also provided technical support to PTT Tunggal, Indonesia, which is planning the development and launch of an injectable contraceptive for LMIC.

Highlights

A completed dossier for a second source of quality-assured API was submitted to the WHO PQP.

PT Tunggal, Indonesia, achieved WHO PQ of its intramuscular injectable contraceptive Triclofem, adding a third generic intra-muscular DMPA product to the list of WHO prequalified DMPA products.

iv. Novel device for postpartum haemorrhage (PPH)

Since October 2021, Concept Foundation has been supporting Obstetrx, a US medical device company in efforts to bring its novel XSTAT® device for treatment of PPH to market. We identified potential clinical trial sites in India, South Africa, and Vietnam together with candidate Contract Research Organizations (CROs) who could support the implementation of a trial. Concept Foundation also undertook an assessment of the regulatory requirements and related barriers for each of the three countries in scope.

In 2022, a total of 12 clinical sites and 11 CROs will be subjected to due diligence to determine their suitability to support a phase III clinical trial, using risk assessment tools developed in-house.
v. Early Menstrual Induction (EMI)

An EMI clinical study was conceptualized by CEMAG Care Ltd (France), WHO and Concept Foundation. The study will investigate the effect of a novel treatment to induce menstruation which can be used between five days after unprotected intercourse and the day before expected menstruation. The proposed treatment regimen is comprised of a mifepristone, levonorgestrel drug combination. In 2021, the trial was approved by WHO-HRP, the Research Ethics Review Committee (WHO-ERC, protocol ID A66016), and the Institutional Review Board (IRB) of the Faculty of Medicine, Chulalongkorn University (IRB No. 309/64). The study has been registered at ISRCTN (ISRCTN18799324). The contract between WHO and Concept Foundation started 1st of December 2021.

vi. Forward activities

In 2022, we will continue the momentum into the next phase for AIM (2.0) through strengthening the pipeline database and expanding the number of TPPs to include additional conditions, tests, and diagnostics. A new focus will be on maternal enteric microbiome and nutritional iron deficiency-related maternal anemia. We will map LMIC research sites and begin to assemble a multi-country research network to execute the trials needed to advance high-priority candidates. Moreover, AIM 2.0 will have a larger focus on gender inequities and develop actionable solutions for the inclusion of pregnant women in clinical trials.

We will continue our support to the MPA API manufacturer in the People's Republic of China through the WHO prequalification process and to PT Tunggal, Indonesia to validate their manufacturing process and establish product safety and efficacy through conduct of a bioequivalence study.

Due diligence will be conducted on the candidate clinical trial sites and CROs for the XSTAT® PPH device and location and timeline established. We expect to further collaborate with the company on finalizing the clinical protocol and preparation for the pivotal study to commence in the last quarter of 2022.

For the EMI study, following the preparation and finalizing of the manual of operations, recruitment and training materials, and setting up the data management system in REDCap, the recruitment of 80 women is scheduled to begin in the second half of 2022.
Quality assurance of reproductive health medicines

i. Introduction

Ensuring the quality of reproductive health medicines has been a cornerstone of Concept Foundation’s work for more than ten years and we are recognized as a global leader in the field. During the year, we continued our leadership in this field by conducting multi-country quality assessments of medical abortion and maternal health medicines.

ii. E-Motive – PPH first response bundle

Since November 2019, Concept Foundation has been 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 health outcomes. The PPH first response bundle includes the administration of oxytocin, tranexamic acid (TXA), uterine massage and fluids and is taking place in a range of health facilities in Kenya, Nigeria, Tanzania, South Africa, and Sri Lanka. In 2021, Pakistan was added to the study. The role of Concept Foundation is to evaluate the quality of the oxytocin and TXA products that the participating health facilities are using.

A total of 33 individual oxytocin samples (17 unique products) were collected and tested (Table 1). In Kenya and South Africa, with all products meeting acceptance criteria for the active ingredient, compared with only one-third of the products collected in Nigeria and Tanzania. Of the 17 products, oxytocin content in ten products was within 90%–110%. The content varied across the other products, ranging between 69.3% and 89.2%. Related substances were measured in 4 out of these 10 products, of which 6 were identified as having adequate content and no related substances. For TXA, a total of 14 individual samples (9 unique products) were analyzed from health facilities. The content of TXA in all 14 samples analyzed was within +/-10% of the specified label claim and met the acceptance criterion. However, three samples contained large amounts of unknown substances. The findings have been accepted for publication in the PPH supplement of the International Journal of Gynecology & Obstetrics and will be published mid-2022.

Table 1. Oxytocin products per country of sample collection.

<table>
<thead>
<tr>
<th>Country of collection</th>
<th>Number of samples (# of samples)</th>
<th>Number of products with active ingredient between 90%–110% (% of products)</th>
<th>Number of products with related substances above limit (% of products)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya</td>
<td>8 (8)</td>
<td>8 (100)</td>
<td>3 (38)</td>
</tr>
<tr>
<td>Nigeria</td>
<td>10 (17)</td>
<td>4 (40)</td>
<td>8 (80)</td>
</tr>
<tr>
<td>Tanzania</td>
<td>3 (8) a</td>
<td>1 (33)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>South Africa</td>
<td>1 (1)</td>
<td>1 (100)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

a One product expired during measurement.

Highlight

Oxytocin products collected from E-Motive facilities in Kenya, Nigeria, Tanzania and South Africa showed that 65% of products (11) do not meet quality standards.
iii. Quality of medical abortion drugs

With funding from WHO Prevention of Unsafe Abortion Unit (PAU), throughout 2021 Concept Foundation partnered with the International Planned Parenthood Federation (IPPF) to conduct a multi-country study to determine the quality of individual and co-packaged misoprostol and mifepristone products in LMIC markets. Batch samples of misoprostol and mifepristone were collected in 11 countries - Burkina Faso, Cambodia, Democratic Republic of Congo, India, Kyrgyzstan, Moldova, Nepal, Nigeria, Pakistan, Uganda and Vietnam and tested by a WHO prequalified laboratory. Products were tested for a range of quality attributes in accordance with WHO’s International monograph where available and where not, testing was conducted using validated in-house methods and specifications generated from innovator product.

Sample collection was completed over a 9-month period from December 2020 to October 2021, with testing of samples being done on a rolling basis as samples became available. Results were analyzed at the end of 2021 and a manuscript detailing the study findings drafted for submission to a peer reviewed journal. The published study will be available in late 2022.

![Quality Testing of Medical Abortion Drugs - Non-compliant Findings Per Product Type and Active Ingredient Type](image)

**Highlights**

A total of 64 pooled batch samples were tested, consisting of 31 combipacks, 26 misoprostol-only products and 7 mifepristone-only products.

Overall, 54.7% of samples were non-compliant with one or more of the specifications, representing 51.6% of combipack products, 57.1% of all misoprostol tablets analysed and 23.7% of all mifepristone tablets. One misoprostol-only product was found to be falsified.
iv. Benzathine penicillin G
We continued to support efforts to make quality assured benzathine penicillin more accessible in LMIC in 2021. Our efforts focused primarily on completion of a laboratory feasibility study to support establishment of an analytical testing method for inclusion in the International Pharmacopeia. This study was completed in mid-2021 and the results shared with WHO counterparts in the Local Production Assistance Unit as well as the two manufacturers in China that we have been supporting since 2019. In January 2021, we played a primary role in a virtual consultative meeting co-convened by WHO/WHF entitled “Strengthening the Supply of Quality-Assured Benzathine Penicillin G for Sustainable Access through Global Procurement Mechanisms”. Key actors working in supply of Benzathine Penicillin participated including UNFPA, USAID, UNICEF as well as other partners from CHAI, MSF, PEPFAR, WHO, GFATM and PAHO.

Forward activities
Our role in the E-Motive study will continue in 2022 with the collection and analysis of samples from Sri Lanka and Pakistan. In addition, preliminary experiments on mixing oxytocin and TXA products will be undertaken to test the impact on stability. We will also be working with partners to better understand and mitigate emerging challenges for TXA in support of implementing WHO guidelines and recommendations at country-level.

In 2022, we will also focus activities on better understand and document the health and economic impact of poor quality uterotonics in LMIC and continue to highlight the importance of improving oxytocin quality in particular.

We aim to publish a manuscript detailing the medical abortion drug study findings to a peer reviewed journal in 2022 and raise awareness of the issues through a dissemination campaign during the year, including hosting a session at the forthcoming ICFP conference in Thailand.

We will continue to contribute to resolving the challenges of access to quality assured BPG through supporting the efforts of WHO to improve and define technical specifications and participation in the ongoing, periodic Technical Working Group meetings.

Country support
i. Introduction
Our country support portfolio included a combination of activities supporting market access, together with initiatives to affect change in normative processes and policies. We engaged with manufacturers of quality-assured products to provide LMIC regulatory assistance and strategy development. Our normative policy work is generating rich data on health systems functioning that is highly context-specific.

ii. Introduction of heat-stable carbetocin (HSC) in LMIC
Since 2016, Concept Foundation has been supporting Ferring Pharmaceuticals on its regulatory strategy and the registration of HSC for its planned introduction in almost 90 LMIC. Under the collaboration, in 2021, HSC was granted regulatory approval in Uganda, Sierra Leone, Democratic Republic of Congo, Republic of South Sudan, Tanzania, Zanzibar and by the Caribbean Community and Common Market (CARICOM), a collaborative mechanism operating in the Caribbean region.

IMPACT
• Our regulatory and local agent work facilitated HSC registration in Project CHAMPION countries
• With our partner WACI Health we enabled normative policy change in five East and West African countries
• We enabled medical abortion policy change in Kyrgyzstan and Uzbekistan
As local representation is a pre-requisite to registration in many countries, it is an additional requirement for non-domiciled pharmaceutical companies which don't have an existing presence in those countries to work with local agents. Concept Foundation successfully identified and conducted due diligence on potential local agents in over 16 countries in 2021.

### Highlights

**Provided regulatory expertise facilitating HSC approval in five countries.**

**Identified and conducted due diligence on 16 candidate local representative companies across project countries.**

#### iii. Self-Care

We analyzed existing regulatory procedures for changing the category from prescription only medicines (POM) to over the counter (OTC) in 30 countries across all WHO regions for oral contraceptive (including emergency contraceptive) pills, and self-administered injectable contraception. We also reviewed the presence of contraceptives on national Essential Medicines (EML) and OTC lists. The initial research (finalized in 2020) focused on five countries from the Eastern Mediterranean Region (EMR): Egypt, Jordan, Morocco, Lebanon, and Tunisia. In the second phase, an additional 25 countries were added: Argentina, Australia, Bangladesh, Brazil, Burkina Faso, Canada, China, Ethiopia, France, Georgia, India, Kazakhstan, Kenya, Lao People's Democratic Republic, Nigeria, Panama, Papua New Guinea, Philippines, Senegal, Thailand, Uganda, United Kingdom, Uruguay, Zambia, and Zimbabwe. We found that in the countries researched:

- **43.3% have formal regulatory procedures in place to change medicines category from POM to OTC.**
- **86.7% have a national EML, which, for all but two countries include contraceptives.**
- **36.3% countries have an OTC list, and of these 13.3% include contraceptives.**

In conclusion, we observed a significant degree of disparity between countries in the approach and management of medicine classification and processes for changing the classification of a medicine from POM to OTC. In April 2021, the findings from the EMR countries were published in *Health Research Policy and Systems* and in May 2021, the report for all 30 countries was submitted to WHO and a manuscript is currently under peer review.

#### iv. Regulatory strategies for inhaled oxytocin

Concept Foundation was contracted by Johnson and Johnson Pharmaceuticals (J&J) in 2021 to support the development of an initial regulatory strategy for the introduction of their novel inhaled oxytocin uterotonic for the prevention of PPH. The product is designed to serve an unmet need in LMIC where the cold chain cannot be guaranteed or where the lack of trained healthcare workers and facilities mean an injection is unable to be administered.

We supported J&J by identifying and proposing regulatory pathway options and regulatory requirements for 12 high-priority countries, together with a broader review of regulatory requirements for a total of 40 LMIC.

#### v. Oxytocin regulatory guidance

As a result of numerous studies indicating that sub-standard oxytocin is circulating in many LMIC, under a grant award from WHO we developed a guidance document “Regulatory guidance for assessment and management of applications for marketing authorization of oxytocin”.
This guidance was developed primarily to support national regulatory authorities, but also contained key information to guide procurement. Development of the document included virtual consultations with international stakeholder experts, the WHO PQP and a number of representatives from regulatory agencies in LMIC. The guidance was published as a Technical Document by WHO on its website in June 2021 and can be accessed.

https://www.who.int/publications/i/item/9789240022133

**vi. Market assessment – medical abortion drugs Argentina**

In 2021 Concept Foundation initiated a project funded by the Reproductive Health Supplies Coalition (RHSC) through RHSC ForoLAC and undertook an in-depth market assessment for medical abortion (MA) Drugs in Argentina to support market shaping following the decriminalization of abortion in 2020. The assessment was designed to support the Argentinian Ministry of Health (MoH) in establishing a supportive environment to ensure access to safe and effective MA drugs. The cornerstone of this project was the enactment of law 27610 in Argentina and a commitment by the Argentinian government to its implementation by the best available standards. This law passed on 29 December 2020 and meant women could now access abortion supplies in Argentina. It therefore became a priority issue for the Argentinian MoH to ensure the availability of quality assured MA drugs, on an immediate basis as well as for the long term.

We partnered with the local NGO, Centro de Estudio de estado Sociedad (CEDES) to conduct the market assessment and consulted with a range of key stakeholders and actors in the country. A report of the findings and recommendations was published in June 2021 and as a direct follow up, a high-level meeting with the Argentinian MoH was held in July 2021 to discuss the findings and strategize next steps. The meeting was attended by high-level MoH officials, and the findings of the assessment were well received. The outcomes of project and MoH consultative meeting were presented via an English language webinar and to the ForoLAC via a Spanish language webinar in October 2021. Links to the webinars can be accessed on the RHSC Safe Abortion Supplies (SAS) workstream webpage.

**vii. PPH Access project**

Funded by MSD for Mothers until December 2022, Concept Foundation expanded collaboration with WACI Health, FIGO and ICM with the goal of accelerating the availability and accessibility of essential maternal health commodities (specifically HSC and TXA) in countries with high PPH burden.
WACI Health continued to undertake advocacy activities in Burkina Faso, DRC, Ethiopia, Ghana, Liberia, Rwanda, Sierra Leone, South Sudan, and Uganda in order to support the update of their national guidelines and EMLs to reflect WHO’s latest recommendations for PPH prevention and treatment. Engagements were also pursued in Senegal, Ivory Coast, and Tanzania with limited progress due to timing and other contextual factors. WACI Health have also been navigating practical approaches and identifying tangible indicators to improve access to HSC and TXA and move towards the Universal Health Coverage (UHC) agenda, while advocating for the inclusion of the two drugs in national Health Benefit Packages (HBPs) in the project countries.

FIGO and ICM collaborated to develop a generic PPH prevention protocol for adaptation into national clinical management protocols and job aids, using the approach demonstrated in Figure 4. Significant progress was made through country activities and strengthening, both in-country partnerships as well as inter-country engagement, to develop country-tailored PPH clinical protocols and job aids to complement protocol dissemination among healthcare providers. FIGO are also working towards launching a PPH supplement in the International Journal of Gynecology & Obstetrics in 2022.

![Schematic of FIGO and ICM's methodology for developing national PPH protocols and job aids](image)

### Highlights

- **In June 2021, joint statements on PPH prevention and treatment were published by FIGO and ICM**
- **5 out of the 9 countries (Burkina Faso, Ethiopia, Ghana, Rwanda, and South Sudan) have successfully updated their national guideline and/or EML**
- **4 of the project countries (Ethiopia, Ghana, Rwanda, and Uganda) have developed national clinical PPH protocols (adapted from the generic protocol) which were approved by the national ministries of health**
viii. Abortion policy change in Central Asia

2021 saw the completion of multi-country safe abortion activities funded by WHO-PUA. This work was implemented over two and a half years and was designed to facilitate and improve access to MA drugs and ensure their appropriate use in target countries. The nature of the activities was themed around addressing supply challenges at different levels of the supply chain and broader health system mechanisms, specifically relating to MA drugs.

In Kyrgyzstan, we built on the successful update of Order 618 by the Ministry of Health (MoH) in 2020. Significant progress was made in identifying optimal procurement pathways for supply of MA drugs and we presented these in the context of a country-wide plan to the MoH at a series of round table meetings held in Bishkek in April 2021. At these meetings the MoH committed to incorporating findings of the procurement analysis into their workplan to ensure access to quality assured MA drugs. It was also agreed by the MoH that the Mandatory Health Insurance Fund (MHIF) and Department of Drug Policy would present the findings of the analysis on paid and free services and procurement to responsible key individuals, to ensure future implementation of the recommendations.

In Uzbekistan, we worked with our local partners on the inclusion of the combination regimen of mifepristone and misoprostol for the management of MA in the National EML. Through the establishment of a working group comprising our country-based partner, WHO country office and a representative from the Reproductive Health Center, engagement with the MOH was undertaken in 2020, early 2021 and late 2021, and co-packaged mifepristone and misoprostol is now included in the Uzbek EML.

In both Kyrgyzstan and Uzbekistan, activities initiated in 2020 to update training modules for provision of MA drugs and services were completed in Spring of 2021. The updated training modules in Russian and local languages are in line with WHO recommendations and will facilitate the safe and accurate provision of MA drugs and services at the health facility level. Follow up Training of Trainer (ToT) workshops were conducted later in 2021 as a separately funded follow up activity, to ensure uptake of the newly updated modules and their widespread implementation in both countries.

Forward activities

2022 represents the final year of the ground-breaking PPH access project during with both ongoing efforts to update guidelines and EMLs in target countries, together with an increased emphasis on supporting additional countries with the inclusion of the two drugs in national Health Benefit Packages. We will also conduct the clinical implementation pilot studies in five countries towards the integration of HSC and TXA into routine care for prevention and treatment of PPH.

Ongoing regulatory support will continue to enable access to HSC in more LMIC markets and we hope to accelerate the process by further maximizing collaborative registration mechanisms.

We are also exploring other areas within PPH prevention and treatment in order to contribute to global efforts towards reducing maternal mortality in high-burden countries.

The dialogue with partners and the MOH is ongoing in Argentina, and we expect to play a continuing role in supporting local manufacturers on the development of introduction of medical abortion drugs into the country in order to meet growing demand.
Concept Foundation
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 with 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. We co-chair the Safe Abortion Supplies and TXA Working Group at RHSC.

**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 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.

**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 2021, 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.

CIFF
WHO
BMGF
University of Birmingham
MSD for Mothers


Webinars

Self-care learning and discovery series
Self-care products from innovation to implementation: lessons from HIV and Family Planning
01-07-2021
Presentation: SRH Self-care product landscape

Virtual meeting on strengthening self-care interventions for sexual and reproductive health in the eastern Mediterranean region
06-05-2021
Presentation: 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

RHSC New/underused RH Technologies (NURHTs) Caucus Safe Abortion Supplies (SAS) Workstream webinar on Argentina Market Assessment for Medical Abortion
12-10-2021

Conferences

32nd ICM Virtual Triennial Congress
16-06-2021
Symposium title: Improving access to essential medicines to prevent and manage postpartum haemorrhage in Africa

FIGO 2021 World Congress
25-10-2021
Session title: Increasing the appropriate use of key and essential maternal health medicines in countries with high PPH burden

Eastern Europe & Central Asia Regional Conference on Safe Abortion and Family Planning, 2nd Edition
16-17 December 2021
Conference title: Bringing the WHO recommendation on safe abortion and family planning closer to women, in countries of Eastern Europe and Central Asia
Session title: The Importance of Quality Drugs for Post-Abortion Care
Session title: Increasing the appropriate use of key and essential maternal health medicines in countries with high PPH burden

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Session title: The Importance of Quality Drugs for Post-Abortion Care

5.

Financial summary 2021

<table>
<thead>
<tr>
<th>INCOME</th>
<th>EXPENSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grants</td>
<td>2,973,071</td>
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<tr>
<td>Service contracts</td>
<td>863,952</td>
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<tr>
<td>Royalties</td>
<td>464,209</td>
</tr>
<tr>
<td><strong>Total Income</strong></td>
<td><strong>$ 4,301,232</strong></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Programs</td>
<td>3,234,796</td>
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<tr>
<td>Operations and General</td>
<td>772,291</td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td><strong>$ 4,007,087</strong></td>
</tr>
</tbody>
</table>
Our team at our 2021 retreat during lockdown