Accelerating access to medicines to protect the lives of women
Our Mission

A Message from our Executive Director

Millions of women & girls suffer from preventable reproductive health conditions

...We take concrete action to change that

An Accelerator of Access to medicines and technologies

Our three functional pillars

From scientific discoveries to market introduction

Progressing towards a Sustainable Future

Quality medicines for all - a matter of health equality & gender equality

Our Impact: Highlights of 2022

Spotlight 1. Detecting life-threatening quality issues in maternal health and abortion medicines

Spotlight 2. Expanding our work to combat Postpartum Haemorrhage

Spotlight 3. Highlighting self-care to expand access to contraceptives

Spotlight 4. Accelerating Innovation for Mothers

Working together to make a difference

Contributing to the SRH evidence base

Our Team

Our Board of Directors

Financial summary 2022

Our partners and donors
Our Mission

Concept Foundation identifies, innovates and enables equitable access to quality-assured, affordable, essential sexual and reproductive health medicines and technologies.

A MESSAGE FROM OUR EXECUTIVE DIRECTOR

Our achievements in 2022 are a testimony to the power of partnerships, including the successful collaborations we have built with Burnet Institute, Policy Cures Research, University of Birmingham, and WACI Health, among others. Our accomplishments also showcase the unique role that Concept Foundation plays in the SRH landscape, as we complement our partners’ respective experiences, with our expertise in R&D, manufacturing and regulatory processes.

Our quality testing of widely used maternal health and abortion medicines revealed never-before detected quality issues with tranexamic acid, and identified several substandard mifepristone and misoprostol products. These findings stress the pressing need for the global SRH community to give higher priority to quality assurance of medicines – in particular of new medicines that are introduced in global guidelines and thus become increasingly used on local markets.

We continuously explore different ways to put an end to substandard SRH medicines in low- and middle-income countries, and their disastrous consequences. We leverage our relationships with the manufacturing industry, to push for quality products - engaging in capacity building, exposing poor-quality medicines, and identifying reliable manufacturers. As an innovative means to advocate for better quality medicines, we have embarked on a new, ongoing project in collaboration with the University of North Carolina Eshelman School of Pharmacy, in which we are modelling how substandard postpartum haemorrhage (PPH) medicines may impact the health and economies of Ghana, Ivory Coast, Nigeria and Senegal, and hinder progress towards achieving Universal Health Coverage.

I am extremely proud of our normative policy project on heat-stable carbetocin (HSC) and tranexamic acid (TXA) for PPH prevention and treatment, respectively. One of our most important learnings from this project was the power of working with civil society organizations to achieve policy change.

We pay particular attention to gender in the context of global sexual and reproductive health and rights, and we leverage the power of partnerships to do so. We supported GENDRO’s response to the WHO pandemic treaty, calling for gender responsive research for health equity and human rights, and most of our Geneva staff have joined the Swiss Chapter of Women in Global Health. Moreover, we received a new grant from MSD for Mothers to conduct a research project with Gender and Women’s Health Department at University of Melbourne, Australia and Jawaharlal Nehru Medical College, India to explore care providers’ and women’s views and attitudes toward participation in clinical trials during pregnancy.

It is with great motivation and excitement that we have entered 2023, a year in which we will continue to leverage our expertise in abortion, contraception and maternal health, while also expanding our focus to other SRH topics, including for the first time engaging in gynaecological conditions. We look forward to continuous collaborations with our partners and donors to meet complex issues with innovative and holistic solutions - solutions that save and transform lives.
MILLIONS OF WOMEN AND GIRLS SUFFER FROM PREVENTABLE REPRODUCTIVE HEALTH CONDITIONS…

270 million women of reproductive age have an unmet need for contraception

In Latin America and Africa
3 out of 4 of all abortions are unsafe
nearly 1 in 2 abortions are unsafe
97% of all unsafe abortions take place in developing countries

Almost 95% of all maternal deaths occur in low and lower middle-income countries

70% take place in Sub-Saharan Africa

800 women die each day from preventable causes related to pregnancy and childbirth

LEADING CAUSES OF MATERNAL DEATH
19.9 – 36.2% Severe bleeding
4.7 – 13.2% Unsafe abortion
11.1 – 17.4% Hypertensive disorders of pregnancy

WHEN MEDICINES ARE
× Unavailable  × Unaffordable  × Of low quality
WOMEN’S LIVES AND WELL-BEING ARE AT RISK
Our initiatives are defined by an existing unmet need for specific sexual and reproductive health medicines or technologies in low-resource settings.

To reflect these needs, and to reduce preventable maternal morbidity and mortality, our work during 2022 focused primarily on products and innovations related to abortion, contraception, and maternal health.

Partnering with the pharmaceutical industry, the World Health Organization, academic institutions, international procurers and governments, we work hands-on to combat health inequalities by challenging current market conditions – ultimately ensuring that more women and girls can access and afford safe, life-changing and life-saving medicines and technologies.

OUR THEMATIC AREAS:
Concept Foundation’s experience across the product development life-cycle and low-and-middle income settings, gives us a unique position in the global SRH landscape.

Our expertise is both deep and wide, and this allows us to adopt a holistic perspective to solving complex SRH issues in some of the most vulnerable settings.

Along the product development life-cycle, we identify gaps and barriers to product access and identify solutions and strategies that accelerate equitable access to medicines in settings where the need is the greatest.
We identify and evaluate new and neglected SRH medicines and technologies through research, and development of target product profiles (TPPs).

We evaluate and assess product characteristics. We improve existing products and develop new ones, based on market needs and gaps – ensuring that more people have access to and can afford quality SRH medicines.

We facilitate the availability of quality assured and affordable SRH medicines and technologies, collaborating with the pharmaceutical industry and acting as a bridge between public and private sectors.

We facilitate access to quality-assured SRH medicines and technologies in high burden countries, by ensuring that SRH needs are reflected in local policies and guidelines. We support manufacturers to introduce their products in LMICs through registration and regulatory support.

DECADES OF ACCUMULATED SKILLS AND KNOWLEDGE FALL INTO OUR THREE FUNCTIONAL PILLARS

RESEARCH & INNOVATION
MANUFACTURING & DEVELOPMENT
COUNTRY SUPPORT & MARKET ACCESS
A holistic end-to-end approach to accessibility of medicines and technologies

Concept Foundation takes a systematic, end-to-end approach to ensuring access to essential SRH medicines and technologies. This means that no matter the focus of a specific project or programme, we consider all steps along the product life-cycle – from early research, intellectual property, cost of raw materials and assuring quality manufacturing; to regulatory approval, procurement, and supply chain. Our holistic view makes us an accelerator for innovation and access, and ensures that our work is complimentary to that of partners and other stakeholders in the SRH space – ultimately maximizing use of resources and impact.

Our core values of quality and affordability remain central to everything we do and are overarching principles that transcend our end-to-end framework.
Our quest to safeguard the quality and affordability of essential medicines in LMICs aligns with the global health community’s commitment to achieve Universal Health Coverage, and is directly linked to two Sustainable Development Goals (SDGs):

3.1 By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 births.

3.7 By 2030, ensure universal access to sexual and reproductive healthcare services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes.

3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

5.6 Ensure universal access to sexual and reproductive health and reproductive rights.

We work under a collaborative agreement with the World Health Organization and HRP (UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction). This relationship has been in place since 2004, and allows us to work closely with WHO on all projects that we are involved in.
QUALITY MEDICINES FOR ALL

A MATTER OF HEALTH EQUALITY & GENDER EQUALITY

Low-quality SRH medicines compromise the performance that they promise, and put women’s health and lives and risk. When a market primarily consists of substandard products, and quality-assured medicines are inaccessible or unaffordable to people, health inequalities are cemented.

Millions of women are deprived of life-saving health care, and of the ability to decide over their own bodies, lives and the futures of themselves and their families.

When a woman dies from giving birth, or from an unsafe abortion, it has devastating consequences for the family and the community that she leaves behind – emotionally, socially, and financially. Moreover, many women who do not have the safe and affordable means to make decisions about if and when to have children, end up struggling to uphold nurturing and dignified life conditions for themselves and their families.

These burdens particularly and disproportionally affect poor women in low-income countries. People and communities who are already in a vulnerable situation are trapped in a vicious cycle of poverty, low education, low productivity and poor health and well-being – perpetuating existing global inequalities.

Women who are empowered to make autonomous decisions about their reproductive health are better equipped to thrive and contribute to the development of sustainable societies, including to support their children’s education, health and well-being. Therefore, confronting the issue of low-quality SRH medicines in LMCs is critical to overturning health inequalities as well as deep-rooted gender inequalities.
OUR IMPACT:

HIGHLIGHTS OF 2022
Significant progress has been made in the global SRH community over the past two decades, in improving the quality of medicines circulating in unregulated markets. However, we continue to detect quality issues with some misoprostol and oxytocin products, and more recently also with some mifepristone and tranexamic acid products.

**QUALITY TESTING OF MIFEPRISTONE AND MISOPROSTOL**

In 2022, Concept Foundation published in a preprint a study that we conducted in 2020-2021 in collaboration with International Planned Parenthood Federation (IPPF). Samples of mifepristone and misoprostol were collected in eleven countries, and tested.

While numerous previous studies have demonstrated quality concerns with misoprostol, mifepristone has not been as extensively assessed for product quality. Our research made important contributions to exposing serious quality issues also for mifepristone in LMICs markets.

**...EXPOSED A FALSIFIED PRODUCT**

For misoprostol, our findings suggest that historical concerns around primary packaging may have been largely resolved – however, that manufacturing processes need to be improved.

Of great concern, our research also revealed a falsified misoprostol product. A report submitted to WHO resulted in further investigations, which identified the presence of the same falsified batch in two neighbouring countries, and a second falsified batch of the same product in two neighbouring countries. As a result, WHO issued a falsified product alert.

- **55%** of all samples tested were non-compliant with specifications
- **57%** of misoprostol samples tested were non-compliant with specifications
- **24%** of mifepristone samples tested were non-compliant with specifications
- **1** falsified misoprostol product was detected
Both innovator and generic TXA products have been on the market for many years, however, using it to treat PPH is relatively new. Concept Foundation conducted the first ever published quality analysis of tranexamic acid (TXA) for PPH treatment, in which we tested 14 samples of TXA, along with 33 samples of oxytocin. This research, which was a component of the E-MOTIVE trial led by University of Birmingham, revealed concerning quality issues among many of the tested products.

The results of this study adds further data on the widespread presence of substandard oxytocin, and provides groundbreaking new evidence on serious quality issues with TXA.

As a result of this research, health facilities in Kenya, Nigeria, South Africa and Tanzania that had used products of substandard quality followed our recommendations, and changed to oxytocin and TXA products of higher quality.

**OXYTOCIN:**

- 33% did NOT meet the criteria of recommended levels of oxytocin and allowed levels of related substances
- 55% had oxytocin content below the acceptance criteria (90-110%)
- 58% had levels of related substances above the allowed limits

**TXA:**

- 29% contained large amounts of unknown substances
Each year, 14 million women experience severe bleeding after childbirth (postpartum haemorrhage or PPH). PPH is the leading cause of maternal deaths. Most cases of PPH-related morbidity and mortality are preventable.

Our work on PPH spans several functional areas of the end-to-end access pathway.

Developing an innovative PPH device
Together with Obstetrx Inc., we are working on a novel innovative postpartum haemorrhage device. In 2022, we completed protocol development as well as assessments of sites and clinical research organizations (CROs).

Studying product characteristics
We have been working to better understand the product characteristics of essential PPH medicines and will continue this work into 2023.

Country registration of heat-stable medicine
We are making excellent progress in our efforts to register a novel uterotonic (heat-stable carbetocin) in 90 LMICs. In 2022, the product was registered in five additional countries (Malawi, Zambia, Ghana, Kenya and Rwanda), meaning that it is now registered in a total of 14 countries. A recommendation from The Caribbean Public Health Agency (CARPHA) has been obtained as a gateway to registrations in. A UNFPA submission has resulted in approval in Madagascar.

We supported registration of heat-stable carbetocin in 5 additional countries.
Supporting concrete country implementation of global WHO recommendations

In 2022, we concluded our Access-PPH project, a two-year initiative funded by MSD for Mothers, which focused on introduction of heat-stable carbetocin (HSC) and tranexamic acid (TXA) to prevent postpartum haemorrhage (PPH). The project involved nine countries in Africa: Burkina Faso, DRC, Ethiopia, Ghana, Liberia, Rwanda, Sierra Leone, South Sudan, and Uganda.

For many years, oxytocin was the only primary drug recommended by WHO to prevent excessive bleeding after childbirth. However, to not compromise the efficacy of the drug, oxytocin requires refrigeration during transport and storage, which is difficult to uphold in many parts of the world. In fact, heat exposure is one of the main causes of poor quality oxytocin.

Heat-stable carbetocin (HSC) is a revolutionary drug, as it does not require cold-chain transport or storage. It remains stable for at least three years in 30 degrees Celsius and in humid climate conditions. Ensuring that this product is available and affordable in low-income countries is critical to save lives of mothers and their newborns.
Concept Foundation advocated in target countries to raise awareness of the importance of quality maternal health medicines, and supported the revision and updating of national PPH policies and guidelines, to include HSC and TXA, in line with WHO recommendations.

Following successful policy change, we worked in countries to update and develop contextualized, national clinical protocols and job aids for PPH prevention and treatment. Through these protocols and job aids, we operationalized global WHO recommendations, taking into consideration local circumstances, and supporting health care providers to use evidence-based practices to identify, prevent and manage PPH.

We also undertook pilot implementation studies in five countries, to better understand the feasibility of introducing HSC and TXA in facilities, as well as health workers’ attitudes to accept and introduce these products in their work.

To support prevention and treatment of PPH, we developed and disseminated:

**CLINICAL PROTOCOLS IN COUNTRIES**

6

**JOB AIDS TO SUPPORT CLINICAL PROTOCOLS IN COUNTRIES**

8
The pilot study exposed concrete examples of local realities and of how access to essential PPH medicines can make the difference between life and death, and shed light on the vulnerability of health systems and women in low-income settings.

As a woman suffering from PPH was transported from a rural area in Sierra Leone towards the nearest hospital, the ambulance broke down and got stuck in the mud. The health care team praised the availability of TXA, which stopped the bleeding.

“The bleeding woman was trapped on the road for hours. We thank tranexamic acid for the magic in saving her life.”

ANAESTHETIST, KABALA GOVERNMENT HOSPITAL SIERRA LEONE
HIGHLIGHTING SELF-CARE TO EXPAND ACCESS TO CONTRACEPTIVES

In 2022, we finalized a review of regulatory policies in 30 globally diverse countries, to:

1. Assess national regulatory procedures for turning prescription only (PO) medicines into over-the-counter (OTC) products, in the case of oral contraceptives, emergency contraceptives and injectable contraceptives.

2. Determine whether national lists of OTC medicines included contraceptives.

We found a huge variability between countries that were reviewed, in terms of their approaches to categorization of contraceptives. We identified a set of remedial actions that could be implemented at the country level, and that would improve regulatory procedures for OTC contraceptives, ensure their efficacy and safety, and increase their accessibility.

The findings were presented at a poster session at the 2022 International Conference on Family Planning (ICFP) 2022 and published in the WHO Bulletin: Policy & Practice.

Enabling the option of self-management of contraception, emergency contraception and diagnostic tests for pregnancy, fertility and ovulation, empowers women and girls to take control of their own health and futures.

The availability of self-care options increases choice and can improve access to care that is person-centred and cost-effective.
ACCELERATING INNOVATION FOR MOTHERS

The goal of the Accelerating Innovation for Mothers (AIM) initiative is to create a movement that will operationalize research, ultimately advancing the development and introduction of innovative technologies for pregnancy-specific conditions. Concept Foundation spearheaded this initiative, which was launched in 2020.

DEVELOPING THE FIRST EVER TPPs FOR MATERNAL HEALTH MEDICINES

Target product profiles (TPPs) describe the minimum and the optimal characteristics of a medicine or medical device. They specify intended use, target population and characteristics related to efficacy, safety, formulation and storage.

TPPs are important tools for driving new product development. TPPs have been used to address numerous public health gaps, including new vaccines, antibiotics, HIV cures and diagnostics for infectious diseases, but are underutilised in sexual and reproductive health. A review of the World Health Organization (WHO) Health Product Profile Directory, as well as of the literature, revealed that there were no publicly available TPPs for maternal health medicines, including pre-eclampsia and preterm birth.

Considering the lack of investment and innovation around new medicines for obstetric conditions, Concept Foundation developed the first ever TPPs for maternal health conditions in 2021: for medicines to prevent and treat pre-eclampsia and preterm labour and birth.

These four TPPs, which were developed under the AIM project, can guide manufacturers in the development towards desired characteristics, and support regulatory processes. In 2022, we published two peer-reviewed papers on the development of these four TPPs.

Following the successful launch of these TPPs, we plan to develop several additional TPPs in the future, for maternal microbiome focused interventions, obstetric ultrasound devices, and diagnostics of pre-eclampsia and preterm labour.
WORKING TOGETHER TO MAKE A DIFFERENCE

Our achievements are a testimony to the power of partnerships. Concept Foundation is a tight-knit, highly committed team of professionals who share a dedication to making effective and safe medicines and technologies affordable and available to those who need it the most.

With the support of our board, donors and partners, we continuously make efforts to make meaningful and groundbreaking contributions to the field of sexual and reproductive health.
CONTRIBUTING TO THE SRH EVIDENCE BASE

In 2022 we published the following research studies and articles in peer-reviewed journals:

Click on a publication to view it online

- **Prophylactic antibiotics for uterine evacuation procedures to treat miscarriage**
- **Quality of oxytocin and tranexamic acid for the prevention and treatment of PPH in Kenya, Nigeria, South Africa and Tanzania**
- **Reclassifying contraceptives as over-the-counter medicines to improve access**
- **Innovations in the prevention and treatment of postpartum hemorrhage: Analysis of a novel medicines development database**
- **Challenges in updating national guidelines and EMLs in SSA countries to include WHO-recommended PPH medicines.**
- **Expert consensus on novel medicines to prevent preterm birth and manage preterm labour: Target product profiles**
- **Target product profiles for novel medicines to prevent and treat preclampsia: An expert consensus**
OUR TEAM

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Concept Foundation is a non-profit organization. The majority of our revenues come from the generous support of our donors.

As part of our mission, we provide technical support services to private sector manufacturing partners, to develop new or existing SRH medicines and technologies, obtain WHO PQ or other SRA approvals and obtain product registrations in LMIC markets. This work supports the sustainability of Concept Foundation.

**FINANCIAL SUMMARY 2022**

**INCOME**

- **12% Royalties**
- **22% Service contracts**
- **66% Grants**

**Total Income** $3,260,112

**EXPENSES**

- **25% Operations and General**
- **75% Programmes**

**Total Expenses** $3,317,303

**INCOME**

- Grants $2,162,449
- Service contracts $711,665
- Royalties $385,998
- Total Income $3,260,112

**EXPENSES**

- Programmes $2,490,895
- Operations and General $826,408
- Total Expenses $3,317,303
We are very grateful to our donors and private sector partners for financially supporting our work to improve access to quality-assured and affordable SRH medicines and technologies:

**OUR PARTNERS**

Academic and research institutions
Clinical and laboratory research organizations
Commercial suppliers of SRH medicines and technologies
Global public health organizations, governments and their health ministries
International procurers
Not-for-profit and nongovernmental organizations operating globally to improve access to quality-assured SRH medicines and technologies

In 2022, special thanks go to our partners Burnet Institute, CEMAG Care, IPPF, Policy Cures Research and WACI Health, who were instrumental in our ability to deliver meaningful impact.

**OUR DONORS**

We are very grateful to our donors and private sector partners for financially supporting our work to improve access to quality-assured and affordable SRH medicines and technologies:

Bill and Melinda Gates Foundation
Children’s Investment Fund Foundation
Ferring Pharmaceuticals
USAID Global Health Supply Chain Program-Procurement and Supply Management project
MSD for Mothers
WHO SRH/HRP
University of Birmingham, United Kingdom
ObstetrX Inc.