REPORT TITLE:	**Partnership for accelerated innovation of health promoting devices for maternal, new-born and child Health in low- resource settings – Maker Innovation Project**
PREPARED FOR:	**Philips Foundation and The Netherlands National Committees of UNICEF**
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PROJECT SUMMARY

PROJECT TITLE:	Partnership for accelerated innovation of health promoting devices for maternal, new-born and child Health in low- resource settings – Maker Innovation Project
DONOR:	Philips Foundation and The Netherlands National Committee for UNICEF
ASSISTED COUNTRY	Kenya
IMPLEMENTING PARTNERS:	Concern Worldwide
DURATION OF CONTRIBUTION:	August 2015 - December 2019
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Map of Kenya[1]

[1] Kenya Reference Map – UNOCHA- 2012+ EHRP - Emergency Humanitarian Response Plan MYR 2012

Abbreviations and Acronyms

CHARM	Children's Automated Respiratory Rate Monitor
HIV	Human Immunodeficiency Virus
IP	Intellectual Properties
KNH	Kenyatta National Hospital
Maker	Maker for Maternal, New-born and Child Health Project
MDG	Millennium Development Goals
MNCH	Maternal and Child Health
MNH	Maternal Neonatal Health
MoU	Memorandum of Understanding
PCA	Programme Cooperation Agreement
SDG	Sustainable Development Goal
UN	United Nations
UNICEF	United nations Children's Fund
UoN	University of Nairobi
US	United States of America
WHO	World Health Organization

Executive Summary

The Sustainable Development Goal 9 (SDG)[2] envisions the building of a "resilient infrastructure, promoting inclusive and sustainable industrialization and fostering innovation." Specifically, target 9b advocates for "domestic technology development, research and innovation in developing countries," which includes a focus on fostering an enabling policy environment. There is a vibrant culture of designers, engineers, and entrepreneurs in Kenya creating products intended to improve people's lives. A strong foundation for widespread innovation exists but is highly constrained by a lack of skills and training and poor access to quality tools and materials. As a result, many manufactured products in the Kenyan market are not designed locally and may fail to meet local needs. While Kenya has committed to industrialize and eventually manufacture products locally in the Government's 'Vision 2030," the reality is that little progress has been made in the development of infrastructure to allow for in-country manufacturing of health devices.[3] The majority of medical supplies in Kenya are imported (over 90 per cent) from abroad. The few items locally procured are generally limited to non-complex equipment such as beds and trolleys.[4]

To catalyse local transfer of technology in the development and manufacturing of health equipment prototypes, Philips Foundation made available to UNICEF Kenya a grant to facilitate the identification and development of prototypes that can be used to drive improved maternal and neonatal outcomes. Subsequently, UNICEF Kenya in partnership with Concern Worldwide, Philips Innovation Africa Hub, University of Nairobi (UoN), Kenyatta National Hospital (KNH) and Gearbox embarked on a partnership with the Government of Kenya (Ministry of Health) to develop and nurture an innovation platform that designs, tests and produces lifesaving health devices predominantly for use in under-resourced maternity hospitals and health facilities. The overall goal of the partnership was to develop innovative, low-cost, locally designed and built health devices and other health solutions that contribute to improved, equitable access to quality care for women, new-borns and children. The project was implemented between August 2015 and December 2019.

The key result of the project include: a functional well equipped "Maker" innovations space established, for use by innovators at University of Nairobi developing of seven medical device prototypes (pneumatic anti-shock garment, phototherapy unit, examination lamp, delivery bed, birthing cushion, drip stand and suction machine; through the Hackathon training program, the number of innovators with technical capacity to develop medical devices was increased from 53 at baseline to 136 (47 females, 89 males); the proportion of Maker Space Innovators actively engaged in the program increased from 34% (of 53) at baseline to 60% (of 136) by the end of project. In addition, the young innovators who graduated from the Hackathon program participated in at least 5 advocacy and/or stakeholders engagement platforms including national and international conferences and advocacy meetings with government ministries to showcase project results and influence policies related to medical device development and management. During the advocacy fora the young innovators shared their experiences and show cased some of the innovations. As well, over the lifetime of the project, key policy contributions were made by UNICEF to the MoH Medical Device Management Policy, Research Policy Framework 2019 - 2023 and Research priorities.

The project experienced some challenges related to sustainability due to limited financial resources necessary for project scale up. However, the University of Nairobi has engaged with other partners who have continued to support the Maker Space after the project completion. One of the key lessons learned is that, the Maker Innovation project proved that young entrepreneurs and engineering students, who are exposed to an environment where they can identify problems and research the best solutions, can lead to development of local capacity to design and manufacture essential medical devices for local use.

[2] United Nations. Sustainable Development Goals Report 2014. New York, 2014.
[3] Vision 2030, GOK, 2014.
[4] Based on consultations with stakeholders, for example the metalworkers' union which described a contract with KNH to produce 100 hospital beds.

2. Background

2.1 Introduction

Since 1990, global maternal and child deaths have been nearly halved. However, despite this progress, the rate of mortality reduction was not sufficient to achieve the MDGs 4 (for children under 5 mortality) and 5 (for maternal mortality) by 2015t.[5] The greatest burden of maternal, newborn and child deaths is concentrated in low resource settings, particularly Sub-Saharan Africa.[6,7]

The effective, evidence-based interventions are well known, however high, equitable coverage is yet to be attained in Kenya and is heavily dependent on a strong health system that can deliver quality services. A crucial health system building block is essential medical products and technologies, as defined by the World Health Organization, which includes the availability of medical equipment and commodities as well as the logistics around their procurement.[8] Many medical/health interventions require access to equipment and/or medical devices considered essential for normal labor, Caesarean section, routine neonatal care, as well as for case management of maternal complications and advanced newborn care including post-operative care for both mothers and newborns.[9,10] This equipment is often unavailable or unsuitable in low resource settings owing to challenges with cost or imported or donated equipment that is not tailored to local conditions. Full use of equipment is further limited by human resource and health infrastructure capacity constraints and lack of standardized regulatory protocols.[11] When equipment is available, it is often in a state of disrepair or is non-functional for multiple reasons, including the prohibitive costs for procurement of replacement equipment and spare parts, inefficiencies in the supply chain or other similar issues.[12,13]

Multiple efforts are underway to tackle the challenge of unreliable access to MNCH equipment in Sub-Saharan Africa in order to ensure equitable, high quality care. These efforts range from designing new technologies to adapting western models of technology for low resource environments to creating e-markets for new technologies. Many of these initiatives are new (initiated in the last five years), so most of the medical equipment is still being built in developed countries.

2.2 Country context (as relates to the programme/project)

While the Government of Kenya continues to make strides in improving maternal, neonatal and under-five mortality situation, progress remains insufficient due to low access, sub-optimal quality and utilization of cost-effective high impact health interventions, especially in underserved communities. Various studies and assessments[14] have shown that many health facilities either lack the basic equipment needed for maternal, newborn and child health (MNCH) service delivery, or items are present but not functional. An assessment of health facilities in Kenya indicates that none of the 40 facilities reviewed in Nairobi had all essential equipment available.[15] Over 90% of medical supplies in Kenya are imported from abroad and

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[5] UN: Millenium Development Goals Report. *New York: United Nations* 2013.
[6] UN Inter-agency Group for Child Mortality Estimation. Levels and trends in child mortality: report 2014. *New York: United Nations* 2014.
[7] Lawn JE, Kinney MV, Black RE, et al. Newborn survival: a multi-country analysis of a decade of change. *Health Policy Planning* 2012; 27 (suppl 3); iii6-28.
[8] Dickson KE, Simen-Kapeu A, Kinney MV, Huicho L, Vesel L, Lackritz E, de Graft Johnson J, von Xylander S, Rafique N, Sylla M *et al*: Every Newborn: health-systems bottlenecks and strategies to accelerate scale-up in countries. *Lancet* 2014, 384(9941):438-454.
[9] Martinez, Alma M, Dung Thi Khanh Khu, Nem Yun Boo, Leakhena Neou, Bounnack Saysanasongkham, and John Colin Partridge. Barriers to Neonatal Care in Developing Countries: Parents' and Providers' Perceptions. *Journal of Paediatrics and Child Health* 48, no. 9 (2012): 852–858. doi:10.1111/j.1440-1754.2012.02544.x.
[10] WHO Regional Office of Europe. Making Pregnancy Safer: Assessment Tool for the Quality of Hospital Care for Mothers and Newborn Babies. Copenhagen, Denmark, 2009. http://www.euro.who.int/__data/assets/pdf_file/0008/98792/E93128.pdf.
[11] Spector, Jonathan M., Jonathan Reisman, Stuart Lipsitz, Priya Desai, and Atul A. Gawande. 2013. Access to Essential Technologies for Safe Childbirth: a Survey of Health Workers in Africa and Asia. *BMC Pregnancy and Childbirth* 13 (1) (February 20): 43. doi:10.1186/1471-2393-13-43. http://www.biomedcentral.com/1471-2393/13/43/abstract.
[12] John Snow Inc. Getting Products to People: The JSI Framework for Integrated Supply Chain Management in Public Health. Arlington, VA, January 2012. http://www.jsi.com/JSIInternet/Inc/Common/_download_pub.cfm?id=11907&lid=3.
[13] Aronovich, Dana, Marie Tien, Ethan Collins, Adriano Sommerlatte, and Linda Allain. Measuring Supply Chain Performance: Guide to Key Performance Indicators for Public Health Managers. Arlington, VA: USAID | DELIVER PROJECT, Task Order 1, 2010.
[14] See, for example: Martinez AM et al. "Barriers to Neonatal Care in Developing Countries: Parents' and Providers' Perceptions." *Journal of Pediatrics and Public Health"* Volume 48, Issue 9, pages 852–858, September 2012
[15] Wamae A, George K, Francis K, Muhunzu I. 2009. *Child Health Services in Kenya.* Kenya Working Papers No. 2. Calverton, Maryland, USA: Macro International Inc.

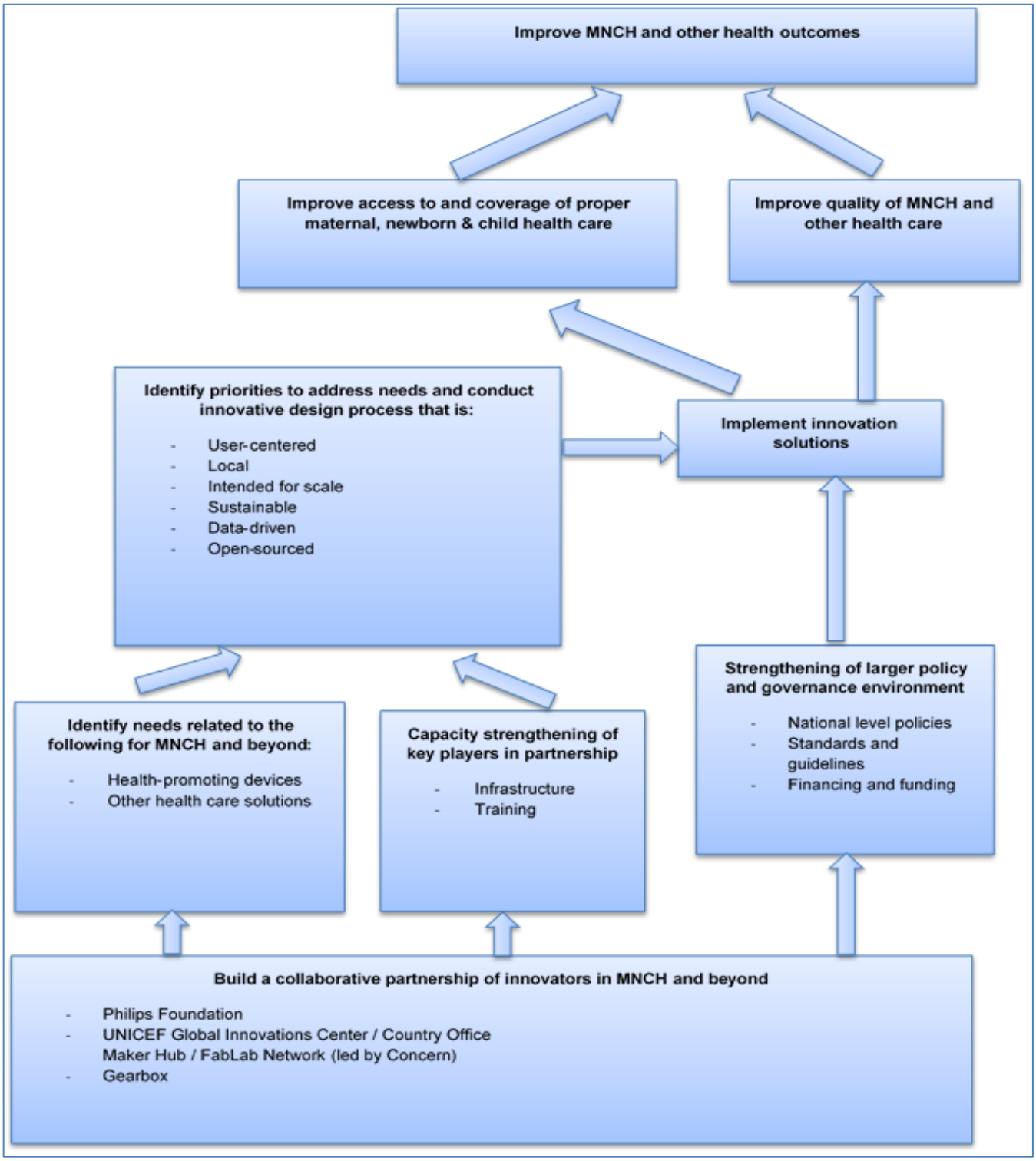
limited equipment is locally procured and this is limited to non-complex equipment such as beds and trolleys.[16] In addition, faulty equipment is not repaired or replaced, leading to reduced quality of care and increased maternal and newborn mortality.

Developing for the African consumer requires a dedicated end user centric approach where the four barriers of affordability, accessibility, availability and acceptability are purposefully addressed. Additionally, capacity building is needed in African markets to address difficulties in the ability to prototype and challenges in coaching and supervision often experienced by innovation platforms.

In this regard, the Philips Foundation funded "Maker" Innovation Project was designed in 2015 to address lack of adequate and appropriate medical devices in maternal, newborn and child health (MNCH). Through the "Maker" Project, social entrepreneurs and engineering students are exposed to an environment where they can identify problems and are empowered to research the best solutions. This project aims to address key health system gaps (e.g. poor capacity to manage post-partum bleeding, poor predictive capacity for at- risk pregnancies, lack of appropriate equipment to manage newborn complications etc.) by increasing access to essential lifesaving medical equipment for mothers and newborns.

[16] Based on consultations with stakeholders, for example the metalworkers' union which described a contract with KNH to produce 100 hospital beds.

Figure 1: Theory of change of this project



3. Programme Description

3.1 Goals and objectives

The goal of the partnership is to develop innovative, low-cost, locally designed and built health-devices and other health solutions that can contribute to improved, more equitable access to quality care for women, new-borns and children in low-resource settings.

This involves:

- Contributing to the establishment of an in-country innovations hub (Maker Hub and Gearbox) for rapid prototyping, innovation and empowerment of innovators.
- Developing innovative locally adapted medical devices, related to maternal newborn and child (MNCH) testing and manufacturing them within the innovations hub.

3.2 Programme components

This project had five key result areas as follows:
Result Area 1: Identify the gaps in the delivery of quality MNCH care and potential innovative solutions to address them.

Result Area 2: Build the capacity of innovations platforms/spaces in the skills required to devise, develop, validate and verify performance and safety of medical devices, health-promoting goods and other health care solutions.

Result Area 3: Scale up the work of the Maker hub and address other priorities identified through the global scoping exercise.

Result Area 4: Facilitate innovative design, prototyping, and limited low-volume fabrication of health-promoting goods and other health care solutions prioritized through the global scoping exercise.

Result Area 5: Encourage scale up of innovative medical devices, health-promoting goods and other health care solutions for the Kenyan market through promotion of an enabling legislative and policy environment for local production, marketing and sales.

3.3 Programme coverage

This project concentrates on the development of affordable and effective technologies for use in frontline health facilities in resource poor settings in Kenya.

The following are expected to benefit from this project:

Beneficiaries (Gender, Age etc.)	Total Number
Pregnant women	1,500,000
Newborns (7 days and below)	1,500,000

4. Results Achieved

4.1 Summary of results-achieved

Despite the one-year delay experienced before commencement of implementation due to prolonged negotiations regarding intellectual property rights, positive results have been realized thanks to the joint efforts of all partners to accelerate implementation and deliver on key milestones. The key results are summarised as follows:

- Infrastructure support: A functional and well equipped ”Maker” innovations space was established for use by innovators at the university of Nairobi (UoN). The “Maker”

innovations space is an innovators' workshop environment, that is conducive and secure for creativity, designing and fabrication. Identification of medical device prototypes: The Hhackathon six-week program was developed with the aim of building capacity of teams to design possible innovative solutions to health problems through 'learning-by-doing' - an experiential method of health systems research, with an output of a prototype design. Participants were taken through weekly intensive practical workshops that addresses various skills including empathy, research, user-centered design thinking, prototyping, standardization and intellectual property. The Hackathon training program started on 22 September 2018, and closed on 8 December 2018.

- The number of innovators with technical capacity to develop medical devices was increased from 53 at baseline to 136 (47 females, 89 males) and the proportion of Maker Space innovators actively engaged in the program increased from 34% (of 53) at baseline to 60% (of 136) by the end of project.
- Development of medical devices' prototypes: The Maker space developed 19 medical devices' prototypes out of which seven were selected for further development and are at different stages of incubation. They include Pneumatic Anti-Shock Garment, Phototherapy Unit, Examination Lamp, Delivery Bed, Delivery Cushion, Drip stand and Suction machine. Two of these completed clinical testing.
- Validation of locally prototyped medical devices through clinical testing: Two medical prototypes i.e. the suction machine and phototherapy machine were submitted to Kenya Bureau of Standards (KEBS) for verification. The suction machine passed the prototype test and the phototherapy machine required some modifications. This was revised and the machine prototype was resubmitted for final review. To accelerate the fabrication of machines, the fabrication partner (UoN) recruited freshly graduated engineers as interns. This led to significant improvement of the fabrication of the medical device prototypes as well as building the capacity of interns.
- Advocacy: key policy contributions were made by UNICEF to the following policies: MoH Medical Device Management Policy and; Research Policy Framework 2019 – 2023 and Research priorities. The project advocated for increased resources for Health Research and Development through the Coalition for Health Research and Development. The project achievements were also showcased in various global and national conferences.

4.2 Results achieved against programme components

Each of the five result areas comprises a series of activities that have been achieved in collaboration with various partners. Below is a detailed update of progress against each output.

Output 1: Improved capacity of the Maker Hub in the skills required to devise, develop, validate and verify performance and safety of medical devices, health-promoting goods and other health care solutions

1.1. Procure additional materials and equipment

During the implementation period, UNICEF supplied various equipment items to Concern Worldwide for use at the Maker Space at the University of Nairobi. The equipment and supplies included: 3D printers, IT Software, scanners, computers and workstations among others (Annex 1). This improved the capacity of the hub and enabled innovators at the Maker Space to devise and develop device prototypes and address common barriers to improving coverage of basic maternal, new-born and child health services.

1.2 Renovation of the Maker Space

Renovations of the Maker Space were undertaken to ensure appropriate space for the new equipment procured. The works included; demolition and alterations, walling works, window works, installation of sanitary fittings and plumbing, re-decoration and general Items. Following

renovation, the Maker Space epitomizes an innovators workshop environment that is conducive and secure for creativity, designing and fabrication.

1.3. Regular Innovation competitions to improve recruitment and retention of Maker Hub innovators and increase visibility of the Maker hub

During the implementation period, innovators from KNH and UoN went through training to improve their capacity in advanced calibration, ideas to marketing, user centered design workshops and design thinking. Cumulatively, 136 Innovators (47 females, 89 males) were trained through the *Hack-a-thon* six-week programs. The Hack-a-thon program was developed with the aim to build capacity of teams to design possible innovative solutions to health problems through 'learning-by-doing' - an experiential method of health systems research, with outputs of a prototype designs. Participants were taken through weekly intensive practical workshops that address various skills including empathy, research, user-centered design thinking, prototyping, standardization and intellectual property. Each hackathon (30-40 participants) had about 5 multi-disciplinary teams, consisting of 5-7 undergraduate students about to graduate.

The Hackathon comprised four teams that came together to brainstorm, problem find, design, think and finally prototype. The teams were focused on finding affordable, efficient and more reliable innovations to improve maternal and newborn health in Kenya. The teams of young innovators visited some health facilities to understand the challenges in the maternal and newborn units and thereafter develop prototypes to address the challenges observed. The following were some of the prototypes displayed by the various teams at the end of the Hackathon:

Automatic Hand Sanitizer: The focus was curbing infections to the newborns through contact, which would in turn reduce the high occurrence of deaths due to infections at the newborn unit. The automated hand sanitizer prototype is designed to help the newborn unit attendants and visitors to adhere to disinfection procedures before accessing the newborn unit. It consists of an automatic smart door with a screen display of reminders to emphasize sanitization before entering the unit. At the door, there is a dispenser with a motion sensor that detects movement of the hands close to it then releases hand sanitizer for cleaning. This action would lead to unlocking of the door. Therefore, the dispenser acts as the key to the door.

Ultrasonic cleaning machine: The aim was to restructure the cleaning process of feeding equipment in the newborn unit through a process that involves five key steps: cleaning, disinfection, rinsing, drying and finally storage. During a case study visit at a health facility newborn unit, the team of young innovators noticed that the unit needed a faster, more efficient way to clean, disinfect and store equipment. The existing process involved dipping all the equipment in a disinfectant which are then removed and taken through sterilization and finally stored in boxes after drying on a piece of cloth. They developed a prototype which comes with an enclosed storage chamber where the cleaned equipment is air-dried and is moved to the top of the chamber where it is picked for use. This process ensures no contamination of the cleaned equipment and the cleaning process is fast and effective to cater for the constant demand of clean equipment in the newborn unit.

Mausoleum Box: This prototype was geared towards an effective and organized system for the storage of still born babies at the newborn unit. It ensures no interference of the bodies in storage as they await movement. The design consists of an auxiliary box with compartments/drawers that allows for great ventilation and provides easy access due to the compartmentalization and presence of one main door to open the box. The box is made from austenitic stainless steel.

Electric Breast Pump: The electric breast pump prototype aimed to reduce the burden on the nurses at the newborn units to ensure more time for caregiving. During a case study visit at a health facility, the team of young innovators noticed that the nurses spent a lot of time cleaning

feeding equipment leaving little time for caregiving. Therefore, they developed the electric breast pump to reduce the number of feeding equipment that need to be cleaned. The electric breast pump combines the existing technology of the manual pump.

The four prototypes above are still undergoing improvements and the UoN is exploring with other partners who can support the various stages of incubation and scale up.

In addition, innovators at the Maker Space were trained by technical experts from the Philips Innovation Services. The training took place at the Maker Space from the 4 - 10 May 2019. The training contributed to the overall program objective and specifically empowered the innovators to have the following skills: business models and value proposition; customer experience flows and designing for medical approval introduction.

Dr. Richard Ayah, Director Science and Technology Park, University of Nairobi at the opening of the Hackathon program

1.4 Design Thinking Introduction

Concern Worldwide supported innovators to go through a one-day training on principles of participatory design in November 2018. The training was attended by approximately 25 innovators and introduced key innovation design principles including problem finding and problem solving as well as value creation with the aim of increasing the value of design for better outcomes, improved processes, expanded capabilities and increased equity and its application on the development of medical devices.

Output 2: Medical devices prototyped and validated through clinical testing and viable scale up plans pre-screened by customer, innovation and market appropriateness analysis

2.1: Identification of Medical devices based on impact on MNH quality of care

Over the duration of the project,19 medical device prototypes were identified. These were: Incucot, Pneumatic anti shock garment, Oxygen concentrator, Nasal continuous positive airway pressure machine, Digital partograph, Food heat retainer, Automated user based tracking device, Intravenous drip stand, Nurse alert system, Fetoscope, Mausoleum box, Modified/electric breast pump, Ultrasonic cleaning machine, Automated sanitizer, Suction machine, Phototherapy machine, Examination lamp, Delivery bed, Birthing Cushion).

The team at the Maker Space met and reviewed the above medical devices and agreed on possible devices for prototyping and fabrication. The following devices were identified for fabrication: pneumatic anti-shock garment, , examination lamp, delivery bed, birthing cushion, Intravenous drip stand, suction machine and phototherapy machine. Other than the standard criteria previously used, the selection also took into consideration the limited project timeline.

2.2: Conduct user-centered design meetings and site visits to develop medical devices specifications and design concepts with participation from clinical staff from clinics in resource poor areas

2.2.1: Fabrication of Selected Medical device prototypes

Following the identification phase, the Maker space developed several medical device prototypes that are at different stages of incubation. They include Pneumatic Anti-Shock Garment, Phototherapy Unit, Examination Lamp, Delivery Bed, Birthing Cushion, Drip stand and Suction machine. Below is a detailed description on some of the fabricated devices:

Suction Machines: The machines use suction to pull out mucus, saliva, blood, secretions or other fluids clearing the airway for easy breathing. Fabrication and clinical testing of suction machines was completed during the reporting period. Ten suction machines were fabricated and are the first of a kind to be fabricated in Kenya by innovators from local Universities with input from clinicians and Biomedical engineers from resources poor facilities of Turkana and Marsabit counties. The development is a demonstration of available local capacity to design and manufacture essential medical devices for local use. Scaling up production and use of the suction machines will eventually help in reducing MNCH mortalities and improve patient health care.

Prototypes of Suction Machines after clinical testing

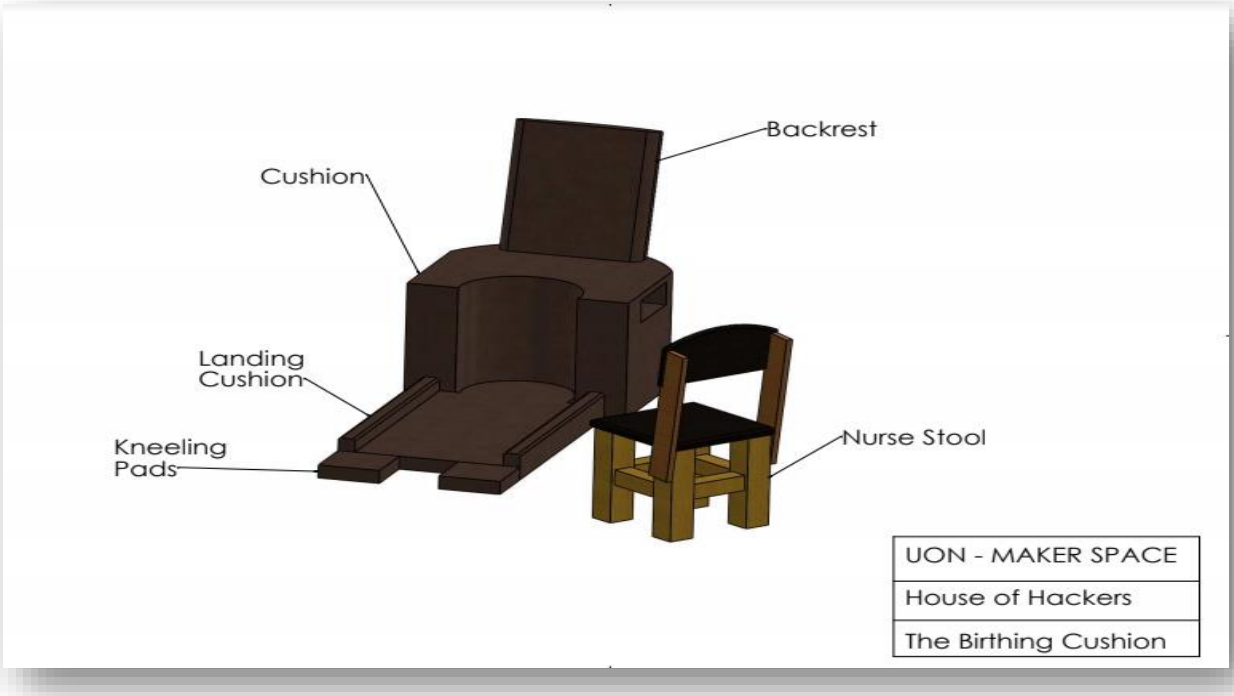
Mr. Patrick Chepkonga (HOD Biomedical Engineering) receiving the technical manual of the Suction Machine from Mr. Barnabas Lolgisoi (Innovator)

Birthing Cushion

The birthing cushion is a modified chair that facilitates delivery by incorporating traditional birthing positions such as modified squatting, propping and kneeling positions without exposing the mother. The squatting position achievable by the birthing cushion offers the following advantages compared to the lithotomy od supine preferred positions in the hospitals: it shortens the second stage of labor (pushing phase), works with gravity to help bring the baby down, increases the pelvic diameter, reduces the need of episiotomy, shortens the depth of the birth canal and it also decreases the need for forceps or vacuum deliveries. Therefore, the birthing cushion has the prospect of being a universal solution for better deliveries in the future, across Kenya and other countries with similar settings.

The House of Hackers (HoH) team that was part of the Hackathon training program was tasked with improving the birthing cushion based on the cultural practice theory that postulates that people do things the way they do, based on their cultural practice or influence. The HoH team visited Kenyatta National Hospital to familiarize themselves with the maternity ward setting and understand the mid-wives/nurse perspectives on the use of birthing cushion. Based on client needs, the incorporated changes to the birthing cushion include: the addition of backrest in both the cushion and nurses' chair, use of grooves in place of handles to offer maximum support during labour and delivery. Furthermore, the addition of kneeling pads will help to protect the pregnant mothers' knees in kneeling position during delivery. Also, addition of a curvature in the receiving cushion to improve the collection of waste fluids and solids. The birthing cushion was covered by leatherette which is waterproof and easy to clean. Finally, the addition of a cushion on the sitting surface will improve comfort of the birthing cushion.

Pictorial presentation of the improved birthing cushion prototype developed by the Maker Space



2.2.2 Internal and external quality assurance through calibration and verification of medical devices in KNH Calibration Centre and KEBS

During the implementation period, two medical prototypes i.e. the suction machine and phototherapy machine were submitted to Kenya Bureau of Standards (KEBS) for verification. The suction machine passed the clinical testing and the phototherapy machine required some modifications. This has been revised and the machine prototype was resubmitted for final review. However, clinical testing of the phototherapy machine was delayed because of the complexity of the machine as well as the limited capacity of KEBS. Therefore, finalisation of clinical testing for the phototherapy machine could not be accomplished within the project timeline.

2.2.3 Conduct validation of medical devices in KNH and 3 health facilities in resource poor settings

To guide the validation of the medical device prototypes, the following key steps were undertaken. These include; development of clinical testing work plan, data management plan, recruitment of research assistants and procurement of data collection tools. A sensitization workshop for KNH staff to create awareness and support for clinical testing took place in December 2018. In addition, a draft manuscript for the clinical testing was developed by KNH and was published for use.

Output 3: Advocate for scale up (including satisfying the needs of local markets) of innovative medical devices, health-promoting goods and other health care solutions through facilitation of an enabling policy environment

3.1.1 Participate in key conferences to disseminate project results

During the implementation period, the University of Nairobi Maker Space team (young innovators and Director of Science and Technology Park) and Head of department Obstetrics & Gynecology at KNH participated in various conferences with the aim of disseminating project results and attracting potential donors to support project scale up. The project achievements were showcased in various global and national conferences including Nairobi Innovation Weeks in 2018 and 2019, FAB 14, federation international of gynecologists and obstetricians

(FIGO) World Congress, and Young Scientists of Kenya. The University of Nairobi t also hosted international delegates including twenty-three delegates from the Global Health Practitioner Conference organized by Core Group who visited the Maker Space in October 2019. This contributed to increased visibility of the project and attraction of partners to the Maker Space. Details of selected conferences that the project staff have participated in are as follows:

FIGO World Congress, Rio de Janeiro, Brazil from October 14-19, 2018: The project was represented by the Head of department Obstetrics & Gynecology in Kenyatta National Hospital (KNH). The purpose of the participation was to disseminate information on innovations in order to gain uptake and scale through a network of global women health professionals (gynecologists and obstetricians). The conference created a forum for dissemination of project activities to a wide range of international audience and this increased awareness of the project activities. Specifically, a presentation was made by Head of department Obstetrics & Gynecology at KNH entitled *Maker for MNCH: A case of using local technology and expertise to address lack of medical devices in MNCH, taking Kenya a step closer to achieving SDG 3*.

2nd International Conference on Maternal Newborn & Child Health (ICMNCH) in Africa 29-31 October 2018: The conference was held in Nairobi under the theme*: "Maintaining Momentum and Focus towards Ending Preventable Maternal and Child Deaths By 2030 - Sustainable Path Towards Africa's Transformation."* The Maker Innovation project and Health Equipment Assessment App pilot project (Kakamega) jointly participated in preconference and conference activities through panel discussions and display of innovations.

During the exhibition, more than 100 participants visited the Maker Space project booth. Many inquiries were made on how the parts of the medical equipment could be locally fabricated to enhance their functionality. This was an opportunity to demonstrate that improved capacity of local biomedical engineers and innovators could solve medical device problems at health facilities.

Dr. Edwin Mbugua (representing the Maker Project) in a panel discussion during the preconference

Maker Space team- Edwins Odhiambo of KNH (Right) and Derick Mugasia presenting to visitors at the booth

3.1.2 Conduct assessment of gaps in existing policies in manufacture of health promoting commodities and devices

During the reporting period, existing policies at the national level on manufacture of medical devices were assessed. Specifically, this activity included identification of existing policy frameworks, identification of key institutions and their role in regulating the manufacture of medical devices and an analysis of the gaps in the policy environment (technical, human resource, financial, research and development, infrastructure, supply chain).

The assessment results guided policy engagements with various stakeholders. As a result, key policy contributions were made to the Medical Device Management Policy and Research Policy Framework 2019 – 2023 and Research priorities. The project advocated for increased resources for Health Research and Development through the Coalition for Health Research and Development.

In addition, the Maker Movement for MNCH was established to contribute to advocacy on improved availability of functional medical devices targeting largely MNCH services. The project forged strong partnership (the Maker Hub) by linking local makers, biomedical engineers and MNCH practitioners in order to leverage their strength and help overcome the obstacles of fully equipping points of care for quality MNCH service delivery.

4.3 Key partnerships

Philips Foundation: In a global partnership, announced in 2015, the Philips Foundation and UNICEF started working together to generate and facilitate meaningful innovations, primarily but not exclusively in the field of maternal, newborn and child health. The Philips Foundation contributed funding, expertise and knowledge to enable collaborative innovation, that is evidence-based and scalable. In this regard, Philips Foundation provided financial support for the Kenya Maker Innovation Project as well as technical capacity building of innovators at the Maker Space.

Ministry of Health: The ministry of health (MOH) provided technical leadership to the partnership especially in the strategic direction and identification and selection of medical devices that can be prototyped by the Maker hub. The MOH also played a key role in the identification of gaps in the policy environment related to research, development, and large-scale manufacturing of locally produced medical devices. In addition, the MOH was the Chair of the project steering committee which governed the project.

Concern Worldwide: Concern Worldwide played a coordination and management role to the project sub-grantees i.e. Kenyatta National Hospital, the University of Nairobi and Gear Box:

- National Hospital Kenyatta - the core clinical testing partner, provided expertise and guidance in the validation of the medical device prototypes through clinical testing as well as the user centered experiences through clinicians and biomedical engineers from the Maternity, the Newborn Unit and the Biomedical units.

- University of Nairobi **-** the core medical device prototype fabrication partner provided technical expertise in developing medical design solutions, prototypes and business models; hosts the Maker Space where the medical devices prototypes are fabricated; and hosts innovators in the development of scalable medical device prototypes.
- Gearbox - a privately funded incubation space which expanded the incubation space and created access for device parts and were involved in fabrication of prototypes.

Other partners included the Kenya Industrial Property Institute and Kenya Bureau of Standards which provided support to the project on intellectual property and standards respectively.

4. Management, Monitoring and Evaluation Framework

Governance/Coordination

Project Steering Committee: The project was governed by a Steering Committee chaired by the Head of Department of Family Health – MOH, who was appointed to represent the Director of Medical Services (DMS) of the MoH. The Steering Committee met on a quarterly basis and provided overall direction to the project, high-level guidance and decision making and recommendations for project implementation, encompassing policy and strategic guidance. The Steering Committee comprised of MOH chairmanship, UNICEF, Philips Foundation and Concern Worldwide.

Partner review meetings: During the implementation period, meetings were held to keep track of program activities and ensure that partners are up to date with project implementation. The meetings included:

(a) Acceleration meetings: Coordinated by Concern Worldwide, weekly meetings were held at the Maker space and partners had an opportunity to provide updates on progress, challenges and next steps.

(b) Semi/annual project review meetings: Annual project review meeting with implementing partners successfully took place in 2018 and 2019. The objectives were to review project progress, brainstorm on synergies, and next steps for the project

5. Lessons Learned

- The Maker project proved that young entrepreneurs and engineering students exposed to an environment where they can identify problems and research the best solutions can lead to development of local capacity to design and manufacture essential medical devices for local use.
- The project demonstrated the potential create jobs, businesses and opportunities for the next generation. Young entrepreneurs and students can be empowered to become agents of change and foster the “Maker” culture of the future.
- Setting up of a virtual platform to enable continued periodic engagement with Philips Foundation was useful in keeping the donor updated on key project milestones and provided a platform for partners to present implementation challenges in real-time allowing for faster learning and joint problem solving.
- The project has exposed the young innovators to support innovations beyond health hence widening their creativity and marketability. The none health projects that are being implemented by the Maker Space include the Air quality sensor project in collaboration with UN Habitat, Uber and Get- Boda. As well, the innovators have developed microscopes from recycled plastic bottles, and these are being supplied to the Ministry of Education.
- Sustainability and Intellectual Property (IP) ownership issues need to be discussed and agreed upon before project start up. This would clarify issues related to project scale up through other partners or government.

6. Expression of Gratitude

UNICEF wishes to thank the Philips Foundation for its generous support for saving the lives of mothers and newborns in Kenya. UNICEF looks forward to a continued, fruitful partnership and welcomes further input and feedback from the Philips Foundation.