

for Maternal, Newborn & Child Health

End of Project Findings



## The Challenge

Despite progress in maternal, newborn and child health and survival, preventable deaths are still occurring at a high rate in Kenya, as in most countries in sub-Saharan Africa. Equitable access to high-quality health care is key to addressing this problem.

The government of Kenya has committed to reducing maternal and child mortality, but large gaps remain. Many resource-limited countries, like Kenya, experience acute shortages of basic, lifesaving medical equipment needed to care for women and newborns and an inability to maintain the existing equipment which is expensive and procured internationally.





# Opportunity

Kenya has earned a reputation for being the hub of excellence and innovation in technology on the African continent, and has an existing network of skilled engineers ready and capable to innovate.

# Project Aim

The Maker for Maternal, Newborn and Child Health (Maker) program, part of Concern Worldwide's Innovations for Maternal, Newborn & Child Health initiative, aimed to forge a strong partnership (the Maker Hub) between clinicians and biomedical engineers at Kenyatta National Hospital (KNH) and engineers at the University of Nairobi (UoN). Together they worked to create low-cost, locally-designed medical device prototypes and spare parts to serve women and newborns.

### Partners

### Implementers

Concern Worldwide US

Kenyatta National Hospital (KNH)

University of Nairobi (UoN)

#### Regulators

Kenya Bureau of Standards (KEBS)

Pharmacy & Poisons Boards (PPB)

Ministry of Health (MOH)/Gov't of Kenya

### **Evaluators**

JSI Research & Training Institute, Inc. (JSI)

Ipsos Kenya

### Funder

Bill & Melinda Gates Foundation (BMGF)

# Objectives

Create a functioning partnership between users (clinicians and biomedical engineers from Kenyatta National Hospital) and engineers (faculty, staff and students from University of Nairobi).





Develop locally-designed medical device prototypes that meet the needs of the users at Kenyatta National Hospital.

## Methods

Needs assessment conducted in 2014 at KNH to identify the major contributors to maternal and newborn mortality, equipment supply chain inefficiencies and their root causes. Data was collected through observations, document reviews and 30 key informant interviews using adapted questionnaires from USAID and WHO. Results were used to prioritize the medical equipment that needed to be built.

**Qualitative data** collected in May 2015 and and March 2016 from partners to understand the process of implementing the project. Data was collected through observations, review of notes from monthly partner meetings, design reports and 26 interviews with partners and stakeholders.

## Results

### *Key Achievements*



Finalized partnership with Kenya Bureau of Standards



Established calibration center at Kenyatta National Hospital

Trained biomedical engineers and a KNH program manager



Built, internally calibrated and secured clinical testing approval for first medical device – a suction machine





Built and equiped "Maker space" – an incubation lab in the Science and Technology Park – to create medical device prototypes



Established partnership with Philips Foundation and UNICEF to continue to expand Maker

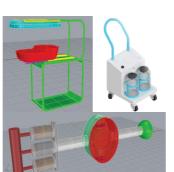
### Timeline

### Enabling factors for success

The leadership and vision of the principal investigators at UoN, KNH and Concern Worldwide was instrumental in motivating teams to strengthen the partnership, produce results and get high level buy-in.

Strong mechanism for communication and collaboration included: monthly Hub meetings during equipment design to keep partners informed of program updates; exchange visits that provided the opportunity for nurses and biomedical engineers to meet with university engineers, review designs and give feedback.

**Dedicated program management** helped establish the hub, coordinated monthly partner meetings, and liaised with government entities and the funding organization.



Clinical testing protocol for 4 pieces approved. This would allow the medical device prototypes to be tested with patients at KNH



Kenya Bureau of Standards reviewed and approved suction machine prototype for clinical testing

Partnership with Kenya Bureau of Standards finalized to ensure safety and quality of prototypes Final design blueprints for the four prioritized medical devices completed First medical device – suction machine - built and internally calibrated



Need assessment conducted and 9 pieces of equipment shortlisted. Four of these were selected for iterative fabrication (vacuum extractor, suction machine, phototherapy machine, examination light)



Process documentation: Two phases of internal monitoring and evaluation to measure the project's progress and achievement of goals undertaken

Calibration center established at Kenyatta National Hospital (inauguration ceremony) and 3 biomedical engineers and 1 KNH project manager trained on medical device calibration techniques at the Flukes Institute in Seattle, USA and on management skills

"Another achievement was overall capacity building for KNH, which was able to take our staff to the U.S. It broadened their scope and capacity and thinking."

- Hub member

Exchange visits held between the engineers and the clinicians to understand needs of clinicians and design equipment with those specifications in mind

"We had the weekly meetings, so we had the nurses coming... You do the back and forth discussion and find the compromise, the center point where you meet... It was a continuous process because the design was continuously changing." – Hub member

Maker Hub established partnership agreement signed between University of Nairobi and Kenyatta National Hospital



"The Maker Space," an incubation lab under the science and technology park, was built and equipped as a platform to ideate and build medical device prototypes.

"The Maker Space has expanded the ability of the Science Park to take ideas to the next level of usability." - Hub member



**2013** July

2014 March April

October 2

March

May

2

2016

## Challenges

### Turnover of engineering students and time restraints due to their university schedules

"Some students started working on Maker while they were on break and once school began, it was difficult to engage with them again. Some of the 4th year students found employment."

- Hub member

Problems and delays procuring equipment needed to fabricate the medical devices, including poor quality of and difficulty in sourcing local spare parts

"Another challenge has been the internal bureaucracies...whereby getting anything procured takes a relatively long time."

– Hub member

"We had many of the versions of the prototypes fail because of poor quality of materials. We also had challenges sourcing the materials locally as well."

- Hub member

#### Operations and management obstacles

"Maybe initially we were too ambitious, but from experience we can say, let's focus on one thing, and give a timeframe...Then maybe it will be achievable"

— Hub member

Lack of national policies related to procurement, safety, and standardization of locally designed medical devices

"Another challenge is building medical devices in an environment without national policies and guidelines on research and development of medical devices."

- Hub member

## Recommendations

#### Wider multi-sectorial engagement:

Strengthen the collaboration with the medical device industry, business and financial experts and more extensively expand the skills, expertise and networks available to Maker hub users.

"It would be useful to engage with medical device experts. We could, for example, engage other corporate entities who have a vast experience making equipment to offer advice and mentorship to the makers on the project."

#### Address retention of the engineering staff:

A potential solution would be to integrate project work into student studies/work so they stick around. Another strategy would be to employ more experienced or graduate students who are committed to the cause.

"Perhaps, the first thing is getting the more senior students involved – maybe if like here, our final year, the students take on a project that lasts the whole final year. If we could bring in those students as part of their final year required project, they would have more motivation to do this. Then they can write a report and present to lecturers and that would be more motivating. These ones [motions to students in the lab], did it more as a hobby, something they chose to do and they can leave whenever."

- Hub member

### Create and nurture new partnerships:

Partner with existing industrial spaces and/or innovation hubs to complement the capabilities of the University of Nairobi Maker space.

The Maker space is not 100% equipped to build all devices. Forming partnerships with industrial spaces that can do what Maker could not do as quickly as we wanted would be a value added."

— Hub member

### Strengthen program management:

Use lessons learned (program successes and failures) to strengthen the management structure to ensure roles and responsibilities are distributed more evenly among the partners in promoting buy-in and improving efficiency of achieving programmatic goals.

## Conclusions & Next Steps

Maker has successfully catalyzed a unique partnership between engineers and clinicians and built several medical prototypes for women and newborns. This hub can creatively strengthen health system gaps, build local expertise and align with the government's national development priorities of finding local solutions for local problems.

All sectors, from government to NGOs to industry, need to engage more intensely to encourage the scale up of innovative, affordable medical devices and other health care solutions for the Kenyan market through promoting an enabling legislative and policy environment for local production, marketing and sales. These activities may include:

- Working with government institutions Pharmacy & Poisons Boards, Kenya Bureau of Standards, Ministry of Health, Ministry of Industrialization and enterprise development to assess and strengthen policies at the national and county level to encourage and enable the manufacture of medical devices and other health care solutions.
- Collaborating with key stakeholders in the private sector and with international agencies to strengthen existing key policies that will improve financing, manufacturing, distribution and utilization of successful innovative medical devices and other health care solutions.

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