JOGECA Journal of Obstetrics and Gynaecology of Eastern and Central Africa

ORIGINAL RESEARCH

Fetomaternal Medicine

# Effectiveness of a locally produced suction machine: An open-label, pragmatic, randomized controlled noninferiority trial in a national referral facility in Kenya

Ong'ech J[1*], Ayah R[2], Mbugua E[3], Waller K[3], Inwani I[4], Abdalla K[5], Gathara D[6], Kosgei R.J[7]

[1] Department of Obstetrics and Gynecology, Kenyatta National Hospital, Nairobi, Kenya.
[2] Science and Technology Park, University of Nairobi, Nairobi, Kenya.
[3] Concern Worldwide, New York, New York, United States.
[4] Department of Pediatrics, Kenyatta National Hospital, Nairobi, Kenya.
[5] United Nations Children's Fund (UNICEF), Kenya.
[6] Kenya Medical Research Institute, Kenya.
[7] Department of Obstetrics and Gynecology, University of Nairobi, Nairobi, Kenya.

***Correspondence**: Ong'ech J, ongechjohn@gmail.com

Received: 17 September 2020; Revised: 20 March 2021; Accepted: 12 May 2021; Available online: July 2021



## Abstract

**Background:** The availability, accessibility, and effective use of essential medical devices play a vital role in delivering quality health services. Unfortunately, in developing countries, including Kenya, it is estimated that as high as 70% of medical devices are partially or entirely non-functional. Therefore, this study sought to evaluate the clinical effectiveness, safety, reliability, and acceptability of a locally made low-cost suction aspirator (Maker) by comparing it to the standard of care equipment in a tertiary referral hospital routine setting.

**Methods:** This was an open-label, pragmatic, randomized controlled noninferiority trial. The mixed-methods approach with quantitative and qualitative data collection approaches was used. Women undergoing cesarean section and their babies (where needed) were randomized to either standard of care or Maker equipment for suction during surgery. A noninferiority margin of risk difference between the standard of care and Maker suction equipment was prespecified at 7%. Key informant interviews were conducted with clinicians and nurses to inform the utility of the Maker equipment.

**Results:** A total of 110 participants were recruited. Of these, 56 and 54 participants were randomly assigned to the standard care and Maker suction equipment arms, respectively. Using a per-protocol approach, suction was reported as successful in 96.4% (54/56) of the participants in the standard of care arm and 92.6% (50/54) of the participants in the Maker's arm. Fifty percent (n=28) of the participants in the standard of care arm, had gauze used in place of the suction machine. Qualitative findings illustrate that the Maker equipment was reliable and acceptable with the improvements made such as overflow protection valve making it the preferred equipment.

**Conclusion:** The Maker equipment is like the standard of care equipment. The high reliability and acceptability, and absence of safety concerns highlights the potential of local development of medical devices to address existing gaps.

**Keywords:** suction machine, medical devices, locally made, low cost, Maker Project

## Introduction

Medical products, vaccines, and technologies, including medical devices, are one of the six building blocks of a health system (1). The availability, accessibility, and effective use of essential medical devices play a vital role in delivering quality health services. In developing countries, including Kenya, it is estimated that as high as 70% of medical devices are partially or entirely non-functional due to various factors (2). A review of 31 health facilities providing 24-hours 7-days a week, essential equipment that included phototherapy machine, suction machine, warming equipment; radiant heaters, resuscitaire, complete caesarean section sets, and diathermy machines were not available in all the facilities (3). Investment in developing and testing equipment within the local context in low and middle-income countries (LMICs) is low. Most of the devices used for maternal and child health are from donations, and a third of them are non-functional and inadequate (4, 5).

The factors that contribute to non-functional medical devices include the donation of equipment without manuals or service contracts, most medical devices are designed in and for high-income settings and not well-suited to environmental conditions in low-resource settings, and the lack of well-trained biomedical technicians in developing countries (6-8). The unavailability of equipment has been linked to inadequate delivery of care processes, consequently impacting patient outcomes. Their non-functionality often impairs service provision and often leads to poor patient outcomes (9). Local production using "context-aware design" is one of the suggested solutions to improving access to medical devices (1, 10, 11). This refers to designing devices with flexible technology that fits the needs of the end-users in resource-limited settings (12). In addition, when devices are developed locally, there is local capacity to support maintenance and servicing, and spare parts are easily available.

The Maker Movement for Maternal, Newborn, and Child Health (MNCH) project ("Maker") sought to address gaps in the supply of MNCH medical devices (examination light, phototherapy machine, suction aspirator, and vacuum extractor) through a collaborative partnership of the key partners in health and academia to create low-cost, high-quality and locally designed and produced essential medical equipment through a network of Makers and MNCH practitioners (13). A detailed description of the collaboration, the role of the partners, and project design are described elsewhere (13). Following a needs assessment in 40 health facilities in Nairobi, Kenya, a suction aspirator was identified as a commonly missing equipment and prioritized by the Maker project. Therefore, this study sought to evaluate the effectiveness, safety, reliability, and acceptability of a locally made low-cost suction aspirator by comparing it to the standard of care equipment in a tertiary referral hospital routine setting.

## Methods

### Development of the suction machine

The suction aspirator is a medical device used to remove mucus and body fluids from body cavities. In MNCH, it is used primarily during resuscitation to remove mucus from the respiratory tract and during abdominal operation to clear body fluids such as blood from the operating field. It has a vacuum pump that provides negative pressure, a pressure monitoring gauge, a vacuum regulator to control the pressure values, and a jar to collect the suctioned fluid. To develop contextually appropriate equipment, consultations with end-users in the newborn unit, maternity theatre, and the biomedical engineering unit were undertaken to understand the types of equipment in use, their functionality, and challenges faced by the users. Further inquiries were made to explore additional functionalities that could be included to make the equipment more user-friendly. The University of Nairobi Fabrication Laboratory (FabLab), together with the Maker for MNCH, through an iterative process combining the roles of the biomedical engineers, health care providers, and engineering professors, designed and developed a suction aspirator equipment locally in compliance with international norms and standards.

The Maker hub comprised of a collaborative partnership that included the Kenyatta national hospital (KNH), the University of Nairobi (UoN), Concern Worldwide, the Kenya Bureau of Standards (KEBS) and the Pharmacy and Poisons Board (PPB). The KEBS and PPB offered technical guidance on the development of medical devices, conducts quality testing of the prototypes, trains staff on testing and approves medical devices designed and built locally (13). Specifically, the Kenya Bureau of Standards regulations on Medical Suction Equipment Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014) regulations were adhered to in this study (14). The equipment was calibrated to a maximum negative pressure gauge scale up to -760 mmHg before the clinical testing. Some of the human-centered approaches included in the fabrication features of the suction aspirator included: castors fitted on the pump for portability, clear calibrated jars, an overflow protection valve to prevent spillage, and a toggle switch to change the reservoir/collection bottle. The housing was made

of galvanized steel. The pump, gauge, filters, valves, tubing, and jars were bought locally.

**Study design**

This was an open-label, pragmatic, randomized controlled noninferiority trial. The mixed-methods approach with quantitative and qualitative data collection approaches was used. Quantitative data were collected prospectively using structured data abstraction tools. Key informant interviews were undertaken for the qualitative component. Comparisons between the locally made low-cost Maker equipment and the standard of care equipment in use in the Kenyatta national hospital (KNH) (electric surgical suction pump / on casters ASKIR C30) were made at the time of the study. Because these were used in place of or to support suction equipment (which was standard of care) in routine practice to clear fluids (including blood) from the surgical site, they were considered as comparators to the Maker equipment during the study period. However, we observed other improvisations used as part of routine practice (e.g., use of gauze where the standard of care equipment was not available or functional). Therefore, three primary outcomes on effectiveness were reported comparing the Maker equipment to: (i) standard of care with analysis restricted to only when suction equipment is used (per protocol); (ii) routine care where suction equipment and gauze were used (intention to treat) including all participants, and (iii) standard of care equipment and gauze (but where gauze use is considered inappropriate) including all participants.

The Outcomes of interest were effective and reliable suctioning. A total of eight Maker suction aspirators were available. However, only three Maker Suction aspirators were deployed to the maternity theatre, with the remaining equipment serving as a backup in case any of the deployed Maker aspirators failed. They were numerically labeled, one to eight for ease of tracking with details of the equipment used for each patient captured in the data collection tool. Of the three Maker aspirators initially made available, while all suction aspirators were calibrated up to -760 mmHg, the suction machine for newborns had a maximum negative pressure of -100 mmHG to avoid any iatrogenic injuries, including the vagal reflex. As such, one of the three suction aspirators (only two maternity theatres were available) was calibrated and dedicated for suctioning newborns.

**Study setting**

The study setting was Kenyatta national hospital. The KNH is the main referral hospital for the whole country, including the East and Central Africa. It has a bed capacity of 2 500. It also serves as the teaching hospital for the University of Nairobi, School of Medicine, the Kenya Medical Training College (KMTC), among other medical training institutions. The KNH labor ward manages on average 1 300 women in labor each month, out of which approximately 12 and 7 undergo cesarean section during the day and night, respectively.

**Study population**

The population of interest was patients undergoing surgery with a low risk of complications with moderate requirements for suction (about 300-500ml of fluid suctioned). Women with other comorbidities considered high-risk for poor outcome, e.g., severe Pre-eclamptic Toxaemia (PET) or eclampsia, fetal abnormalities identified during the ultrasound, and neonates with comorbidities including a diagnosis of severe fetal distress, were excluded from the study. This device was tested among women undergoing cesarean section (both emergency and elective) and neonates requiring suction in Kenyatta National Hospital maternity theater for three weeks between November and December 2018.

**Sample size calculation and recruitment rate**

The primary outcome was effective suctioning, defined as the ability to clear the surgical site without the need to use additional gauze while suctioning surrounding tissue in the theatre. For neonates, the primary outcome was considered as clearing all secretions from the airway without causing irritation to the baby. Noninferiority between standard suction machine and Maker suction machine was defined apriori as a risk difference in the effectiveness of suctioning with an upper bound 95% confidence interval of 7.5%. Assuming a conservative estimate of 50% of the patients being effectively suctioned in the standard of care arm, a power of 80% and 5% significance level, at least 52 patients in each arm (total 104) were required to detect a noninferiority within a margin of 7.5% while assuming effectiveness of 70% in the Maker's arm. Mothers and neonates were randomly allocated to the standard or Maker based on a prior generated randomization list.

**Randomization**

Computer-generated random sequences were created in blocks of randomly varying sizes of 4–6 by an individual independent of the investigators. Intervention allocations were stored in sealed opaque envelopes given to the study team in complete blocks. Envelopes were issued to recruited participants in order of enrolment. Due to the nature of the intervention (Maker equipment structurally different from existing suction equipment or gauze), blinding was not achieved. However, envelopes containing the assigned

treatment were only opened by the recruiting research assistant after a potential study patient was determined to have fully satisfied eligibility criteria ensuring allocation concealment. In addition, a screening log was maintained to show corresponding accountability for all opened allocation envelopes.

**Data collection and management**

A structured data collection tool was designed using the Research Electronic Data Capture (REDCap) software (15). The REDCap software was adopted since it is free and allows both online and offline data entry with synchronization to the online platform when an internet connection is established. The REDCap software was installed on three study tablets that were used for data collection. Hard copy tools were also printed for backup purposes. The instrument was piloted by the research assistants and the study supervisors over two days. User profiles with defined rights, usernames, and passwords were created to ensure data security and audit trails for the entered data. The data collection team comprised four research assistants, nurses with at least one year of experience working within the maternal and newborn inpatient care settings. They all undertook training on good clinical practice, responsible conduct of research, and the study procedures over four days, one of which included piloting. Data collection was done round the clock, including day and night shifts, weekdays, and weekends.

To evaluate the health workers' perceptions on the effectiveness, acceptability, and reliability of equipment, we conducted six key informant interviews equally distributed among nurses, doctors performing a cesarean section, and anesthetists. The key informant interviews were conducted using a structured guide. Two pairs of research assistants interviewed six clinicians and nurses working in the theater ward. The interviews were conducted in the English language. The interviews focused on the functionality, safety, reliability, and acceptability of the Maker equipment and its comparison to the standard equipment. The interviews were undertaken and audio recorded by one research assistant. Transcription was done verbatim by a third party who was not privy to the interviews. The research assistants also took field notes during the quantitative data collection phase, which contributed to interpreting the quantitative data and helped enrich the qualitative data.

**Data analysis**

Descriptive data analysis was undertaken for the demographic and clinical characteristics with the proportions reported for overall and stratified equipment type (Standard vs. Maker). A Chi-Square test was used to test for association between the different characteristics and type of equipment used. An intention to treat approach was used to test for the effectiveness of the Maker equipment. The proportion of mothers effectively suctioned in each group was computed, and the risk difference and accompanying 95% confidence interval between the groups reported. A similar approach was used for a per-protocol analysis. Data analysis was done using STATA, version 13 software. A coding framework was developed based on the questions and probes in the interview guides. Additional codes were generated based on the review of participant answers and prior themes specified in the study's specific objectives. The authors compared and discussed the results before arriving at an agreed set of themes for coding and final analysis. Broad themes were then created by grouping related themes together by making logical connections and incorporating any emerging themes. Finally, the codes were applied to each transcript.

**Ethical consideration**

A scientific and ethical approval for this study was granted by the Kenyatta National Hospital/University of Nairobi Ethics Research Committee (registration number P441/08/2013). Written informed consent was sought from all eligible study participants. Administrative permission to conduct the study was also sought from the hospital management.

## Results

A total of 110 participants were recruited. Of these, 56 and 54 were assigned to the standard care suction equipment and the Maker suction equipment arm, respectively. The mean age of the participants was 29 (SD ±6) years, with at least a quarter of those enrolled being aged less than 24 years and were similar between Maker and standard equipment (Table 1).

Over 85% of the newborns had a birth weight of between 2500 - 4000 grams and an Apgar score at 5 min over 8/10. Women with a gestation of 38 - 42 weeks constituted 91.8% (n=101) of the participants. Suction equipment was used in 66.4% (n=73) of the mothers, and 31.8% (n=35) in both the mother and baby. Of the participants in the standard of care arm, 50% (28/56) had gauze used in place of the suction machine (Table 2).

**Main outcomes**

The per-protocol analysis comparing Maker equipment with the standard of care equipment, there was no significant difference observed (Maker 50/54 (92.6; 95% CI 82.1 – 97.9); standard of care 28/28 (100 (95% CI 87.7 – 100). In the

Table 1: Demographic characteristics of the study participants

| | Overall (N=110) | Standard (n=56) | Maker (n=54) | Chi-square test P- value |
|---|---|---|---|---|
| **Education level** | | | | |
| Primary | 21(19.1) | 11 (19.6) | 10 (18.5) | 0.573 |
| Secondary | 50(45.5) | 23 (41.1) | 27 (50.0) | |
| College | 35(31.8) | 20 (35.7) | 15 (27.8) | |
| None | 4(3.6) | 2 (3.6) | 2 (3.7) | |
| **Marital status** | | | | |
| Single | 8(7.3) | 3 (5.4) | 5 (9.3) | 0.411 |
| Married | 101(91.8) | 53 (94.6) | 48 (88.9) | |
| Divorced | 1(0.9) | 0 (0.0) | 1 (1.9) | |
| **Occupation** | | | | |
| Employed | 22(20.0) | 11 (19.6) | 11 (20.4) | 0.245 |
| Self-employed | 43(39.1) | 18 (32.1) | 25 (46.3) | |
| Unemployed/Housewife | 43(39.1) | 26 (46.4) | 17 (31.5) | |
| Student | 1(0.9) | 1 (1.8) | 0 (0.0) | |
| Other | 1(0.9) | 0 (0.0) | 1 (1.9) | |
| **Maternal age categories** | | | | |
| <=24 years | 30(27.3) | 14 (25.0) | 16 (29.6) | 0.813 |
| 25 - 29 years | 31(28.2) | 17 (30.4) | 14 (25.9) | |
| 30 - 34 years | 26(23.6) | 12 (21.4) | 14 (25.9) | |
| 35 -45 years | 23(20.9) | 13 (23.2) | 10 (18.5) | |

Table 2: Clinical characteristics of the study participants

| | Overall (N=110) | Standard (n=56) | Maker (n=54) | Chi-square test P-value |
|---|---|---|---|---|
| **Birth weight** | | | | |
| <2500 grams | 6 (5.5) | 5 (8.9) | 1 (1.9) | 0.035 |
| 2500 - 4000 grams | 97 (88.2) | 45 (80.4) | 52 (96.3) | |
| >=4000 grams | 7 (6.4) | 6 (10.7) | 1 (1.9) | |
| **Apgar Score at 5 minutes** | | | | |
| <=7 | 8 (7.3) | 5 (8.9) | 3 (5.6) | 0.496 |
| 8 - 10 | 102 (92.7) | 51 (91.1) | 51 (94.4) | |
| **Gestation by dates** | | | | |
| <=37 weeks | 7 (6.4) | 4 (7.1) | 3 (5.6) | 0.347 |
| 38 - 42 weeks | 101 (91.8) | 50 (89.3) | 51 (94.4) | |
| Missing | 2 (1.8) | 2 (3.6) | 0 (0.0) | |
| **Number of live births** | | | | |
| No children | 26(23.6) | 14 (25.0) | 12 (22.2) | 0.698 |
| One child | 41(37.3) | 19 (33.9) | 22 (40.7) | |
| 2 Children | 24(21.8) | 14 (25.0) | 10 (18.5) | |
| 3 or more children | 19(17.3) | 9 (16.1) | 10 (18.5) | |
| **Procedure** | | | | |
| Cesarean section | 73 (66.4) | 38 (67.9) | 35 (64.8) | 0.944 |
| Neonatal suction | 2 (1.8) | 1 (1.8) | 1 (1.9) | |
| Both | 35 (31.8) | 17 (30.4) | 18 (33.3) | |
| **Adverse event** | | | | |
| None | 104 (94.6) | 54 (96.4) | 50 (92.6) | <0.001 |
| Failure to suction effectively | 6 (4) | 2 (3.6) | 4 (7.4) | |
| **Suction volume** | | | | |
| <=300 mls | 28(25.5) | 10 (17.9) | 18 (33.3) | <0.001 |
| 301 - 500 mls | 32(29.1) | 10 (17.9) | 22 (40.7) | |
| >=501 mls | 19(17.3) | 6 (10.7) | 13 (24.1) | |
| Missing/NA | 31(28.2) | 30 (53.6) | 1 (1.9) | |

Table 3: Effectiveness of the standard vs. Maker suction equipment

| | **Standard (n=56) N (%; 95% CI)** | **Maker (n=54) N (%; 95% CI)** | **Risk difference** | **P value** |
|---|---|---|---|---|
| *Per Protocol standard of care– only when suction machine was used | 28 (100 (87.7 – 100) | 50 (92.6; 82.1 – 97.9) | 7.4 (0.4 – 14.4) | 0.124 |
| ¥ intention to treat- as per study arm (routine care includes the use of gauze) | 54 (96.4; 87.7 – 99.6) | 50 (92.6; 82.1 – 97.9) | 3.8 (-4.7 – 12.3) | 0.831 |
| Intention to treat- routine care (gauze use was assumed to be inappropriate) | 28 (50.0; 36.3 – 63.7) | 50 (92.6; 82.1 – 97.9) | 42.6 (-57.4 - -27.8) | <0.001 |

*N for the standard of care =28 (28 of the participants had gauze used in standard of care;
¥ Failures were linked to malfunctions/inadequate suction noted during the procedure

intention to treat analysis allowing the use of gauze only as part of routine care and an acceptable method for clearing fluids and blood from the operation area, suction was reported as successful in 96.4% (54/56) of the participants in the standard of care arm and 92.6% (50/54) in the Maker's arm. However, an intention to treat analysis for standard care but recognizing that use of gauze is inappropriate, effectiveness where only participants where suction equipment was used, suctioning was effective in 50% of the respondents in the standard of care and 92.6% of those in the Maker's arm (Table 3). In the four cases where suctioning was not effective in the Maker equipment, there was a failure to effectively suction (inadequate suction pressure) and hence prolonged the procedure. In comparison, the two cases in the standard of care resulted from spillage and splashing of liquids when gauze was used.

**Qualitative findings from key informant interviews**

Qualitative data were collected to triangulate and enhance the results from the quantitative study on aspects of the Maker equipment. While the target sample size was eight to ten respondents, after six respondents, saturation was achieved, and hence additional interviews were not conducted. The findings were described according to the following themes: effectiveness, acceptability, and reliability of the equipment. Three different cadres working in the maternity theater were interviewed. A clinician (Obstetric Gynecology specialist, a registrar in obstetrics (A doctor undergoing specialist training in Obstetrics and Gynecology), an anesthetist, and theater nurses.

***Effectiveness***

The device could perform as intended, from suctioning the oral cavity for the anesthetist to suctioning blood on the surgical areas during surgery. During surgery, the respondents did point out that it helped clear the surgical site faster and consequently allowed interventions to stop bleeding to be applied more quickly and more efficiently.

Respondent one (Clinician working in the theatre);

> "It was able to suction as expected, so it has minimal waste and minimal loss because when you are able to see what you are doing then you are able to do it fast and more efficient and you are also able to easily achieve hemostasis (stop bleeding). At least it's a route through which you get to achieve hemostasis quickly".

When compared to the standard of care on instances when gauze only was used, it was reported that the Maker equipment saves time. Respondent two (nurse 1 working in the maternity theatre);

> "Aah it was sucking very well, making the area neat and..... then it was aah...time saving compared with the use of gauzes, yeah."

The Maker was reported as being more efficient when compared to the standard machine in that it had less spillage. This referred to instances when the collection bottle for the suction fluid would fill up and overflow, pouring onto the floor. In the Maker equipment, an overflow protection valve was an improvement to the existing standard of care equipment. Further, the collection bottles were two and larger in the Maker machine with a toggle switch that allowed moving between the two collection chambers.

Respondent three (nurse 2 working in the maternity theatre);

> "aah aah...the suction rate is high, there is still no spillage in the same just as the standard and when we are using the standard method we use plenty of gauze, so we prefer using the Maker than the standard."

Respondent four (nurse 3 working in the maternity theatre);

> "I have said spillage, there was little spillage. Actually in the use of standard method was reduced at least we save commodities during the same period."

***Acceptability***

This describes how satisfactory the Maker equipment was to the users compared to the standard of care. It is described by a proxy measure [how much people felt that they would prefer to use it compared to the standard of care].

Respondent one: (Clinician working in the theatre)

> "Well, it is effective, so I would prefer using it actually."

***Reliability***

This measure was used to check on how confident the users had in the ability of the Maker equipment to suction effectively. This was mainly due to fewer breakdowns and additional improvements of an overflow valve and additional collection bottle, making it easy to use as it did not require any change in between or even intraoperatively. This was useful as the standard equipment required an exchange of the only chamber for the standard device.

Respondent one (Clinician working in the theatre)

> "Easy to use. It quite simple to use actually. I don't need to do exchanges in between or when I am intra-op. so the fact that it is there makes a difference especially so for us who deal with a lot of meconium, amniotic fluid, you know! You just suction, and it is easier."

It was also pointed out that the device made the work environment to be more conducive as it produced less noise than the standard equipment, which had some disturbing noise.

Respondent six (Anesthetist in maternity theatre)

> "It was kind of silent comparatively to the other noisy suctioning units."

The device was not very reliable in suctioning bigger clots as described by the registrar doctor.

Respondent five (Registrar doctor);

> "Yes, it did. However, there were some problems when it came suctioning off big clots from the abdomen.... abdominal cavity or just generally the big clots which we would encounter. However, it would suck the small like blood which would have...blood form."

The suction pressure was also slightly lower than the standard machine; this was probably due to the machine's calibration. This could explain the inability to suction the bigger clots, which may require more pressure.

Respondent five (Registrar doctor);

> "I have earlier said.... let say the force or the pressure it has....it has lesser pressure than the standard vacuum machine. That's the only issue I have encountered with it. Otherwise it's a good equipment and kudos to the team who produced it."

## Discussion

This study aimed to evaluate the effectiveness, safety, reliability, and acceptability of a locally made low-cost suction aspirator. Overall, the Maker equipment was effective in 92.6% of the patients compared to 96.4% in the standard of care arm, suggesting that the Maker equipment is good. A high reliability (92%) was reported. There were no safety concerns reported. The most common problem described was the failure to generate enough suction pressure effectively. It was linked to poor calibration of the equipment with suction pressure settings for neonates being used in equipment used for abdominal suction. These findings are consistent with the literature on locally developed equipment that has illustrated the feasibility and success of developing medical devices in LMIC settings. For instance, the Three-Dimensional (3D) printed umbilical cord clamps locally produced in Haiti (16). The success of the Maker suction equipment was due to the elaborate development and co-design process involved in the development of the equipment as described elsewhere (13). This approach addresses a critical gap between the design and development of safe and effective medical devices within LMICs on developing technical skills and contextually relevant devices (17).

While equipment breakdown and challenges in medical device maintenance have been highlighted as a significant bottleneck in the availability of medical devices (17), no significant incidents were identified in this study. The involvement of biomedical technicians and engineers in the co-design process and use of locally available materials helped create capacity and an environment that would promote sustainability of the equipment development and maintenance. This addressed concerns about medical device maintenance previously reported as a significant challenge to access and provision of quality care in LMICs (18). In addition to establishing safety and efficacy, the design and development process of the Maker suction equipment addressed several

challenges linked to the previously donated or procured standard equipment that limited the functionality of the equipment. In particular, the inclusion of safety measures like an overflow prevention valve, an easy suction pressure calibration process, an extra reservoir bottle with an easy-to-use toggle switch between bottles, and easy to change and locally available filter were reported as essential and especially useful improvements. Furthermore, qualitative findings illustrated good acceptability of the device by the health care workers, a finding that could be attributed to staff involvement from the inception during the development process, absence of any safety incidences, and the improvements mentioned above.

The availability, accessibility, and effectiveness of medical devices are vital in achieving the highest quality of care within health systems (19). Previous studies in Kenya have highlighted the lack of essential equipment for MNCH as one of the main challenges in providing high-quality care (3). This study's approach illustrates the feasibility of designing and developing such medical devices in an LMIC setting at a low cost while building capacity, ensuring sustainability, and addressing a critical gap in access to equipment. However, such a process needs to be complemented by a co-design process that involves all stakeholders to help identify priorities, inform the design, and participate in the field-based testing of the prototype to enhance ownership and identify potential devices failures (13). Reports on the development and testing of locally developed devices in LMICs have sighted skepticism in the quality and safety of the devices, sighting inadequate capacity in local expertise and regulatory processes to ensure quality assured devices and, therefore, low acceptability of devices. For instance, in Ethiopia, physicians and patients reported that they were not confident about the quality and effectiveness of locally produced drugs and had concerns about the capacity of LMICs to match the quality of drugs from High-Income Countries (HICs) (20). However, qualitative findings in this study highlight similar perceptions that changed over time and after using the Maker equipment without any safety incidents. Therefore, this suggests an opportunity to build on such successes to build trust in the local capacity to address local challenges through local production.

### Study strengths and limitations

This is the first study on locally made suction machine locally and in the region. However, this study was not without limitations. First, the sample size was limited to only low-risk women undergoing cesarean section. However, the Maker suction machine would not perform differently in more complex or high-risk patient groups as the demands and skills for suctioning are unlikely to be different. This approach was mainly for ethical reasons so as not to increase the risk for poor outcomes in the event the device failed since it had not been field-tested before. Secondly, the sample size was achieved in a relatively short period (≈1 month), and this did not allow enough time to observe for any equipment breakdown resulting from prolonged use. Further research on how the equipment performs in routine use is recommended.

## Conclusion

The Maker equipment is like the standard of care equipment. The high reliability and acceptability, and absence of safety concerns highlights the potential of local development of medical devices to address existing gaps.

## Recommendations

This study highlights the need for continued investments by governments and product development partnerships to support local device development to addresses the critical gap in access to medical devices and requisite resources, including human resources and availability of parts locally to support maintenance and hence sustainability of such initiatives.

## Funding

The Phillips Foundation funded this study through grants managed by the United Nations Children's Fund (UNICEF) and Concern Worldwide. However, the funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

## Availability of data and materials

All data generated or analyzed during this study are included in this published article.

## Acknowledgments

The authors thank Dr. Chris Ouma and Muna Shalita of UNICEF, Dr. Mohammed Sheikh and Dr. Wangui Muthigani of the Ministry of Health, Mr. Mboi Misati of KIPI, the staff and patients in Kenyatta national hospital who made the study possible, and Mr. Peter Kahihia of KEBS for their technical input during the implementation of the project.

## Competing interests declaration

The authors declare no conflicts of interest.

## References

1. WHO. Local Production and Technology Transfer to Increase Access to Medical Devices Addressing the barriers and challenges in low- and middle-income countries Geneva2012

2. Perry L, Malkin R. Effectiveness of medical equipment donations to improve health systems: How much medical equipment is broken in the developing world? Medical & biological engineering & computing. 2011;49:719-22.

3. Murphy GAV, Gathara D, Abuya N, Mwachiro J, Ochola S, Ayisi R, et al. What capacity exists to provide essential inpatient care to small and sick newborns in a high mortality urban setting? - A cross-sectional study in Nairobi City County, Kenya. PLoS One. 2018;13(4):e0196585.

4. Ademe BW, Tebeje B, Molla A. Availability and utilization of medical devices in Jimma zone hospitals, Southwest Ethiopia: a case study. BMC Health Services Research. 2016;16(1):287.

5. Sinha SR, Barry M. Health technologies and innovation in the global health arena. N Engl J Med. 2011;365(9):779-82.

6. Moyimane MB, Matlala SF, Kekana MP. Experiences of nurses on the critical shortage of medical equipment at a rural district hospital in South Africa: a qualitative study. Pan Afr Med J. 2017;28:100.

7. Sabet Sarvestani A, Sienko KH. Medical device landscape for communicable and noncommunicable diseases in low-income countries. Global Health. 2018;14(1):65.

8. Wong AL, Lacob KM, Wilson MG, Zwolski SM, Acharya S. Design and preliminary validation of a mobile application-based expert system to facilitate repair of medical equipment in resource-limited health settings. Med Devices (Auckl). 2018;11:157-69.

9. Diaconu K, Chen YF, Cummins C, Jimenez Moyao G, Manaseki-Holland S, Lilford R. Methods for medical device and equipment procurement and prioritization within low- and middle-income countries: findings of a systematic literature review. Global Health. 2017;13(1):59.

10. N. B. Rage Against The Busted Medical Machines 2016 [Available from: https://www.npr.org/sections/goatsandsoda/2016/09/08/492842274/rage-against-the-busted-medical-machines.

11. UNICEF and The Philips Foundation, together with partners, launch the Maternal and Newborn Health Innovations Project. [press release]. 2015.

12. M Miesen. The Lancet Global Health Blog. 2014. Available from: https://www.mikemiesen.com/2014/03/04/designing-medical-devices-for-predictably-unpredictable-environments/.

13. Ayah R, Ong'ech J, Mbugua EM, Kosgei RC, Waller K, Gathara D. Responding to maternal, neonatal and child health equipment needs in Kenya: a model for an innovation ecosystem leveraging on collaborations and partnerships. BMJ Innov. 2020;6(3):85-91.

14. ISO. ISO 10079-3:2014(en) Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source 2014 [Available from: https://www.iso.org/obp/ui/fr/#iso:std:iso:10079:-3:ed-3:v1:en.

15. Kragelund SH, Kjaersgaard M, Jensen-Fangel S, Leth RA, Ank N. Research Electronic Data Capture (REDCap(R)) used as an audit tool with a built-in database. J Biomed Inform. 2018;81:112-8.

16. Dotz A. A Pilot of 3D Printing of Medical Devices in Haiti. 2015. p. 33-44.

17. Fonjungo PN, Kebede Y, Messele T, Ayana G, Tibesso G, Abebe A, et al. Laboratory equipment maintenance: a critical bottleneck for strengthening health systems in sub-Saharan Africa? J Public Health Policy. 2012;33(1):34-45.

18. WHO. Local Production and Technology Transfer to Increase Access to Medical Devices. 2016 [Available from: https://www.who.int/medical_devices/1240EHT_final.pdf.

19. WHO. Systems Thinking for Health Systems Strengthening 2017 [Available from: https://www.who.int/alliance-hpsr/resources/9789241563895/en/.

20. UNCTAD. Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A series of case studies 2011 [Available from: https://unctad.org/system/files/official-document/diaepcb2011d7_en.pdf.

**Supplementary file**

Figure 1: Maker suction machine