HUMANITARIAN INNOVATION FUND

Development and Implementation Phase Grant Final Report

Organisation Name	Action Against Hunger USA

Project Title	The Click-MUAC Project - Development and testing of a simplified Mid-Upper Arm Circumference (MUAC) tool for use by mothers and caregivers for the screening of severe acute malnutrition
Partner(s)	Brixton Health, University of Tampere, Isiolo County Health Management Team, University of Michigan
Problem Addressed / Thematic Focus	Thematic focus: nutrition Addressing the problem of low community detection of severe acute malnutrition (SAM) by simplifying SAM diagnosis for mothers and caregivers
Location	Global and Kenya
Start Date	01 November 2015
End Date	05 August 2017
Total Funding	165,000 GBP 150,000 GBP (HIF) 15,000 GBP (Action Against Hunger)
Total Spent	£153,043

Reporting Period	01 November 2015 – 05 August 2017
Type of Innovation	Piloting of new diagnostic tool for the detection of severe acute malnutrition at community level
Project Impact Summary	The aim of the Click-MUAC project was to determine if the development of simplified prototype Click-MUAC bracelets could improve the sensitivity of mothers and caregivers to classify the nutritional status of their own children. Three prototype Click-MUAC bracelets were developed in collaboration with nutrition experts and an epidemiologist in 2016. The initial designs were developed with 3D printing. In order to produce more flexible, finished models for testing, plastic moulding was used to make the final three prototypes, in

	collaboration with a plastics design company. The performance of the three Click-MUAC prototypes was compared to an improved MUAC tape design in Isiolo County Kenya. The improved MUAC tape design was previously developed by a collective of NGOs, led by Médecins Sans Frontières. The methodology used in the study was a retrospective, non-randomised, partially-blinded, clinical diagnostic trial describing and comparing the performance of the three "Click-MUAC" devices and the improved MUAC insertion tape. The study took place in twenty-one health facilities providing integrated management of acute malnutrition (IMAM) services in Isiolo County, Kenya. Mothers/caregivers classified their child (n=1040), aged 6-59 months, using the "Click-MUAC" devices and a MUAC insertion tape. These measurements were compared to a "gold standard" classification (the mean of three measurements taken by a research assistant using the MUAC insertion tape). The results of the trial indicated that all the prototypes performed well , with mothers/caregivers demonstrating a high sensitivity (>93%) with all devices. This is the **first major impact of the Click-MUAC project: it has demonstrated that mothers/caregivers can conduct sensitive and specific classifications of their child's nutritional status**, with far better results than reported in previous studies. This has had, and will continue to have, an impact on the global nutrition community in terms of supporting uptake of the family/mother MUAC approach. An unexpected finding of the study was that, though the Click-MUAC prototypes performed well, the improved MUAC insertion tape actually performed significantly better with regards to sensitivity. This has been the **second major impact of the Click-MUAC project: we have demonstrated that an improved version of the traditional MUAC tape appears to be the best means to support the family MUAC approach, particularly as it can be made at lower cost than the Click-MUAC prototypes.** This has fuelled the discussion at global level on the need to adopt better designed MUAC tapes to support community-level detection of acute malnutrition. As a result of the findings demonstrated in Phase 1 of the project (i.e. the improved tape is the best means to support the family/mother MUAC approach), Phase 2 sought to develop and test a simplified colour-banded version of this tape and pilot it in an operational context. This was done in the period May-August 2017 in Isiolo County. This resulted in the **third major impact of the Click-MUAC project: gathering operational evidence on the ability of mothers to use the simplified tape in their own communities.** Quantitative and qualitative analysis of Phase 2 results indicate that the mothers and caregivers were able to measure the MUAC of their own children, using the simplified colour-banded tape with minimal training and demonstration.

	Consequently, mothers and caregivers who found red (SAM) or yellow (MAM – moderate acute malnutrition) MUAC measurement in their children were able to refer themselves and their children to the health facilities for treatment. Over 66% of mothers and caregiver measurements agreed with health workers measurements upon verification at the health centre, which is encouraging given the minimal training that was provided and short implementation time for Phase 2 (two months). The use of the simplified colour-banded tape in the communities led to earlier detection of MAM as indicated in the median MUAC at admission in the participating health facilities (median MUAC at admission for MAM treatment: 120mm at baseline; 123mm at endline).

PROJECT ACTIVITIES AND OUTPUTS

The final workplan for the Click-MUAC project can be found in **Appendix 1**

1. With reference to the final workplan, what have been the key achievements of the project?

The following points can be highlighted as key achievements of this project that contributed to organisational learning and capitalisation:

- The project was instrumental in **developing learning among nutrition experts around product design for mid-upper arm circumference devices**. Initially 3D printing was used to develop designs and assess functionality. This was helpful in discarding flawed designs and discussing with experts on what type of design elements should be incorporated (i.e. what is the best width to be used? How flexible should the material be? How intuitive can the design be made). This process enriched expert knowledge on the key elements to consider when designing such devices. The project also allowed for cross-pollination of ideas with regards to product design between spheres that do not normally interact, i.e. 3D printing experts, nutrition specialists, epidemiologists and plastic production experts.
- Another key achievement of this project was **designing the appropriate methodology to test the performance of the prototypes.** The methodology drew from previous published evidence but also took into consideration other groups (i.e. clinic staff), a larger sample size (n=1,040), a measurement standardisation process for the data collection team and calculated a series of additional measures of agreement that had not been calculated in previous studies (Fleiss' Kappa, Younden's J). The development of the study protocol was a collaboration between Action Against Hunger (both HQ and Kenya teams), Brixton Health, the University of Tampere and the Kenya Nutrition Information Technical Working Group. The study protocol was submitted in a timely manner and ethical approval was secured with very few revisions to the originally-submitted protocol.
- The study achieved **high quality data collection**. This was in part due to the high level of in-house technical expertise within the Action Against Hunger Kenya team and their strong existing partnership with the Isiolo County Health Management Team, who also provided close collaboration and oversight to the trial from start to finish. Real-time data monitoring allowed the team to monitor admissions and made it possible to request an extension to the data collection period in December 2016 in order to reach the allocated sample size for SAM cases (n=115). By strengthening community mobilisation activities and expanding data collection to additional

health facilities, the study team were able to comfortably reach the allocated 115 SAM cases by mid-January 2017.

- Once the sample size for admissions for each case definition (SAM, MAM, normal) was reached data collection was complete and data analysis on the final datasets was initiated. A key success in this respect was the cleanliness of the data produced, which required minimal cleaning**. This meant data analysis could be completed in a timely manner, allowing for rapid re-appraisal of the evolution of the project.** Indeed the results indicated that, though the prototypes performed well, the improved MUAC tape performed even better. It was therefore suggested to re-allocated funds (that had been earmarked for a second round of production of the Click-MUAC prototypes) to support the piloting of a simplified model of the improved MUAC tape at community level, in an operational setting.
- This innovation project in turn led to another innovation which was **the development of a simplified colour-banded version of the improved MUAC tape**[1]. This tape was designed with mothers and caregivers in mind, and is, to our knowledge the only such simplified uniMUAC tape produced in the world so far.
- Upon sensitization of the national and county nutrition stakeholders on the newly-developed simplified uniMUAC tape, **over 75 community health volunteers (CHVs) were trained on its use by the project research assistants. The CHVs in turn trained 3,363 mothers and caregivers on how to take MUAC measurement and assess oedema on their own children using the simplified MUAC tape**. A total of 3,363 mothers and caregivers were issued with a simplified MUAC tape after their training and were advised to take the MUAC measurement and check for oedema on their own children every two weeks. **A total of 3878 children aged 6-59 months were assessed for MUAC and oedema by their own mothers** during the implementation of Phase 2 (July-August 2017).
- **Mothers and caregivers understand the process of MUAC measurement and can do it**. This is confirmed through the verification of 128 children whose MUAC measurements showed red or yellow on the simplified MUAC tape and were referred to health facility by their mothers/caregivers. Out of 128 SAM and MAM cases, as measured by the mother/caregiver, who were subsequently verified by the health staff at the health facility, **66% (72 cases - 4 SAM, 68 MAM) were confirmed as true SAM/MAM cases**. The remaining discrepancy between the mother/caregiver measurements and the health worker measurements was investigated and qualitative feedback from participants indicated that some mothers/caregivers were deliberately tightening the MUAC on the arm with the aim of getting their children admitted to the IMAM program to benefit from therapeutic/supplementary foods (RUTF/RUSF). The project team took this valuable feedback on board and refresher trainings were conducted during mother support group meetings and during household visits to ensure that mother and caregivers understood not only how to conduct MUAC measurement but also the admission procedures at health facility level.
- **Early diagnosis and treatment of MAM cases as a result of the mother-led MUAC screening was noted when median MUAC at admission for MAM treatment increased from 120mm at baseline to 123mm at endline** (baseline was conducted one month after the start of Phase 2 and endline was conducted one month after the closure of the project). The median MUAC at admission for SAM showed no change at baseline and endline. This is attributable to the short implementation period and also the protracted health worker strike in Isiolo county during Phase 2 which hampered mothers/caregivers ability to rapidly seek SAM treatment at the health facility.

The broader achievements of the project related to impact of the innovation study on the wider humanitarian community and other stakeholders include:

[1] Also known by its MSF name “UniMUAC” or universal MUAC

- This project has produced **strong and credible evidence to support the ability of mothers and caregivers to perform sensitivity and specific classifications of the child's nutritional status**. This evidence is crucial in supporting the mother/family-MUAC approach globally. The approach has the potential to radically improve community case-detection and even prevention of acute malnutrition through regular MUAC monitoring by mothers/caregivers.
- The results of this project has been shared and disseminated in a number of fora both at national and global level. This has been successful in **promoting the evidence to support the mother/family MUAC approach and has also been helpful in gathering input and advice as to the development of the simplified MUAC tape and its scalability in other contexts**. The mother/family MUAC approach has received a great deal of attention in the past year, thanks in part to the results of this study and other previous studies. The approach is featured on the State of Severe Malnutrition Website, it has been highlighted as a key approach to scaling-up SAM management within the No Wasted Lives initiative and has been featured as an approach in the recently revised CMAM statement co-authored by UNICEF, WFP and WHO. In addition, the **Click-MUAC project has resulted in increased national momentum for the mother/family MUAC approach in Kenya**. Mother/family MUAC has generated enthusiasm among nutrition stakeholders in Kenya and is being considered as a feasible approach to be included in the community component of the national surge mechanism for Integrated Management of Acute Malnutrition. This integration is expected to increase early case-detection. The approach has the potential to increase admissions into the national IMAM program at health facility and, with good facility monitoring, possibly reflect the true acute malnutrition burden at community level.
- The project was flexible enough to respond to changes in the understanding of the innovation needed. When it became apparent that the improved MUAC tape performed better, it was possible to pursue the production of the simplified MUAC tape and test it in the community. Gathering the programming evidence on this device and approach at community level has been instrumental in **affirming previous studies that mothers understand and can correctly take MUAC measurement on their own children in a Kenyan context**. When adopted in the context of Isiolo County, the mother/family-led MUAC approach helped to address the problem of over-reliance on unmotivated, unremunerated CHVs to conduct mass screening, which has proved to be an unsustainable approach in the Kenyan community health strategy.
- Another achievement of the project has been working with communities and local authorities on the development and roll-out of the devices. This has promoted **local engagement on the issue of acute malnutrition,** by involving mothers, fathers and siblings in monitoring the nutritional status of their own children. The enthusiasm and appreciation shown by mothers, caregivers and the community on the approach was demonstrated during mother support group meetings and community dialogue engagement meetings conducted by the project team. Communities also stated that they felt empowered by the approach and felt they could request treatment services from the health service providers with more confidence.

INNOVATION OUTCOMES

Whether this innovative project was successful, not successful, or a mix of both, the HIF would like you to report as much detail as possible, so that success can be built on and failures can be learned from. By 'success' we mean that the innovation has achieved the planned positive impact/outcome, or that it has performed better than the current process, product or system.

2. Has the project demonstrated the success of the innovation? *(Please choose only one answer.)*

☒ Completely successful
☐ Significantly successful
☐ Partially successful

☐ Completely unsuccessful

2b. Please select the successes that your project have achieved:
(You may choose more than one)

☒ There is real evidence that the project achieved the planned outcome(s)
☐ There were perceived contributions or improvements to the planned outcome(s)
☒ Learning was achieved within the project cycle
☒ 'Lessons learned' were gathered and circulated to humanitarian stakeholders and actors
☒The completion of this project has led to another innovation
☐ Other *(please comment)* _____

2c. Please select the challenges your project has encountered:
(You may choose more than one)

☐ The project did not complete its planned activities
☐ There is no real evidence that the project achieved the planned outcome(s)
☐ There were few perceived contributions or improvements to the planned outcome(s)
☐ Learning was not achieved within the project cycle
☐ 'Lessons learned' were not circulated to humanitarian stakeholders and actors
☒ Other *(please comment)* : The project encountered delays in the procurement of the simplified tapes to Isiolo County due to contracting issues with the producer. The implementation of family/mother MUAC activities in Phase 2 was also affected by the protracted health worker strike on-going in Kenya which restricted referral possibilities for children diagnosed SAM/MAM and also affected project implementation timelines.

2d. If there is any evidence for the successful performance of the innovation, please describe it further:

The project produced strong and credible evidence that **all the devices tested (prototype Click-MUACs and improved MUAC tape) demonstrated high sensitivity (>93%) and very high specificity (>96%)**. However there was a significant difference in performance between the best performing Click-MUAC device (prototype 3) and the improved MUAC tape. Mother/caregiver sensitivity for SAM and GAM classification was higher using the MUAC insertion tape (100% sensitivity for SAM and 99% sensitivity for GAM) than using Click-MUAC devices. Younden's J for SAM classification, and sensitivity for GAM classification, were significantly higher for the MUAC insertion tape (99% and 99% respectively). The detailed manuscript describing the methods and results of the study is available in **Appendix 2.**

Therefore, although the prototypes were successful, the improved MUAC tape performed best, and can be produced more cheaply. It appears therefore to be more suited to larger-scale implementation of the family MUAC approach. **The sensitivity of mothers/caregivers in our study was much better than in previously published studies** (e.g. Blackwell et al. 2015). This may have been due to the use of an **improved design for the MUAC tape** (previous studies used regular UNICEF MUAC tapes) and also the fact that the mothers/caregivers received **one-on-one training** on the use of the devices (in previous studies mass demonstration was used). The results of the study **bolster the global evidence to support the mother/family-MUAC approach in communities**.

Given the results of the study in Phase 1 it was decided in Phase 2 of the project to pursue the **development of a simplified improved MUAC tape**, based on the improved MUAC tape that was used in Phase 1. The simplified MUAC tape was piloted in the community in an operational setting. The pilot demonstrated that **mothers and caregivers understand the process of MUAC measurement and can do it**. This is confirmed through the verification of 128 children whose MUAC measurements showed red or yellow on the simplified MUAC tape and were referred to health facility by their mothers/caregivers. Out of 128 SAM and MAM cases, as measured by the mother/caregiver, who were subsequently verified by the health staff at the health facility, **66% (72 cases - 4 SAM, 68 MAM) were confirmed as true SAM/MAM cases**. This is encouraging given the minimal training that was provided and short implementation period for Phase 2 (two months). The project team were also able to investigate and provide solutions (i.e refresher trainings) to the discrepancies in measurements observed, as described in the previous section of this report. **Early diagnosis and treatment of MAM cases, as a result of the mother-led MUAC screening, was noted when median MUAC at admission for MAM treatment was increased from 120mm at baseline to 123mm at endline**, based on health facility monitoring data. The median MUAC at admission for SAM showed no change at baseline and endline. This is attributable to the short implementation period and also the protracted health worker strike in Isiolo county during Phase 2 which hampered mothers/caregivers ability to rapidly seek treatment for SAM at the health facility.

3. Please show the components of the project which contributed the most to any *successes*:
   (where 1 = most influence 3 = least influence)

Component	*1*	*2*	*3*	*N/A*
Design and placement of the innovation	☐	☒	☐	☐
The methodology or approach to collecting evidence	☒	☐	☐	☐
Context	☒	☐	☐	☐
The availability of resources and capacities (financial, human, technical etc.)	☒	☐	☐	☐
Success in identifying and responding to different project and innovation risks	☐	☒	☐	☐
Strength of relationships and collaborations within the team and with other stakeholders	☒	☐	☐	☐
The process was flexible and responsive to emerging results	☒	☐	☐	☐
Ability to draw on experience and expertise of existing practice, codes and standards	☐	☒	☐	☐
Other:	☐	☐	☐	☐
Other:	☐	☐	☐	☐

4. Please show the components of the project which contributed the most to any unsuccessful elements of the project

Component	*Yes– contributed to failures*
Weaknesses in the design and placement of the innovation	☐
The methodology or approach to collecting evidence	☐

Context	☐
A lack of access to resources and capacities (financial, human, technical etc.)	☐
Difficulty in identifying and responding to different risks	☐
Lack of good relationships and collaboration within the team and with other stakeholders	☐
Having a process that was not flexible or responsive to emerging results	☐
No ability to draw on experience and expertise of existing practice, codes and standards	☐
Other:	☐
Other:	☐

5. What are the top three, key lessons learnt relating to the innovation? *This should relate to the innovation or the sector in which it operates, rather than project implementation.*

1. We now know that mothers and caregivers, with adequate minimal training, can conduct sensitive and specific classifications of their child's nutritional status. Using all four devices in this study, the mothers were able to conduct classifications with high sensitivity (>93%) and very high specificity (>96%), which bolsters the argument to scale-up mother/caregiver-led MUAC screening in other contexts. The results reported from this project are much more successful than those reported in previous studies.

2. We now know that, even though all the devices were successful, the improved MUAC tape was the best performing device. This may have been due to the fact that some mothers were concerned about skin pinching with the Click-MUAC devices. It may also have been due to the fact that the improved MUAC tape had new design features that contributed to higher sensitivity. These included: a large tab to enable controlled tensioning of the tape; a three slot "buckle" to hold the tape straight while measurements are taken; a broad tape to reduce the effect of over-tensioning and to increase the probability that the tape covered the mid-point of the upper arm; measuring points that extend to the edge of the tape; and a corrected measurement scale to remove a systematic error of at least +1.8 mm in MUAC measurements found in other conventional design MUAC tapes[2]. It is thought that all devices benefitted from a one-on-one demonstration to the mothers, which may have helped to improve sensitivity results, as compared to previous studies that used mass demonstration techniques.

3. We now know that, in an operational Kenyan context, mothers/caregivers can take MUAC measurements correctly with a simple and short group training session in the community. Buy-in and uptake for family MUAC measurement in this context was high. Mothers/caregivers are willing to take MUAC measurements of their children and subsequently seek treatment services for SAM/MAM if necessary. However, a potential risk identified is that some mothers/caregivers could seek to modify their child's measurement to fit the admission criteria even if they are not actually malnourished. Hence the need for increased sensitisation to mothers/caregivers on admission procedures (i.e. that a second verification process will take place at health facility).

[2] This is due to a failure to account for the thickness of the tape material when positioning the scale and/or measurement point.

6. Do the final outcomes support the initial rationale for the innovation?

☒ Yes, completely
☐ Yes, significantly
☐ Partially
☐ No, not at all

Please describe further:

The initial rationale for this project was that there was some evidence that the mother-MUAC approach was feasible however that the sensitivity of mother's MUAC measurements could be improved (see Blackwell et al. 2015). The project therefore set out to design simplified MUAC measurement bracelets and test them against an improved MUAC tape amongst mothers conducting measurements at health facility level. The outcome was that all devices performed very well in terms of sensitivity (>93%) supporting the initial rationale that new devices were needed to improve sensitivity. What was surprising was that the best performing device was a modified/improved version of the existing MUAC tape. Using this improved MUAC tape could help to improve the sensitivity of measurements and can be produced more cheaply than the Click-MUAC devices. It therefore better suited to supporting the larger scale-up of the mother MUAC approach at community level.

7. How has your understanding of the innovation changed through the project period?

It was initially thought that a semi-rigid plastic locking mechanism device would be the best way to improve the sensitivity of mother's MUAC measurements. Whilst it was confirmed that these devices (the Click-MUAC devices) did demonstrate improved sensitivity compared to previous studies using traditional MUAC tapes, the best performing device was in fact an improved version of the traditional MUAC tape. It is thought that concerns regarding skin pinching (which don't exist with the MUAC tape) could have contributed to the Click-MUAC devices performing less well than the improved MUAC tape. The new design features of the improved MUAC tape (see 5.2) may have contributed to better sensitivity results, as compared to the traditional UNICEF tape used in previous studies.

8. Did the innovation lead to any unexpected outcomes or results? How were these identified and managed?

As described above, it was expected that the Click-MUAC devices would be the best performing devices in terms of sensitivity. However, unexpectedly, the improved MUAC tape was the best performing devices and this difference was statistically significant.

The project had initially budgeted for a second-round of production of Click-MUAC prototypes, to be tested in the communities. When the results from Phase 1 were released, it became apparent to the project team that a re-allocation of funds was necessary to support the development of a simplified version of the improved MUAC tape for use in the community. Thanks to support and guidance from the HIF team and the timely re-orientation of activities by the AAH teams, the project was flexible enough to incorporate this change of direction. The project was able to successfully design and pilot test the simplified improved MUAC tape in communities in Isiolo and gather further evidence on the impact of the device and approach in an operational context.

METHODOLOGY

9. Was the methodology successful in producing credible evidence on the performance of the innovation?

☒ Yes, completely
☐ Yes, significantly
☐ Partially
☐ No, not at all

Please describe further:

The methodology adopted in Phase 1 to provide evidence on the performance of the innovation was **a prospective, non-randomised, partially-blinded, clinical diagnostic trial describing and comparing the performance of three "Click-MUAC" devices and a MUAC insertion tape**. The study took place in twenty-one health facilities providing integrated management of acute malnutrition (IMAM) services in Isiolo County, Kenya. Mothers/caregivers classified their child (n=1040), aged 6-59 months, using the "Click-MUAC" devices and a MUAC insertion tape. These measurements were compared to a "gold standard" classification (the mean of three measurements taken by a research assistant using the MUAC insertion tape). **The methodology was straightforward to implement and was supported by local authorities**. When, in December 2016, it was noted that the SAM sample size would be hard to reach, **the methodology was flexible enough to be able to expand data collection activities to other health facilities**.

The **quality of the data collected was high and required minimal cleaning**. Data were analysed using purpose-written R language scripts managed using the R-AnalyticFlow scientific workflow system. Bootstrap methods were used to calculate 95% confidence intervals on summary statistics using r = 9999 replicates. Exact binomial confidence limits were calculated in two cases where 100% sensitivity was observed.

The analysis of the data indicated that the sensitivity of mother/caregiver classifications was high for all devices (> 93% for severe acute malnutrition (SAM), defined by MUAC < 115 mm, and > 90% for global acute malnutrition (GAM), defined by MUAC < 125 mm). Mother/caregiver sensitivity for SAM and GAM classification was higher using the MUAC insertion tape (100% sensitivity for SAM and 99% sensitivity for GAM) than using "Click-MUAC" devices. Younden's J for SAM classification, and sensitivity for GAM classification, were significantly higher for the MUAC insertion tape (99% and 99% respectively). Specificity was high for all devices (> 96%) with no significant difference between the "Click-MUAC" devices and the MUAC insertion tape.

The methodology adopted in Phase 2 consisted in close monitoring of routine health facility data (i.e. nutrition treatment admissions, MUAC at admission, concurrence of mother diagnosis with health facility diagnosis) along with simultaneous community-level monitoring of CHV training implementation, training roll-out to mothers/caregivers and qualitative feedback on the implementation of the approach through community engagement discussions and mother support groups. **This methodology was successful in producing operational evidence of the impact of the innovation and approach within a short time-frame**.

PARTNERSHIPS AND COLLABORATION

10. How and why did the partnership change during the course of the project?

The project was a collaboration between Action Against Hunger, the University of Tampere, Brixton Health and the Isiolo County Health Management Team. This partnership was incredibly valuable in harnessing academic, operational and logistical support to the project. All stakeholders were involved in the project from start to finish and participated in the final write-up of results for peer-review publication. In its initial stages the project also benefitted from 3D printing support from the University of Michigan. This was extremely helpful in providing mock-ups of the initial designs before moving on to a plastic moulding production process for the prototypes. The project also benefited from the on-going support of the Kenya Nutrition Information Technical Working Group, which provided input and guidance on the development of the study protocol, review of the trial results and advice on the implementation of the operational pilot.

11. Are there plans to continue your partnership, either while scaling up this innovation or on other projects?

☒ Yes, with this innovation
☐ Yes, with another project
☐ Maybe
☐ No

Please describe further:

Action Against Hunger will continue to partner with the Isiolo County Health Mangement Team to explore means to sustainably scale-up the approach of family MUAC in Isiolo County, using the simplified colour-banded MUAC tape. Action Against Hunger will also continue to work with national authorities and the Nutrition Information Technical Working Group to disseminate the results of the study and advocate for the mother/family MUAC approach at national and regional level.

Action Against Hunger is also interested in piloting the approach, and the use of the simplified tape, in other contexts where it operates. A number of country programmes and donors have shown keen interest in the approach, which looks to be replicable in a number of other contexts.

DISSEMINATION

12. Please describe any steps taken to disseminate the outcomes of the project.
Please include all completed and forthcoming, as well as all planned and unplanned products (for example, research and policy reports, journal articles, video blogs, evaluations).

The results of the trial conducted in the Phase 1 have been written up for peer-review publication. In September the manuscript was submitted to the Archives of Public Health, a peer-review publication that has already featured a number of articles on the mother MUAC approach. The manuscript can be found in **Appendix 2**.

The results pertaining to the Phase 2 operational pilot of the simplified tape are in the process of being written up for the Field Exchange publication of the Emergency Nutrition Network.

In addition the results of Phase 1 have been presented in a number of different fora: New York Nutrition Partners Group, Kenya Nutrition Information Technical Working Group, Action Against Hunger International Scientific Committee Meeting. The results from Phase 1 will also be presented at the upcoming Research for Nutrition Conference in Paris in November 2017 and featured as part of Humanitarian Evidence Week 2017.

13. Has the project received any third party coverage during the project (from news media, third party blogs, researchers or academics etc.)?

Formal dissemination of the results (including to third parties) is embargoed until the publication of the results in a peer-review publication. Until that time, Action Against Hunger is communicating on the outcomes of the project in oral presentations and in meetings, in order to gather inputs on the results and promote the mother-MUAC approach and utilisation of the simplified MUAC tape.

SCALE UP AND DIFFUSION – WHAT NEXT?

14. Is the project or innovation to be replicated or scaled up?

- ☒ Yes, we will scale up in the same or similar context
- ☒ Yes, we will scale up within our organisation (including running more pilots or trials)
- ☐ Yes, we will replicate the innovation/project in another context or country
- ☐ Yes, the innovation/project will be replicated or scaled up by another organisation or stakeholder
- ☐ Yes, other
- ☐ No

If you answered *yes* to question 14, please answer 14b:

14b. What model are you pursuing to scale up or sustain your innovation?

- ☒ Applying for more donor funding
- ☐ Selling the innovation or patent
- ☐ Cost recovery (for example, selling your service or being paid as a consultant to implement the innovation)
- ☒ Innovation to be taken up by organisation or government as standard and included in standard planning and core funding by them
- ☒ Other_____

Please describe further:

Action Against Hunger is exploring possibilities to expand the mother/family MUAC approach and the use of the simplified MUAC tape in other contexts where it operates. This could be done within existing programmes with designated community mobilisation budgets, or as additional operational pilots with enhanced data monitoring to gather more evidence on mother/family MUAC feasibility within other contexts.

In addition, Action Against Hunger is advocating for the approach to be featured in national guidance, particularly in national IMAM guidelines and community health strategies at Kenya level. Action Against Hunger also plans to advocate to UNICEF to include the approach as part of its strategy for scaling up acute malnutrition treatment in East Africa, as part of the No Wasted Lives Initiative. Action Against Hunger will also advocate to UNICEF to incorporate new design features into its existing MUAC tape to improve sensitivity, based on the learning learnt in developing the simplified MUAC tape.

15. If the project or innovation could be replicated or scaled up, please list the three most important issues or actions that will need to be considered:
(where 1 = most important and 3 = least important)

Suggestion/issue	*1*	*2*	*3*

1 In order for the mother/family MUAC approach to be substantially scaled-up it needs significant buy-in from national authorities (ministries of health) and to be supported by UNICEF at a global level. This requires that the approach (and the means to adequately conduct it – i.e. with an improved MUAC tape design) needs to be included in national training plans, acute malnutrition treatment guidance and community health strategies. UNICEF buy-in for the approach is fundamental because as an organisation they support the majority of national institutions related to child health and nutrition. UNICEF have supported the approach in the recently revised CMAM statement (co-authored by WHO and WFP) at a global level however this has yet to translate into policy and practice at country level in a number of contexts. Further advocacy also needs to take place to ensure a revision of the existing UNICEF MUAC tape to ensure it captures the design features that proved successful in this project.	☒	☐	☐
2 In order to cost-effectively scale-up the mother MUAC approach, we need to have a better understanding of the bare minimum required as a training package for mothers, based on rigorous context assessment. Depending on the context (and levels of literacy) some training approaches might be more feasible than others. Creating a tailored training package and a clear, costed scaling-up plan for different contexts would help to scale-up the approach globally.	☒	☐	☐
3 A critical question in the future with regards to this approach and innovation will be its impact on the coverage of acute malnutrition treatment and also its ability to prevent malnutrition (through regular screening a mother may be able to prevent her child from developing acute malnutrition). This type of evidence will help to quantify the impact the approach is having on the global burden of acute malnutrition and help promote it as a preventative life-saving intervention.	☐	☒	☐

Appendix 1. Final Workplan

Below is a table that is the same as the workplan that you submitted with your original application. There are **three ways** to respond to this section.

1. If there have been no changes at all through the project you may cut and paste your original workplan here.

2. If there have been changes to the project but these changes **were previously reported to the HIF** in an *Agreement Amendment* form, please adjust your original workplan so that these changes are recorded in it here.

3. If there have been changes which were **not previously reported to the HIF**, please **also** fill in Table 2 (which is on the next page). In particular, please make sure to explain any budget various greater than 15% in Table 2.

The workplan for the Click-MUAC project was changed in March 2017. These changes were reported to and approved by HIF in an Amendment Agreement signed by both parties on the 5th of May 2017. The project duration, budget and activities were realigned to take into account the new activities in Phase 2 of the project, which were not previously considered in the original workplan. The revised workplan, as outlined in the Amendment Agreement, is presented below. For the detailed budget report breakdown, please see the attached final budget report to this narrative report.

Expected Results	Main Planned Activities	Implementation Period 2015 -2017 (months)																						Responsible Party
		N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	
	Phase 1: Planning																							
Study prototypes and study tools developed and validated	Identify and map plastics specialists for the development of a range of specimens based on three Click MUAC designs	X	X																					AAH and technical partners
	Collate a selection of specimens based on the three designs. Select three most appropriate prototypes in collaboration with academic and technical partners			X	X	X																		AAH and technical partners
	Finalise and produce prototypes for testing with plastics specialist						X	X																AAH and technical partners
	Development of study protocol and data collection tools						X	X																AAH and Brixton Health
	Finalisation of study protocol and data collection tools							X	X															AAH and Brixton Health
	Submission for ethical clearance in country								X															AAH Kenya Mission
	Recruitment of Study Coordinator							X	X															AAH Kenya Mission

	Recruitment of Research Assistant								X	X														AAH Kenya Mission
	Data collection tool development							X																AAH and Brixton Health
	Training of Study Coordinator and Assistant on data collection tool use								X	X														AAH Kenya Mission
	Phase 1: Data collection																							
		N	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	
High-quality data collected on prototype performance	Deployment of Study Coordinator to Isiolo County – identification of targeted health facilities with ACF team									X														AAH Kenya Mission and Isiolo CHMT
	Recruitment of data entry manager and data collection team									X	X													AAH Kenya Mission
	Data collection											X	X	X	X	X								AAH Kenya Mission and Isiolo CHMT
	Preliminary results feedback to Kenya ACF team, national authorities and NITWG															X								AAH Kenya Mission
	Phase 1: Data analysis and write-up																							
Data analysis enables conclusions to be drawn on performance of prototypes	Data analysis and reporting – write up initial results brief																X	X						Brixton Health and AAH
	Development of manuscript for peer-reviewed journal																		X	X	X	X		AAH and technical partners
	Submission of manuscript																						X	AAH
	Phase 2: Planning																							
Materials and tools available for community pilot	Based on Phase 1 results: develop simplified MUAC tape																		X	X				AAH and Brixton Health
	Print and send simplified MUAC tape to Isiolo																				X			AAH
	Develop community mobilization strategy																			X	X			AAH Kenya Mission
	Phase 2: Implementation																							
		N	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	
Learning	Implement enhanced data monitoring at the health centres and																				X	X	X	AAH Kenya

generated on feasibility of approach and device for scale-up	in the targeted communities																								Mission
	Implement training and community mobilization activities																					X	X	X	AAH Kenya Mission
	Monitor data collection at health centre and in communities																					X	X	X	AAH Kenya Mission
	Data analysis, compilation of lessons learnt																						X	X	AAH Kenya Mission
	Capitalization and potential development of proposal for further scale-up																						X	X	AAH and technical partners

Appendix 2. Manuscript of results for PRJ

Comparing performance of mothers using simplified mid-upper arm circumference (MUAC) measurement devices with an improved MUAC insertion tape in Isiolo County, Kenya

By

Angeline Grant[1*], James Njiru[2], Edgar Okoth[2], Imelda Awino[1], André Briend[3], Samuel Murage[4], Abdirahaman Saida[5], Mark Myatt[6]

1. Action Against Hunger, One Whitehall St, New York, NY 10004, United States. agrant@actionagainsthunger.org ; iawino@actionagainsthunger.org
2. Action Against Hunger, Nyangumi Road, PO Box 39900-00623, Nairobi, Kenya. nutiycn.ke@acf-international.org ; hod-nut@ke-actionagainsthunger.org
3. Department of International Health, University of Tampere School of Medicine, , PB 100, Tampere, Finland and Department of Nutrition, Exercise and Sports, Faculty of Science, University of Copenhagen, DK-1958 Frederiksberg, Denmark. andre.briend@gmail.com
4. National Ministry of Health Unit of Nutrition, Monitoring and Evaluation Department, Old Mbagathi Road, PO Box 43319-01000, Nairobi, Kenya. matymesam@gmail.com
5. Isiolo County Health Management Team, Hospital Road, PO Box 36-30600, Isiolo, Kenya. saidaabdirahaman@yahoo.com
6. Brixton Health, Alltgoch Uchaf, Llawryglyn, Trefeglwys, Caersws, Powys, Wales SY17 5RJ, United Kingdom. mark@brixtonhealth.com

***Corresponding Author**: Angeline Grant, One Whitehall St, New York, NY 10004, United States. Email: agrant@actionagainsthunger.org

ABSTRACT

Background: A novel approach for improving community case-detection of acute malnutrition involves mothers/caregivers screening their children for acute malnutrition using a mid-upper arm circumference (MUAC) insertion tape. The objective of this study was to test three simple MUAC measurement devices to determine whether they improved the sensitivity of mothers/caregivers at detecting acute malnutrition.

Methods: Prospective, non-randomised, partially-blinded, clinical diagnostic trial describing and comparing the performance of three "Click-MUAC" devices and a MUAC insertion tape. The study took place in twenty-one health facilities providing integrated management of acute malnutrition (IMAM) services in Isiolo County, Kenya. Mothers/caregivers classified their child (n=1040), aged 6-59 months, using the "Click-MUAC" devices and a MUAC insertion tape. These measurements were compared to a "gold standard" classification (the mean of three measurements taken by a research assistant using the MUAC insertion tape).

Results: The sensitivity of mother/caregiver classifications was high for all devices (> 93% for severe acute malnutrition (SAM), defined by MUAC < 115 mm, and > 90% for global acute malnutrition (GAM), defined by MUAC < 125 mm). Mother/caregiver sensitivity for SAM and GAM classification was higher using the MUAC insertion tape (100% sensitivity for SAM and 99% sensitivity for GAM) than using "Click-MUAC" devices. Younden's J for SAM classification, and sensitivity for GAM classification, were significantly higher for the MUAC insertion tape (99% and 99% respectively). Specificity was high for all devices (> 96%) with no significant difference between the "Click-MUAC" devices and the MUAC insertion tape.

Conclusions: The results of this study indicate that, although the "Click-MUAC" devices performed well, the MUAC insertion tape performed best. The results for sensitivity are higher than found in previous studies. The high sensitivity for both SAM and GAM classification by mothers/caregivers with the

MUAC insertion tape could be due to the use of an improved MUAC tape design which has a number of new design features. The one-on-one demonstration provided to mothers/caregivers on the use of the devices may also have helped improve sensitivity. The results of this study provide evidence that mothers/caregivers can perform sensitive and specific classifications of their child's nutritional status using MUAC.

Key words: Screening by mothers, Severe acute malnutrition, Community management of acute malnutrition, Mid-upper arm circumference

Clinical trials registration number: NCT02833740

Word count: 3,310

Background

It is currently estimated that, at any one time, over 17 million children under the age of five years suffer from severe acute malnutrition (SAM) [1], possibly translating to more than 100 million global incident cases each year [2]. Over the past two decades there has been a shift from an in-patient, hospital-based treatment approach for SAM to a decentralised model combining both out-patient care for uncomplicated cases of SAM and in-patient care for SAM children with medical complications or those not responding to treatment [3]. Uncomplicated cases of SAM are treated in an out-patient therapeutic programme (OTP) while complicated cases of SAM are medically stabilised in a nutrition stabilisation centre before being referred for out-patient care in the OTP. This model, known as community management of acute malnutrition (CMAM), or integrated management of acute malnutrition (IMAM) in some contexts, has significantly increased the number of SAM cases receiving treatment in recent years. However, despite these gains, it has been estimated that less than 20% of SAM children are currently accessing treatment globally [4].

A key component of CMAM is ensuring regular screening and case-finding at community level. Since the scaling up of CMAM, mid-upper arm circumference (MUAC) measurement has become the most common form of anthropometric measurement used at community and primary health centre level for the case-finding and admission of cases of acute malnutrition. Most acute malnutrition case-finding is carried out by community health workers (CHW) or community health volunteers (CHV) who measure MUAC and refer children with a MUAC of less than 115 mm for therapeutic feeding and medical care [5].

Children with a MUAC of less than 125 mm are referred for supplementary feeding support if this is available. MUAC has been shown to be the best prognostic indicator for mortality in children aged 6-59 months at community level [6], especially when repeated over time [7]. If a SAM case is detected and acted upon early in the disease episode this can decrease mortality and morbidity related to malnutrition, reduce per-case treatment costs thanks to shorter treatment times and lower the numbers of children requiring expensive in-patient care for SAM with medical complications [8,9]. A combination of high cure rates and short treatment lengths often acts to increase SAM treatment programme coverage [8].

A novel community screening approach involves mothers and caregivers using MUAC to detect acute malnutrition in their own children [10]. This may enable mothers and caregivers to develop a better understanding of the signs of malnutrition, be engaged in monitoring their children's nutrition status and increase the frequency of child screening at community level.

A study conducted in Niger in 2013-2014 [11] demonstrated a significantly higher median MUAC at admission to OTP and better OTP Sphere standards performance indicators [12] in areas where mothers were screening their own children compared to areas where CHWs were responsible for screening children. The study also showed lower proportions of children needing in-patient care at admission and during treatment and reduced numbers of rejected referrals (i.e. children who did not fulfil OTP entry criteria of MUAC < 115mm - an important barrier to coverage [13]) in areas where mothers did the MUAC screening. The coverage of the OTP in the areas where the mothers did the screening was comparable to coverage of the OTP in the areas where the CHWs did the screening.

The work carried out to date on supporting mothers to measure MUAC is based on the utilisation of conventional MUAC tapes. These tapes are colour-coded and/or graduated. They are made of flexible material (e.g. polypropylene or plasticised paper) about 1 cm wide. As per international guidelines [14] the MUAC tape is placed on the middle of the left upper arm of the child. The tension of the band is adjusted by the person undertaking the measurement. Errors with too tight or too loose tape measurements can be

observed. Measurement error may decrease the sensitivity of the diagnosis. A previous study conducted in rural Niger [15] found that mothers could use colour-banded MUAC tapes to identify cases of SAM (defined by MUAC < 115 mm) with 73% sensitivity and 98% specificity. It was therefore proposed to develop three simplified and standardised (either 115 mm circumference or including both 115 mm and 125 mm circumferences) MUAC bracelets ("Click-MUAC" devices) to support the mother-led MUAC screening approach and to test these prototypes in an operational setting. The prototypes would be compared to a universal design (i.e. for use with adults, children, and neonates for chest and head circumference), colour-banded MUAC insertion tape ("uniMUAC"). The uniMUAC tape is a modified design (i.e. to improve accuracy) compared to existing models such as the UNICEF MUAC tape.

The primary aim of the study was to describe and compare the performance of a set of prototype "Click-MUAC" devices against a "gold standard" of classification, in terms of five measures (sensitivity, specificity, agreement, Fleiss' *Kappa* and Youden's *J*), for the classification (diagnosis) of nutritional status (SAM, moderate acute malnutrition, normal).

The secondary aim of the study was to determine the difference in agreement with the "gold standard" classification amongst mothers/caregivers using "Click-MUAC" devices versus mothers/caregivers using a MUAC insertion tape.

Methods

Three "Click-MUAC" devices and one MUAC insertion tape were used in the study. The "Click-MUAC" devices were developed with the support of nutrition specialists, plastics specialists and 3D-printing experts in France, the United Kingdom, the United States and Kenya. The prototypes underwent five rounds of product appraisal by the study team before being tested in the field. Each "Click-MUAC" prototype was made of semi-rigid plastic with a standard measurement of 115 mm (prototypes 1 and 2 – see **Figure 1**) and 115 mm and 125 mm (prototype 3 – see **Figure 1**).

The study also used a universal design, colour-banded MUAC insertion tape, with 1 mm graduation, designed and produced by a consortium of Non-Governmental Organisations and academics led by Médecins Sans Frontières. The universal MUAC tape was designed to minimise measurement error by having a large tab to enable controlled tensioning of the tape; a three slot "buckle" to hold the tape straight while measurements are taken; a broad tape to reduce the effect of over-tensioning and to increase the probability that the tape covers the mid-point of the upper arm; measuring points that extend to the edge of the tape; and a corrected measurement scale to remove a systematic error of at least +1.8 mm in MUAC measurements found in other conventional design MUAC tapes, which is due to a failure to account for the thickness of the tape material when positioning the scale and/or measurement point. These design elements are shown in **Figure 2**. The universal MUAC tape has shown increased accuracy and similar precision, when compared to conventional design MUAC tapes, in tests using soft plastic tubes of known circumference (between 100 mm and 160 mm) [16].

The study was conducted according to the Declaration of Helsinki guidelines and is registered at clinicaltrials.gov (Trial number: NCT02833740). The study protocol was granted ethical approval by the African Medical and Research Foundation (AMREF) Ethics and Scientific Review Committee, Kenya (ESRC number P249/2016) in July 2016.

Superiority was defined as an increase in case-finding sensitivity of 15% or more accompanied by little or no change in specificity. It was calculated that a sample size of $n = 115$ for each of the three groups (i.e. SAM, moderate acute malnutrition and normal) would be sufficient to determine superiority with better than 95% power, with one-sided $p = 0.05$, and was feasible to collect in the study programme.

The study took place in Isiolo County, Kenya. Action Against Hunger has been active in Isiolo County since 2009, supporting nutrition-specific and nutrition-sensitive programming in collaboration with the Isiolo County Management Team. The county offered IMAM services, supported by Action Against Hunger, where the devices could be tested.

The study was carried out by the Isiolo County Health Management Team (CHMT), with support from Action Against Hunger. Eight research assistants were trained by the CHMT and Action Against Hunger on the study protocol, interview techniques, obtaining informed consent and detection of acute malnutrition through the measurement of MUAC and testing for oedema. Two measurement standardization tests were conducted and analysed using Emergency Nutrition Assessment software (July 9, 2015 version) in order to verify the accuracy and precision of the measurements taken by the research assistants, following the Habicht method [17]. The questionnaire was pre-tested by the study team on patients at Isiolo County Hospital, prior to starting data collection. Sensitisation on the study, its protocol and its objectives, was also provided to participating health facility staff by the CHMT prior to starting data collection. This helped to facilitate the integration of the study into the routine screening activities conducted within the Isiolo County IMAM programme.

Data collection took place in 7 health facilities offering IMAM services. The selected sites were high-caseload facilities and were chosen in order to be able to test the prototypes on a large number of children with SAM or moderate acute malnutrition (MAM). The selection of the health facilities was done by the CHMT, based on county health records. Data collection took place from the 26th of September 2016 to the 26th of January 2017.

During data collection the health facility staff described the study and presented the prototypes to mothers and caregivers during health sensitisation sessions, which took place early in the morning, before the start of clinic appointments. Thereafter, the data collection team discussed the study individually with mothers and caregivers of children aged 6-59 months (the standard age range for IMAM services) who were entering triage at the health facility. The data collection team provided mothers and caregivers with information on the study, what participation entailed, the risks and benefits of participation and how data confidentiality would be maintained. The mothers/caregivers who agreed to participate, and whose children met the inclusion criteria, were asked to provide consent. Consent was obtained by the data collection team in either written or verbal form and was recorded through signature or thumb prints on

individual consent forms. The consent forms that recorded consent through thumb prints were signed by a literate witness with no connection to the study team. The witness was often a community health volunteer (CHV) known to the mother/caregiver. Those not known to the CHV had their thumb prints witnessed by a literate mother who happened to be at the same health facility that day. Children enrolled in the study were mainly children starting or already receiving IMAM treatment services, children visiting the paediatric outpatient department, children attending the child welfare clinic or children whose mothers were involved in mother-to-mother support group meetings for infant and young child feeding at the health facility.

Once a child was enrolled, the data collection team collected identifying and demographic data and then demonstrated the use of the 3 "Click-MUAC" devices and the colour-banded MUAC insertion tape to the mother/caregiver. The mother/caregiver then classified her child's nutrition status with the 3 "Click-MUAC" devices and the colour-banded MUAC insertion tape. These 4 classifications were recorded by the data collection team. The recorded data was then obscured (by means of a folding data collection form) allowing for partial blinding of the results. The series of MUAC classifications was then repeated by the health facility staff. These 4 health facility staff classifications were also recorded by the data collection team and obscured by folding the data collection form a second time. Mothers/caregivers and health facility staff were also asked to identify their preferred device.

The data collection team then took 3 measurements of the child's MUAC with the colour-banded MUAC insertion tape at the measured mid-point of the left arm of each study subject. Classifications were made by comparing the arithmetic mean of the three measurements (i.e. the "gold standard" classification) against case-defining thresholds for global acute malnutrition (i.e. MUAC < 125 mm) and severe acute malnutrition (i.e. MUAC < 115 mm). Any child identified as SAM or MAM, who was not already enrolled in the IMAM programme, was referred for IMAM services.

A mid-term review of the data collection process in December 2016 highlighted that the SAM case numbers were lower than had been expected. To ensure that the SAM sample size (n = 115) was reached, data collection was expanded to an additional 14 facilities and community-based case-finding was strengthened.

Collected data were entered into a purpose-designed EpiData v3.1 database [18]. Data were checked for range and legal values during data-entry. Data were double-entered and validated with discrepancies resolved by reference to data collection forms.

Five measures (sensitivity, specificity, agreement, Fleiss' *Kappa*, and Youden's *J*) for the different measurer groups (i.e. study staff, clinic staff, and mothers/caregivers) with regard to MUAC classification were calculated from two-by-two contingency tables. Sensitivity was defined as the ability of a device to correctly detect patients with the condition (SAM or MAM), specificity was defined as the ability of a device to correctly detect patients without the condition (SAM or MAM) and agreement was defined as the proportion of cases where the classification was the same as that of the "gold standard". Fleiss' *Kappa* [19] and Younden's *J* [20] are both chance-corrected measures of agreement.

Data were analysed using purpose-written *R* language scripts managed using the *R-AnalyticFlow* scientific workflow system [21, 22]. Bootstrap methods were used to calculate 95% confidence intervals on summary statistics using r = 9999 replicates. Exact binomial confidence limits were calculated in two cases where 100% sensitivity was observed.

Results

Table 1 shows the description of the study sample. The total sample size for the study was 1040 children. The minimum sample (i.e. n = 115) was reached for each of three groups (i.e. MUAC ≥ 125 mm; 115 mm ≤ MUAC < 125 mm; and MUAC < 115 mm). The majority of children enrolled in the study came from the paediatric outpatient appointments (61.4%), followed by children attending the child welfare clinic or

those whose caregivers were participating in infant and young child feeding support (29.3%). The distribution of the "gold standard" measure (i.e. the mean of 3 measurements of the MUAC as taken by a research assistant) ranged from 86 mm to 190 mm, with a median of 137 mm.

Figure 3 shows the age and sex distribution of the study sample. The distribution of ages was similar for males and females (Chi-square = 6.0074, df = 4, p = 0.1986).

Table 2 shows that for SAM classification by mothers, compared to the "gold standard" measurement, all three "Click-MUAC" devices demonstrated good sensitivity (> 93%) and excellent specificity (> 98%). The chance-corrected measure of agreement (Younden's *J*) between mothers' classification for SAM with the "Click-MUAC" devices and the "gold standard" was also high (> 92%). Prototype 3 performed the best out of the 3 "Click-MUAC" devices with a sensitivity of 96.1% [95% CI 92.3%; 99.2%] compared to the "gold standard". However the device that produced the most sensitive classification (100.0% [95% CI 97.1%; 100.0%]) for mothers, with the highest level of agreement (98.9% [95% CI 98.3%; 99.5%]), was the MUAC insertion tape (device 4). The difference in agreement between prototype 3 and the MUAC insertion tape is statistically significant for Younden's *J*: 94.9% [95% CI 91.0%; 97.9%] versus 98.8% [95% CI 98.0%; 99.5%].

SAM classification by clinic staff using the three "Click-MUAC" devices, compared to the "gold standard", was good (sensitivity > 92%, specificity > 98%, Younden's *J* > 91%) however the MUAC insertion tape performed better with a sensitivity of 100.0% [95% CI 97.1%; 100.0%], a specificity of 99.2% [95% CI 98.7%; 99.8%] and a Younden's *J* of 99.2% [95% CI 98.7%; 99.8%].

Table 2 also shows that for GAM classification by mothers, prototype 3 demonstrated good sensitivity (90.7% [95% CI 87.4%; 93.7%]) and specificity (96.2% [95% CI 94.6%; 97.5%]). Younden's *J* for GAM classification by mothers with prototype 3 was 86.8% [95% CI 83.2%; 90.1%] compared to the "gold standard". However the sensitivity, specificity and agreement for GAM classification by mothers with the MUAC insertion tape was better: the sensitivity was 99.1% [95% CI 98.0%; 100.0%], the specificity was

96.5% [95% CI 95.0%; 97.7%] and Younden's *J* was 95.6% [95% CI 93.7%; 97.2%]. The difference in Younden's *J* for GAM classification by mothers using the prototype 3 compared with using the MUAC insertion tape is statistically significant: 86.8% [95% CI 83.2%; 90.1%] versus 95.6% [95% CI 93.7%; 97.2%] respectively.

The better performance of the MUAC insertion tape for GAM classification was also reflected in the results of the clinic staff. GAM classification by clinic staff using prototype 3 demonstrated good sensitivity (91.8% [95% CI 88.9%; 94.6%]) and specificity (97.2% [95% CI 95.8%; 98.3%]). Youden's *J* for GAM classification by clinic staff with prototype 3 was 89.0% [95% CI 85.6%; 92.0%]. However both sensitivity and agreement for GAM classification by clinic staff with the MUAC insertion tape was significantly better: the sensitivity was 98.0% [95% CI 96.4%; 99.4%] and Younden's *J* was 95.4% [95% CI 93.4%; 97.2%].

The study also sought to gather information on preference with regards to the devices used. **Table 3** demonstrates that a higher proportion of mothers (33.3%) preferred prototype 3 to the other devices. The majority of clinic staff (70.7%) preferred the MUAC insertion tape.

Discussion

The results of this study indicate that, although the "Click-MUAC" devices performed well, the improved MUAC insertion tape performed best for mothers and caregivers classifying the nutritional status of their own children. The results for sensitivity of SAM classification by mothers with the MUAC tape are higher than those previously reported in the Blackwell et al. study [14] which demonstrated that mothers had a sensitivity for the classification of their child's nutritional status of 73% and 90% respectively for SAM and GAM. It is possible that the high sensitivity reported in this study for both SAM and GAM classification by mothers with the MUAC insertion tape is due to the use of an improved MUAC tape design which has a number of modifications as compared to the conventional MUAC tape design, as illustrated in **Figure 2**. It is also possible that the method of demonstration of the use of the tape to the

mothers led to improved sensitivity. In the Blackwell et al. study [14] the use of the MUAC tape was demonstrated to the whole participating village. In this study however, mothers were provided with a one-on-one demonstration on the use of the MUAC insertion tape and the "Click-MUAC" devices by a member of the study team.

There are some limitations to the study which could have biased the results presented in this paper. The study was only partially blinded and there may have been potential demonstration bias. It may also have been the case that mothers got better at fitting the devices as they worked through them, which could have influenced the sensitivity of the final device (the MUAC tape). The study team reported that mothers were concerned about pinching their child's skin with prototypes 1 and 2.

Conclusion

The results of this study demonstrate that although the "Click-MUAC" devices performed well, a well-designed MUAC insertion tape remains the best means to support mother-led MUAC screening. The MUAC insertion tape is also less costly to produce and may therefore be better suited to supporting larger-scale mother-led MUAC screening initiatives.

The results of this study provide strong evidence to support the ability of mothers to perform sensitive and specific measurements of their child's MUAC. With an improved MUAC tape design and adequate minimal training, low MUAC children can be reliably identified by their mothers and caregivers. Given the potential for mother/caregiver MUAC screening to improve community case detection, early care-seeking behaviours and acute malnutrition treatment coverage, the approach should become central to efforts to scale-up acute malnutrition treatment globally.

List of abbreviations

AMREF: African Medical and Research Foundation; CHMT: County Health Management Team; CHV: Community Health Volunteer; CHW: Community Health Worker; CMAM: Community Management of Acute Malnutrition; ESRC: Ethics and Scientific Review Committee; GAM: Global Acute Malnutrition;

IMAM: Integrated Management of Acute Malnutrition; MAM: Moderate Acute Malnutrition; MUAC: Mid-Upper Arm Circumference; OTP: Out-patient Therapeutic Programme; SAM: Severe Acute Malnutrition; uniMUAC: Universal Mid-Upper Arm Circumference

Declarations

Ethics approval and consent to participate: The study protocol was granted ethical approval by the African Medical and Research Foundation (AMREF) Ethics and Scientific Review Committee, Kenya (ESRC number P249/2016). The study is registered at clinicaltrials.gov (Trial number: NCT02833740). Consent was obtained by the data collection team in either written or verbal form and was recorded through signature or thumb prints on individual consent forms.

Consent for publication: Not applicable.

Availability of data and material: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

Funding: The study was conducted with funding from the Humanitarian Innovation Fund (HIF).

Authors' contributions: AG, MM and AB designed the prototypes and study. The study was coordinated by AG and IA. The data collection was conducted by EO, JN, SM and AS and data was analysed by MM. The manuscript was drafted by AG. It was reviewed, edited and approved by MM, AB, IA, EO, JN, SM and AS.

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Advisory Committee and the Kenya National Nutrition Information Technical Working Group for their perspectives and support in the development of the protocol, implementation of the study and review of the results.

Tables

Table 1: Description of the study sample

Item	Group	Number	Percentage
Sample size	All children	1040	100.0%
Sex of child	Females	513	49.3%
	Males	527	50.7%
MUAC class*	MUAC ≥ 125 mm	698	67.1%
	115 mm ≤ MUAC < 125 mm	217	20.9%
	MUAC < 115 mm	125	12.0%
Source	OTP or SFP program	96	9.2%
	Paediatric outpatients	639	61.4%
	Other source	305	29.3%
Item	**Summary**	**Value**	**Units**
Age of child	Minimum	6	Months
	Lower quartile	11	
	Median	18	
	Upper quartile	29	
	Maximum	59	
	Mean (SD)	21.37 (13.0)	
MUAC**	Minimum	86	Mm
	Lower quartile	123	
	Median	137	
	Upper quartile	148	
	Maximum	190	
	Mean (SD)	136 (16.6)	

* Case-definitions applied to the mean of 3 measurements taken by a research assistant

** Mean of 3 measurements taken by a research assistant

Table 2: Results for "Click-MUAC" devices and uniMUAC tape used by mothers/caregivers and clinic staff compared to case-definition applied to the mean of 3 MUAC measurements taken by a research assistant

	Test	Device**	Sensitivity***	Specificity***	Agreement***	Kappa***	Youden's J***
SAM**	MSD*	1	93.7% (89.0%, 97.5%)	98.8% (98.0%, 99.5%)	98.2% (97.3%, 98.9%)	0.92 (0.87, 0.95)	92.5% (87.6%, 96.4%)
		2	93.8% (89.1%, 97.5%)	98.7% (97.9%, 99.4%)	98.1% (97.2%, 98.9%)	0.91 (0.87, 0.95)	92.4% (87.7%, 96.3%)
		3	96.1% (92.3%, 99.2%)	98.8% (98.0%, 99.5%)	98.5% (97.7%, 99.1%)	0.93 (0.89, 0.96)	94.9% (91.0%, 97.9%)
		4	100.0% (97.1%, 100.0%)	98.8% (98.0%, 99.5%)	98.9% (98.3%, 99.5%)	0.95 (0.92, 0.98)	98.8% (98.0%, 99.5%)
	CSD*	1	92.1% (86.9%, 96.4%)	99.1% (98.5%, 99.7%)	98.3% (97.4%, 99.0%)	0.92 (0.88, 0.95)	91.3% (86.0%, 95.6%)
		2	94.6% (90.1%, 98.2%)	98.9% (98.2%, 99.6%)	98.4% (97.5%, 99.1%)	0.92 (0.88, 0.96)	93.5% (89.0%, 97.0%)
		3	96.1% (92.1%, 99.2%)	99.0% (98.3%, 99.6%)	98.7% (97.9%, 99.3%)	0.94 (0.90, 0.97)	95.1% (91.1%, 98.1%)
		4	100.0% (97.1%, 100.0%)	99.2% (98.7%, 99.8%)	99.3% (98.9%, 99.8%)	0.97 (0.94, 0.99)	99.2% (98.7%, 99.8%)
GAM**	MSD*	3	90.7% (87.4%, 93.7%)	96.2% (94.6%, 97.5%)	94.3% (92.9%, 95.7%)	0.87 (0.84, 0.90)	86.8% (83.2%, 90.1%)
		4	99.1% (98.0%, 100.0%)	96.5% (95.0%, 97.7%)	97.3% (96.3%, 98.3%)	0.94 (0.92, 0.96)	95.6% (93.7%, 97.2%)
	CSD	3	91.8% (88.9%, 94.6%)	97.2% (95.8%, 98.3%)	95.4% (94.0%, 96.6%)	0.89 (0.86, 0.92)	89.0% (85.6%, 92.0%)
		4	98.0% (96.4%, 99.4%)	97.4% (96.2%, 98.5%)	97.6% (96.6%, 98.5%)	0.95 (0.92, 0.97)	95.4% (93.4%, 97.2%)

* MSD = Classification by mother/caregiver made using the specified "Click-MUAC" device or uniMUAC tape; CSD = Classification by IMAM clinical staff using the specified "Click-MUAC" device or uniMUAC tape

** Numbers 1, 2 and 3 refer to specific "Click-MUAC" devices. Device 4 is the uniMUAC tape.

*** Point estimates and associated 95% confidence intervals of summary measures are reported.

**** SAM is defined as MUAC < 115 mm; GAM is defined as MUAC < 125 mm. Devices 1 and 2 did not allow for GAM assessment.

Table 3: Device preferences for mothers and IMAM clinic staff

	Device			
	1	**2**	**3**	**MUAC tape**
Mothers	290 (27.9%)	156 (15.0%)	347 (33.3%)	247 (23.8%)
IMAM clinic staff	85 (07.9%)	58 (05.6%)	164 (15.8%)	735 (70.7%)

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