Author’s response to reviews

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

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Version: 1 Date: 23 Nov 2017

Author’s response to reviews:

“I believe the explanation in the differences in the sensitivity column are an issue and need a much better explanation. Why were 4-6% of the users of muac click bands not able to identify that the circumference of the arm of the child was under the 115mm? If designs 1, 2, or 3 were appropriately sized and they clicked shut -- this would be a binary test. How are they so far off. The idea that mothers were afraid to pinch their children's arms if anything would have pushed this metric in the opposite direction if I understand the study correctly.”

--> Sensitivity in this study is defined as the ability of a device to correctly detect patients with the condition (SAM or MAM). With a regular MUAC tape, if sensitivity is low, it will usually mean that there is under-tensioning of the MUAC tape (i.e. the tape has not been tensioned/tightened sufficiently to measure 115 mm). This is also applicable for the Click-MUAC devices, i.e. if not properly tightened to click shut/lock then the sensitivity of acute malnutrition classification will be reduced.

In this study, we posit (based on anecdotal evidence from the data collection team) that mothers were frightened of pinching the skin of their children, which would have had the same effect as
that of under-tensioning a regular MUAC tape. That is, it would reduce sensitivity. Pinching risk is present only in designs 1 and 2 and we see the sensitivity reduced most and to the same degree with these two devices (both at sensitivity = 93.8%). Sensitivity is less reduced with device 3. Given the nature of the design (similar to that of a tape) sensitivity would have been affected by under-tensioning the device. This may have been due to the thickness of the plastic which may have compromised the device’s flexibility and hindered the mother’s ability to tension it/tighten it properly. The tail of the tape in device 3 may also have been too short or too slippery for mothers to get a good grip.

We have inserted additional text in the manuscript reflecting the above points (lines 226-233).

“If it can be explained by ‘practice’ -- why wasn’t the order of the use changed/randomized? or the measurements repeated?”

--> We also speculate in this study that mothers may have gotten better at using the prototypes as they worked through them. However, when the study was conceived and designed, we did not think to randomize the order of the use, or have the mothers repeat the measurements. This is a limitation to the study.

If we were to repeat the study we would certainly look to include this as a consideration. For any future study we would randomise the order of the use of the prototypes.

We have inserted additional text in the manuscript reflecting the above points (lines 247-248).

“How were the prototypes manufactured? How many of each were there? What was the difference in their tolerances/repeatability? (e.g. was the reason for the discrepancy in the data because the prototype tolerances were wrong or because the users used them incorrectly?)”

----> Six specimens of each of the three Click-MUAC designs were produced, making a total of eighteen prototypes used in the study.

The eighteen prototypes were produced by a plastics manufacturing company using a plastic printing injection process (see new reference included in manuscript). The manufacturing company used a process of plastic injection into a resin mould to create functional prototypes made of polypropylene.
The tolerance and repeatability of the final prototypes were assessed and deemed by the manufacturer and the study team to be similar across the 18 specimens. Therefore the study team does not think that the differences in the sensitivity data are a result of differing prototype tolerances.

We have inserted additional text in the manuscript reflecting the above points (lines 72-80).

“In the description of figure 1 - 3d printing is mentioned - -if this is conventional FDM all of the 3 designs would not have printed properly (e.g. match the CAD) as shown because of overhangs and bridges unless support was printed as well. Were the actual bands used injection molded or milled? Please provide full details”

--> Brainstorming around product design was initially supported with 3D-printed prototypes. A number of different 3D-printed specimens were produced, discussed and appraised by the study team for usability and functionality. However 3D-printing was not pursued as a manufacturing process for the final study prototypes as the prototypes required a level of detail and design functionality that necessitated a more sophisticated production process.

We have inserted additional text in the manuscript reflecting the above points (lines 74-76).

“The lit review for this work also does not appear complete. There is considerably more articles discussing the efficacy of muac tapes than shown here. More importantly, click band literature does not appear. For example, why wasn't the first "click muac band" in google scholar used? https://doi.org/10.1017/S1368980017000726 and How did the 3 designs used here differ from that one in application?”

--> We have added references to the manuscript regarding the efficacy of MUAC for detection of acute malnutrition and its effectiveness as an anthropometric criterion for admission to acute malnutrition treatment. However the literature on the accuracy and sensitivity of the actual tapes is limited. In this regard we quote the MSF presentation comparing the accuracy and sensitivity of the UniMUAC tape, compared to the UNICEF tape.

We have included the reference to the University of Michigan 3D-printed Click-MUAC prototypes. The University of Michigan supported initial brainstorming on potential Click-MUAC designs. It then separately pursued one of the designs with 3D printing.

In this study, 3D printing was not retained as a manufacturing process as the prototypes required a more sophisticated production process. The main design elements that were modified in device 1 (compared to the University of Michigan design) were: an increase in the width of the bracelet
(to avoid compression of tissues), larger tabs to support an easier grip on the prototype and a latching “button” to avoid slippage and act as a validation (“click”) to the classification.

We have inserted additional text in the manuscript reflecting the above points (lines 26-28; lines 59-61; lines 72-74).

“What was the standard deviation in the gold standard 3 measurement mean?”

--> Within-subject differences between the three MUAC measurements used to create the "gold standard" classification were investigated by comparing all possible pairs of within subject-measurements (n = 3120 measurements). We found that 3075 (98.6%) differences were less than or equal to 2 mm. The maximum difference found was 4 mm present in 3 (0.01%) of measurements. The mean difference was close to zero (mean = 0.0032, SD = 1.0227).

We have inserted additional text in the manuscript reflecting the above points (lines 181-186).

“Are the scripts in ref 21-22 available/accessible? No hyperlinks?”

--> R: https://cran.r-project.org

R AnalyticFlow: http://r.analyticflow.com

The scripts are the same for both R and R Analytic Flow. They are available in the attached file, along with a copy of the data.

“Lastly on Table 3-- it appears that the vast majority of the mothers preferred some form of click muac band while the clinical staff preferred tapes. Please discuss why there is a difference? Ability to quantify vs yes-no? experience with old way? or is something else going on?”

--> The study did not collect further qualitative data to investigate why the mothers and clinical staff preferred certain devices. This is a limitation.

We can hypothesize that the mothers preferred prototype 3 as it had the possibility to screen for both SAM and MAM but was sturdier and simpler to use than the uniMUAC tape. We can also hypothesize that the clinical staff preferred the uniMUAC tape because it closely resembles the UNICEF MUAC tape that they are currently using. The clinical staff may have also preferred the uniMUAC tape because it enabled them to quantify the degree of malnutrition, rather than have just a binary classification.

We have inserted additional text in the manuscript reflecting the above points (lines 249-254).