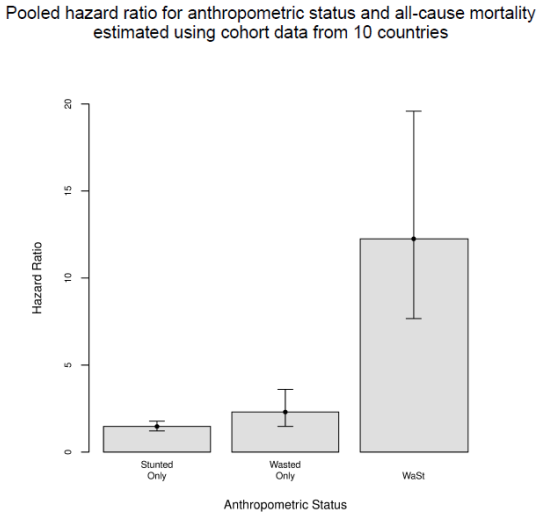
A small cohort study to bring new evidence on undernutrition and mortality risk into practice. Briefing Note

The Emergency Nutrition Network (ENN) and partners, with funding from USAID/OFDA and the Global Health Bureau, are embarking on a research project to incorporate new evidence relating to the relationship between wasting and stunting and their combined impact on mortality into existing programme practices. This briefing note provides information about why this research is important, what the approach will be, and how you can stay engaged with the project as it progresses.

Why this is important

The ENN co-ordinated Wasting and Stunting Technical Interest Group (WaSt TIG[i]) have been investigating the relationship between wasting and stunting since 2014 examining whether the current separation between these manifestations of undernutrition within research, programmes, policy, and funding is justified[ii]. Recently published analyses by the group (illustrated below) have highlighted the very high risk of death in children who are simultaneously (concurrently) wasted and stunted (WaSt). The level of mortality risk is about as high as that of a child with severe acute malnutrition who would normally be in a CMAM programme, and is considerably higher than children suffering from moderate acute malnutrition and other levels of wasting or stunting. Analysis of a large amount of secondary data indicates that weight-for-age (WFA) z score (WAZ) < -3 and MUAC <115mm, when used independently, identify all children who are at risk of near-term mortality including those who are simultaneously wasted and stunted or who are severely wasted (by either MUAC or WHZ). Although WFA has been eclipsed in recent years by separate measures of wasting and stunting, it has remained in use in many child health and growth monitoring and promotion systems. There is, therefore, an opportunity to test how children with a high risk of mortality identified by WFA may be usefully re-integrated into programme approaches (e.g. CMAM) for child survival and development. This study aims to test whether WFA and MUAC can be effectively (and cost-effectively) utilised in existing programmes to reach considerably more children at a high risk of death.



Based on results presented in McDonald CM et al. (2013)

The questions we are asking and what we will do

This phase of the project aims to answer the following question:

1. What intensity, duration of treatment, and discharge criteria are appropriate for children identified using WAZ < -3 and MUAC < 115mm?

Presently, any child with MUAC < 115 mm is treated with a therapeutic protocol that is internationally accepted and is of known efficacy for this group of children. We have some uncertainty about the required treatment intensity and safe discharge criteria for the group of children that are above this MUAC cut-off but have a WAZ < -3. **This study will provide data that will help to clarify treatment requirements and appropriate discharge criteria for children with WAZ <-3 and MUAC ≥ 115mm.** To answer

[i] A broad group of international experts working in research and programming for wasted and stunted children,

[ii] Child wasting and stunting: Time to overcome the separation A Briefing Note for policy makers and programme implementers. Emergency Nutrition Network 2018. See: https://www.ennonline.net/attachments/2912/WaSt-policy-brief.pdf

this question we will recruit three hundred and fifteen children aged between 6 and 59 months of age that fall into the MUAC ≥ 115 mm & WAZ < -3 case-definition. Eligible children will be identified at EPI, MCH, GM / GMP, OTP consultations or paediatric outpatient's clinics and will be referred to a small number of study participating CMAM (OTP) clinics for treatment.

Recruited children will be randomized to one of two cohorts that vary in intensity of treatment and frequency of contact. They will be followed up from admission through discharge from treatment and at home for 6 months following discharge. Treatment protocols will follow those outlined in the relevant national protocol for the treatment of SAM in all aspects except the RUTF dose (see Table 1). This includes the administration of a broad spectrum antibiotic at admission[iii].

The dosage of RUTF provided in each cohort is informed by work completed by the ComPAS project that aims to simplify and unify the treatment of uncomplicated severe and moderate acute malnutrition (SAM/MAM) for children aged 6-59 months into one protocol[iv].

Table 1: Treatment protocol in 2 study cohorts

Cohort	Protocol
High intensity	Higher dose RUTF ration with weekly contact including: • 2 sachets (1000 kcal) of RUTF per day • At admission: Vitamin A Amoxicillin Antimalarial Measles immunisation* • At 2nd visit: Deworming
Low intensity	Lower dose RUTF ration with fortnightly contact including: • 1 sachet (500 kcal) of RUTF per day • At admission: Vitamin A Amoxicillin Antimalarial Measles immunisation* • At 2nd visit: Deworming
*Immunisation status will be checked at admission and updated if necessary	

Participation is dependent on the mother / caregiver and the household head for each child being willing to give voluntary informed consent. All cases identified as SAM during case-finding, including any children excluded from the study, will be referred to the nearest CMAM delivery site to receive appropriate treatment. A study report will present

- Recovery, death, default, transfer and non-recovery rates in each cohort.
- Relapse and death during post-discharge follow-up in each cohort.
- The duration of treatment for children in each cohort by outcome (the focus will be on recovered cases).
- Cohort and individual level weight change and MUAC change from admission to end of post-discharge follow-up for each outcome in each cohort (the focus will be on recovered cases).
- Growth curve analysis for recovered cases to examine response to treatment in each cohort.
- Cause of death for children in each cohort that die during treatment or post-discharge follow-up.

Next steps: This study will inform a bigger operational study that will provide information on practicability, coverage, caseloads, effectiveness, and cost effectiveness of treating children with a WAZ <-3. It will pay particular attention to the addition of WFA in CMAM programme settings. At each stage of the study and for each output, the results will be shared and discussed widely with national and international stakeholders.

How we will do it: A partnership between USAID-OFDA/Global Health Bureau, ENN and Implementing Partners (IPs) in the relevant country will work in close liaison with national and local ministries of health. An ENN study team will design, oversee and support the research study, working closely with high level experts from the WaSt TIG on elements of design and analysis. Country level IPs will conduct the operational research and support close liaison between the full study team and all relevant in-country bodies/stakeholders to ensure all elements are appropriate to the context and national priorities. Necessary registration and permissions for the study will be sought both in the UK/USA and in country.

Contact for more information: For periodic progress updates on this project (and other related ENN activities), please contact the study co-ordinator Kate Sadler on kate@ennonline.net or visit the ENN website**.**

[iii] Our work has shown that children with a MUAC ≥ 115mm and a WAZ < -3 have a mortality risk that demands a therapeutic protocol. There exists no good evidence that we do not need to give antibiotics to this group of children.

[iv] Bailey J, Chase R, Kerac M, Briend A, Manary M, Opondo C, et al. (2016) Combined protocol for SAM/MAM treatment: The ComPAS study. *Field Exchange* No. 53