

# EFFECTIVENESS, COST-EFFECTIVENESS AND COVERAGE OF SEVERE ACUTE MALNUTRITION TREATMENT DELIVERED BY COMMUNITY HEALTH WORKERS IN EMERGENCY CONTEXTS OF MALI AND SENEGAL

#### **Study protocol**

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#### **ACRONYMS**

AAH Action against Hunger

CHWs Community Health Workers

CMAM Community Management of Acute Malnutrition

cRCT Cluster Randomized Control Trial

**EPINUT** Epidemiology of Nutrition Research Group of the Complutense

University of Madrid

HCs Health Centers

iCCM Integrated Community Case Management approach

iCCM+Nut iCCM approach including severe acute malnutrition treatment

INRSP Institut National de Recherche en Santé Publique

LARTES Laboratoire de Recherche sur les Transformations Economiques et

Sociales- Institut Fondamental d'Afrique Noire Cheikh Anta Diop

MAM Moderate Acute Malnutrition

MoH Ministry of Health

MUAC Mid Upper Arm Circumference

RUTF Ready-to-Use Therapeutic Food

SAM Severe Acute Malnutrition

SLEAC Simplified Lot Quality Assurance Sampling Evaluation of Access

and Coverage

SMART Standardized Monitoring and Assessment of relief and Transition

UNICEF United Nations Children's Fund

WHO World Health Organization

WHZ Weight-for-Height Z score

#### 1 INTRODUCTION

#### 1.1 RATIONALE

According to the latest estimates, 16.6 million children under-five worldwide suffer from severe acute malnutrition (SAM), making it a major public health concern<sup>1</sup>. Over the past two decades there have been significant shifts in the way the world addresses SAM, changing from inpatient to outpatient treatment due to the development of Ready-to-Use Therapeutic Food (RUTF) and the Community Management of Acute Malnutrition (CMAM) protocol. However, a study in 21 low-and-middle income countries showed that CMAM programmes reach less than 40% coverage due to critical barriers such as carers' awareness of children's conditions, awareness of programme existence and high opportunity costs mainly due to distance from health centers (HC)<sup>2,3</sup>.

These challenges are not unique to SAM and public health services have sought ways of making key child survival interventions more integrated and more accessible. The integrated Community Case Management (iCCM) approach was introduced to improve uptake of services in areas where access to facility-based health services is poor. It is based on the training of non-medical Community Health Workers (CHWs) to provide selected curative services for high mortality infectious diseases<sup>4</sup>. Given the influence of nutritional status on the recovery<sup>5</sup>, this protocol also includes the identification and referral of SAM children. Thus iCCM has been described as logical platform and missed opportunity for increasing the coverage of uncomplicated SAM treatment and for preventing malnutrition<sup>6</sup>.

Current international and national organisations recommend treating SAM and moderate acute malnutrition (MAM) in separate programmes, with different protocols and products (also managed by separate United Nations Agencies: RUTF managed by UNICEF and Ready-to-Use-Supplementary-Food or fortified corn/soy blend by the World Food Programme). This leads to a more expensive set-up of programmes which often results in a prioritization of SAM over MAM<sup>7</sup>.

Evidence on the effectiveness of CHWs treating SAM has been summarized in a recent review published by our team<sup>8</sup>. It included nine operational experiences in non-emergency contexts. Most reach 90% cure rates with default and death rates below 7% and 1.5% respectively. These results are even better than those from facility-based programmes<sup>9</sup>, having the potential for early detection and thereby preventing complications. Coverage assessments were conducted in three studies, reaching 80% and cost-effectiveness was demonstrated in the two programmes which assessed it (compared with inpatient and CMAM). However, no evidence has been found on CHWs treating SAM in emergency settings.

Current evidence on the integration of SAM and MAM into the same protocol is scarce. There is one example in Angola achieving 93.8% recovery<sup>10</sup>. In addition, another study at health facility-level in post-conflict Sierra Leone shows that integrating care for SAM and MAM allows reaching a 71% treatment coverage and

83% recovery for GAM (versus 55% and 79% respectively in the standard care applying two different protocols)<sup>11</sup>. SAM children receiving integrated management recovered faster, resulting in lower spend on RUTF (\$36 vs. \$68) whilst the cost for MAM was equal (\$12). Authors recommended this model as an alternative in humanitarian crises where time is essential since it reduces logistics complexity and is easy to deliver based on MUAC-only criteria. Another similar study ('ComPAS') is currently being implemented in South Sudan and Kenya but results are not yet available<sup>7</sup>.

The study aims to provide the first evidence on iCCM+Nut in emergency contexts by comparing the effectiveness and cost-effectiveness of two different decentralized models of care for uncomplicated SAM children. As indicated by previous studies, this could lead to a significant improvement in coverage and cost saving in the proposed crisis region where access to health services is a major issue. Results would contribute to strengthening the health systems in the country, and potentially the entire subregion in dealing with SAM care during protracted nutritional crisis as well as acute ones. This project also responds directly to various research gaps identified in ELRHA's systematic review on health interventions in humanitarian crises<sup>12</sup>: "most effective way of delivering nutritional programmes: health facilities vs. CHWs", "Cost-effectiveness of nutrition interventions", "Effectiveness of different models of delivering (vertical vs. integrated)" and "Coverage and early detection related to SAM treatment".

In addition, the proposed research is also based on Action against Hunger (AAH) previous experience. In 2014, in partnership with the Ministry of Health (MoH), the *Institute National de Recherche et Santé Publique (INRSP)* of Mali, and the Innocent Foundation, AAH launched a study to explore whether CHWs could successfully treat SAM in the southern region (non-crisis area). The evidence showed that CHWs are able to reach high quality of care<sup>13</sup> achieving better outcomes than CMAM (cured: 94.2% vs. 88.2%; defaulted: 4.5% vs. 10.8%), increasing the coverage by two-fold (baseline: 43.9%, endline: 86.7%)<sup>14</sup> and demonstrating this is a cost-effective intervention with lower costs incurred by beneficiaries<sup>15</sup>. Further similar studies are ongoing in Mauritania, Niger and Kenya. A second phase of Mali's study started in 2017 to determine the most efficient method of scaling up treatment with CHWs by comparing three different models of training and supervision<sup>16</sup>.

#### 1.2 STUDY CONTEXT

#### For Mali:

Northern Mali is classified as a "forgotten crisis" 17, and ranked as "High Risk" in the INFORM index for Risk Management 2019 (16th out of 191 countries). This is characterised by a deterioration of the security situation, difficult access to basic social services and exposure to climatic hazards. The Gao district population is 333,692 habitants (2018 National Statistics Institute of Mali). The Integrated Food

Security Phase Classification (IPC) in March 2018, estimated 15% of the population would be entering a food insecurity phase (Phase 2) and 8% would be entering a crisis phase (Phase 3). In 2019, this is expected to deteriorate. Prevalence rate of acute malnutrition is the highest in the country: 3.1% [1.9-4.8] for SAM and 14.2% [11.6-17.3] for Global Acute Malnutrition (GAM). These rates exceed the WHO emergency threshold for SAM (2%).

Zone intervention: District sanitaire de Gao

The study will be ipmented at 12 health areas at Gao District as listed below (Bagnadji, Boulgoundie, Magnadoue, Gadeye, Wabaria, Forgho, Tacharane, Château, Sossokoira, Zinda, Lobou, Bagoundje). Twlve iCCM site will be setted up at these areas.

For Senegal:

In Senegal, 152,798 people are currently in food insecurity crisis phase (stage 3) and it is estimated that this number will increase to 342,262 people during the next lean season (June-August 2019) - around 3% of the population<sup>18</sup>. GAM and SAM prevalence rates are 8.2% and 2.1% respectively<sup>19</sup>. The regions of Louga and Matam, and the department of Podo in the Saint-Louis region are new WHO's 10% GAM threshold<sup>20</sup>, and Matam region has among the highest SAM rate in the country: 3.1% (1.9-5.0). Matam remains vulnerable to nutritional crises. Estimated number of children suffering from SAM in 2019 is 57,817 cases in 2019, while the SAM target is 45,438. 7,090 new SAM admissions (out of which 7% in IPF) were recorded between January and April 2019 (15.6% of annual target). Poor rainfalls and protracted food crisis (170,000 people in crisis in the Matam region in 2018) make Matam a region vulnerable to recurrent nutritional crisis.

The study will take place in the four health districts of the region: the districts of Matam, Thilogne, Kanel and Ranérou. According to the sampling strategy (see below), the study will work with 12 URENs and include 12 CHWs that are already trained in regular iCCM activities (case management of malaria, IRAs and diarrhoea, health promotion and prevention, and referrals of cases with complications).

#### 2 CONCEPTUAL FRAMEWORK

#### 2.1 RESEARCH QUESTION

Can the CHWs obtain equal or higher SAM cure rates and increase treatment coverage by using a combined/simplified protocol compared to using the current CMAM protocol in emergency context of Mali/Senegal.

#### 2.2 OBJECTIVES

#### 2.2.1 GENERAL OBJECTIVE

To assess the effectiveness, cost-effectiveness, and coverage of adding SAM treatment delivered by CHWs into the iCCM protocol in an emergency setting of Mali/Senegal.

#### 2.2.2 SPECIFIC OBJECTIVES

- ✓ To determine if CHWs can treat SAM children and respect the SPHERE standards in an emergency setting;
- ✓ To assess whether coverage increases by including SAM treatment within iCCM package delivered by CHWs in an emergency setting;
- ✓ To assess whether CHWs can effectively use a combined/simplified protocol to treat SAM children in an emergency setting;
- ✓ To analyze cost and cost-effectiveness of three different models of SAM treatment.
- ✓ To analyze the impact of integrating SAM management in iCCM on CHW workload (just for Senegal)

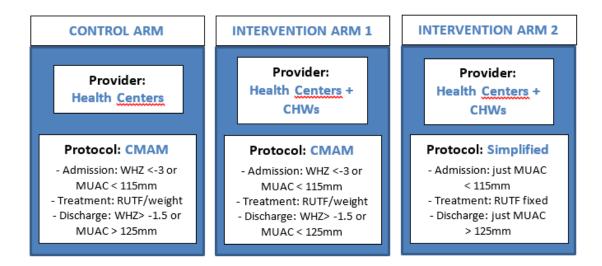
#### 3 METHODOLOGY

#### 3.1 GENERAL APPROACH

Study will take place from July 2019 to July 2022 with a recruitment and follow-up expected period from November 2019 to January 2021 but depending on Ethical Committees approval date.

It has been designed a cluster Randomized Control Trial (cRCT) with a non-inferiority design to compare three different protocols for SAM treatment (different diagnosis plus different RUTF dosage) as show in figure 1. A RCT design was chosen because it is considered the 'gold standard' methodology to evaluate healthcare interventions. A cluster approach is applied due to the impossibility of randomization at individual level. Although blinding is not possible for treatment providers, they will not have access to overall outcomes and children's caregiver attending health facilities are very unlikely to know in advance whether they will be receiving treatment based on standard or combined/simplified protocols.

Figure 1. Study design based on three different models of treatment of uncomplicated SAM children 6 to 59 months.



#### 3.2 EFFECTIVENESS ASSESSMENT

#### 3.2.1 SAMPLE SIZE AND CLUSTERING

The sample size was calculated for a binary outcome (recover/not recover) assuming 5% non-inferiority margin, 80% power, 95% sensitivity, a recovery rate of 75% in the control group (as required by SPHERE standards), a recovery rate of 85% in the intervention group (as assumed in the similar ComPAS study<sup>7</sup> described in the introduction section).

The number of clusters required has been calculated according to Hayes and Bennett formula<sup>21</sup> assuming a 0.05 intra cluster correlation coefficient (same as in the ComPAS study). Including 10% loss to follow-up, this resulted in a sample size of 576 SAM children per arm requiring 6 clusters each (96 children per cluster). Therefore, total sample will consist of 1,728 children by country.

Each cluster will correspond to one treatment provider (HC or its group of CHWs) which means that there will be 6 groups of providers by arm. However, in order to avoid final real imbalance in clusters size, the unit of randomization will be the health center with an allocation ratio of 2:1:1. Using this approach, there will be 6 HC allocated to control arm (=6 providers) and 3 HC allocated to each intervention arm with their 3 groups of CHWs (=6 providers). This allocation ratio is based on the figures from our previous studies in Mali were each CHW treated more children on average than each HC during a 12-month period. If all arms involved the same number of HC, the intervention arms would recruit many more children than the control (children from 6 HC plus those of their CHWs).

#### 3.2.2 CHILDREN'S ENROLLMENT

The sample will consist of children aged 6-59 months with uncomplicated SAM. In all arms children with severe edema, failing appetite test or having other severe medical complications will be excluded (they will be referred for inpatient treatment). In the arms with CMAM protocol inclusion, criteria will be: bilateral pitting edema (+/++) and/or weight-for-height below -3 Zscore of the World Health Organization Growth Reference and/or MUAC<115mm. In the intervention arm 2, the combined/simplified protocol considers just bilateral pitting edema (+/++) and/or MUAC as only anthropometric admission criteria.

SAM children enrolled in treatment with the CMAM protocol will receive RUTF doses according to their weight (200Kcal/kg/day) whilst those in the combined/simplified protocol will receive a fixed quantity (two sachets RUTF=1000Kcal/day). MAM treatment will be assured in all arms consisting of 500Kcal/day (CMAM: 1 sachet RUSF; Combined/Simplified: 1 sachet RUTF) although MAM children will not be included in analysis. The prevalence of MAM usually triples that of SAM and including MAM data would imply a huge increase in sample size and the need of hiring more supervisors to collect disaggregated data and to keep data quality. This economical overrun couldn't be assumed by the project's budget.

In all arms, discharge criteria will be: absence of edema and reaching the anthropometric cut-off point and maintaining these criteria for two consecutive visits. In CMAM protocol, this depends on the reason for admission (weight-for-height  $\geq$  - 1.5 Zscore or MUAC  $\geq$ 125 mm) and in the combined/simplified protocol it is only MUAC  $\geq$ 125 mm.

#### 3.2.3 DATA COLLECTION AND ANALYSIS

The comparability of the three arms is assumed due to randomization process but even so, it is intended that carers of the children enrolled will complete a short socio-economic survey at admission containing questions related to characteristics of household, livelihoods, hygiene practices and health services utilization according to the Demographic and Health Surveys Program methodology<sup>22</sup>, as well as a Household Dietary Diversity Score<sup>23</sup>. Those socio-economic variables will enable us to describe the sample and they will be used as possible confounders for the adjustment of regressions and risks analysis and to explore which of that has more impact on children's recovery in each arm.

To achieve our objectives, we will consider two main independent variables:

- Treatment provider (HC vs. HC+CHWs)
- Protocol applied in the case of CHWs areas (CMAM vs. Combined/Simplified).

The dependent variables to compare within SAM children (enrolled with MUAC<115mm in the three arms) will be the rates of: recovery (discharge as cured), default (children absent from treatment two consecutive follow-up visits), unresponsiveness (children not improving their nutritional status in two consecutive visits), transfer to inpatient treatment due to health complications and death.

Other variables to be compared will be severity at admission (MUAC measurement and presence of edema), prevalence of non-severe complications at admission and during treatment, treatment length and average daily weight and MUAC gain. Other routine information will be recorded monthly such as referral records and stock supplies.

Disaggregated data on the study subjects will firstly be recorded on paper (patient cards) by HC staff and CHWs according to the specific requirements of the MoH. The data will then be periodically reported by the supervisors via tablet using KOBO software which allows control of transcription errors improving data quality.

#### 3.3 COVERAGE ASSESSMENT

Potential coverage increases in the intervention arms compared to the control arm (second objective) will be analysed by conducting baseline and endline assessments using the 'Simplified lot quality assurance sampling evaluation of access and coverage' (SLEAC) methodology. This had been specifically designed for community-based management of SAM and it combines routine programme monitoring data and small-sample quantitative survey. It also provides some information related to barriers of access<sup>24</sup>.

The intervention seeks to improve following Sphere indicators as:

- Percentage of target population that can access on-site programmers within one hour (it should be >90%). As 60% of people in Mali are living more than 5km from the HF, achieving this will be only possible if we work directly with CHWs
- Percentage of SAM cases with access to treatment services (it should be >50% rural areas). The actual coverage is under 30%.

#### 3.4 COST-EFFECTIVENESS ANALYSIS

For the cost-effectiveness analysis (fourth objective), it will be carried out from a societal perspective. An activity-based costing method will be applied by collecting data from accounting records and information from structured interviews with key stakeholders. Costs linked to research only will be excluded. Cost will reflect only treatment of non-complicated SAM cases. We will present costs for different cost centres per arm, calculate cost-efficiency and incremental cost-effectiveness ratio for children cured (comparing children in the intervention arms 2 and 3 vs. control arm with standard

CMAM protocol rather than a do nothing attitude) and DALYs. A sensitivity analysis will be conducted. The team has previous experience performing this type of analysis in non-emergency settings in Mali<sup>15</sup>.

# 3.5 IMPACT ON WORKLOAD ASSESSMENT (JUST IN SENEGAL)

One aim of this study is to understand how the addition of SAM to the CHW's workload affects the time allocation to other preventive or curative tasks. Toward this end, a time use assessment will be conducted among CHWs working in the intervention and control areas. Specifically, this analysis will provide information on differential time allocation between groups of workers on shared tasks (including management of cases of malaria, diarrhea and pneumonia), and average time to manage a SAM case for CHW in the intervention area.

Prior research suggests that self-administered time diaries are a method producing estimates of health worker's contact time with patients, which are similarly robust as the gold-standard time motion studies<sup>25</sup>. Time diaries will be distributed to CHWs to fill out on purposively-selected work days. Diaries will be administered using a "left-behind" approach wherein respondents are given a diary to carry with them for the day, recording time spent on work activities as or just after they occur<sup>26</sup>. A self-administered method will enable a larger sample of time observations than the use of recall interviews or surveyor observations. Every effort will be made to assure CHW of the confidentiality of their responses, so that the likelihood of their reporting ideal instead of actual time use is minimized.

The time diaries will contain open-intervals so that CHWs can fill in up to 2 activities completed at a time, and can enter in details about the activities. Coding of time activities will be done ex-post, with a standardized list of main CHWs activities developed in collaboration with a few CHWs and their supervisors. This list will have a cap of 30 main activities (including options for administrative paperwork, cleanup and non-productive time) to facilitate ex-post data coding. The study will be carried out during the peak period.

#### 3.6 RISKS OF IMPLEMENTATION

The cases enrolled in the study are not representative of the total population of the region, as only SAM cases treated by CHWs and HCs will be included in the study to evaluate the effectiveness of each model of SAM treatment.

Within the scope of the implementation of this research, we anticipate the following risks:

In Mali:

- The deterioration of the security situation in the intervention zone: AAH in partnership with AAG and the MoH will constantly monitor the status of the security situation and negotiate access if the need arises.
- Reduction of admissions in SAM cases at the CHW sites and in the supported healthcare centres: A Memorandum of Understanding (MoU) will be signed with the Health-Nutrition Partner in the intervention zone (Home-based Malaria Treatment - HMT) in order to maintain the continuity of community screening by community volunteers.
- Shortage of stock inputs: The project will put in place a buffer stock to ensure a continuous supply in case of stock shortages.
- Mobility of caring staff: The CHWs and HCDs who leave their positions will be replaced by the Health District in collaboration with the community authorities and will receive training aimed at quick deployment.

#### In Senegal:

- Shortage of RUTF inputs: the project is planning to reinforce the National Health Scheme, including the supply chain. A buffer stock of medical-nutritional products will be available.
- Political tensions due to the next presidential elections in 2019 and strike actions by the Health staff. Regular monitoring of the current political and social situation of the country will be carried out to prepare the teams in the field in the event of political tension and guarantee their security.

#### 4 STUDY PLANNING AND MANAGEMENT

#### 4.1 RESEARCH PARTNERSHIP

Underpinned by a collaborative partnership model, this project will be delivered by a strong consortium consisting of:

- <u>Humanitarian organisation and consortium lead</u>: AAH is a global humanitarian organisation and for almost 40 years has been at the forefront of the fight against hunger. Operating in nearly 50 countries, last year we reached over 20 million people through our humanitarian and development programmes.
- <u>Academic research partner</u>: EPINUT research group of the Complutense University in Madrid. EPINUT are regularly assessed by Spain's National Office for Research in the Ministry of Science, Innovation and Universities and recently went through a 3-year validation process.

#### - National research institute:

In Mali: INRSP is the National Research and Public Health Institute. Established in 1992, it is composed of highly qualified researchers and conducts public health research for MoH.

In Senegal: 2 research institutes from the Université Cheikh Anta Diop:

LARTES is the Research Laboratory for Social and Economic Transformation and is part of the *Institute Fondamental de l'Afrique Noire* (IFAN).

IPS is the Institute for Social Paediatrics.

In addition, the research will be supported by a <u>collaborating implementation partner</u>:

In Mali: Association d'Aide pour Gao (AAG) is a key partner of AAH in many research as well as operational projects.

In Senegal: Cellule de Lutte contre la Malnutrition (CLM) responsible for malnutrition care in the community in Senegal with strong ties to AAH.

#### 4.2 MANAGEMENT FRAMEWORKS

In both countries there is already a technical committee to follow up differences studies related to combined/simplified approach. These committees are under the lead of UNICEF together with the Ministries of Health. It has been created in several countries in West Africa. Other NGO working in management of acute malnutrition are part of them, as The Alliance for International Medical Action (ALIMA) or International Rescue Committee (IRC).

The study will be carried out with the supervision of a Steering Committee, composed of technical experts from the research consortium that is expected that will meet quarterly in order to plan and to ensure the good running of the study. An independent Scientific Advisor Committee composed of external members will bring relevant, independent, scientific expertise on a punctual basis and on specific topics, and advise on the way forward.

#### 4.3 ETHICAL CONSIDERATIONS

The study protocol will be submitted for review to the Spanish Ethical Committee assigned to the Complutense University of Madrid ("Comité de Ética Clínica Hospital Clínico San Carlos"), the Ethical Committees of academic institutions of both countries (Mali and Sengeal) and

The following principles will be adopted:

- Upon approval of the protocol, ACF in Mali/Senegal will inform the local and regional health authorities and the community representatives. The objective and procedures of the study will be explained to the caregiver. All the applicants will have the right to refuse participation in the study. Each CHW will be asked to read the voluntary and informed consent declaration in its entirety, slowly and in the local language of the participant. The CHW will then ask if the consent declaration was understood, and if there are any questions.
- √ The CHW will ask the caregiver if she or he agrees to participate in the study. At that
  moment, the opportunity to refuse participation in the study will be given to the
  applicant. The CHW will explain that it is possible to withdraw participation at any
  point in the study, without any repercussions on the patient or her/his family.
  Voluntary and informed consent for children will be given by the parents or legal
  guardian. A voluntary and informed consent form will be signed (or fingerprinted) by
  the principal caretaker, and, if present, the head of household. Those who refuse to
  participate will benefit from the same treatment as the other children, but their data
  will not be included in the study.
- Emergencies: Every participant in the study, whether in a control and intervention arms, will benefit from medical care in the event of medical complications linked to a change in their nutritional status during the study. The program will bear medical expenses related to these interventions. Acute malnutrition treatment is nevertheless available for free in every healthcare centre.
- Declaration of conflicting interests: Research team's sole interest is to contribute to an improvement in SAM treatment coverage and thus to an improvement in access to healthcare for remote communities with no treatment facilities, as well as to improve equity in iCCM care.
- Anonymity: precautions will be taken to ensure the anonymity of participants when collecting, managing and analysing data, and when disseminating the results. The forms containing data will be anonymized. SAM children will be identified by their SAM unique number. The data will be accessible to database managers, project managers, co-investigators and statisticians. All will be bound by terms of confidentiality.

#### 5 RESEARCH IMPACT

#### 5.1 EXPECTED RESULTS

This intervention it is expected to contribute to an improvement in access to care during humanitarian crises and a reduction in the number of children dropping out of acute malnutrition management programs. The advantages of this approach are the early diagnosis and care of malnourished children, which could lead to a reduction in the development of medical complications and impact on the health costs for households.

More cost-effective interventions will also allow health authorities to develop strategies for reaching a higher number of malnourished children during crises.

By improving CHW's capacities, and integrating SAM management into the iCCM package, the intervention also aims to have a positive impact on the management of other illnesses with a high mortality rate (diarrhoea, malaria and pneumonia).

The results generated by this research could provide key evidence for the full scale-up of this approach at country-level and in the Sahel region, improving SAM treatment coverage and contributing to a reduction in child mortality, particularly during humanitarian crises.

The specific results expected from the research are:

- 1) Effectiveness of a new intervention model with CHWs
- Evidence on the performance of the SAM care delivered by CHWs: Non-inferiority of the cure rate of children receiving care from the CHWs (greater or equal to the care provided by staff at HC).
- Evidence on the performance of the SAM care delivered using the simplified/combined protocol: Non-inferiority of the cure rate of children receiving care with this protocol.
- Evidence of an increase in the coverage of SAM treatment, in the health areas where treatment is available at HC level and CHW sites.
- 2) Contribution to the continuity of care
- Improvement of the continuum of care for SAM children across all levels of the health pyramid, starting from the Hospital Referral Health Centre (for SAM children with complications), to the HC (for SAM children without complications
   CMAM Approach), through to community-level care delivered by CHWs (for SAM children without complications - iCCM approach).
- 3) Cost-effectiveness of the intervention
- Cost-effectiveness analysis of the different models of SAM treatment: with the hypothesis of sharing the costs already in place for the iCCM intervention, but with an increase in the provision of services including SAM in the Community Primary Healthcare services package.
- Evidence on the reduction of costs for household and of treatment duration. We are seeking to remove barriers (such as geographical access and economic obstacles) to the provision of care in a humanitarian crisis context.

#### **5.2 UPTAKE PLAN**

A detailed research uptake plan and stakeholder mapping will be developed at the

start of the project at a country level a regional level

#### Uptake at country/regional level

Change expected: Modify and adapt Primary Health Care policies at country level, to include SAM treatment into the task assigned to the CHWs.

Stakeholders: MoH and CLM, WHO, UNICEF, WFP, Scaling Up Nutrition (SUN), Economic Community of West African States (ECOWAS) at the regional level, Dakar University, NGOs

- Nutrition and health clusters: To contribute to the improvement of humanitarian actions, AAH will share findings at cluster level. This will facilitate the MoH authorities, in charge of changing policies, monitoring the project and updating the treatment of SAM for humanitarian context.
- Technical Committees: The progress of the project will be presented by INRSP and LARTES's focal points, and the committees will report directly to National MoHs. Monitoring of objectives will facilitate the ownership of the research.
- Local partners: direct influence over the activities of local NGOs is expected. They are key to responding to humanitarian crises when access is not possible for others (e.g. international NGOs).

Indicators: Cluster presentation, once every three months, Technical committees, twice per year, meetings with AAG partner, once a month.

#### Internal uptake within AAH

Change: AAH positioning document and replication of the research in other West-African countries.

Stakeholders: AAH Technical Directors, Health-Nutrition Technical Advisors, Country Directors and in-country technical and operational staff.

 Findings from the research will be disseminated to internal stakeholders to influence the design of future programmes across AAH through: international meetings, annual technical nutrition and health workshop with representatives from all AAH country teams; <u>AAH's Knowledge Hub</u> (open-access website collating knowledge products)

Indicators: Meeting with Technical Directors and Country Directors twice a year, International AAH nutrition-health workshop, once a year, Knowledge hub, sharing the preliminary results, once a year.

#### Uptake at global level

Change: Contribute towards growing body of evidence on use of CHWs in order to ultimately provide an effective model for national scale-up.

#### Stakeholders:

- Child Health Task Force group: AAH is part of the nutrition subgroup and iCCM institutionalisation subgroup
- No Wasted Lives platform: International initiative with the objective of coordinating and supporting NGOs and governments in the fight against malnutrition. It will publish findings of the research and include SAM treatment by CHWs in their advocacy agenda.
- R4NUT: Annual international conference led by AAH, which aims to disseminate research findings to International NGOs, donors, and MoHs.
- Core group conference. From the second year onwards, share preliminary results.
- ENNs Nutrition Exchange: Free-access publication that collates malnutrition or large-scale impact illness studies. Sharing preliminary results
- Peer review articles: During the third year.

Indicators: Meeting with the child health task force group, every three months, NWL, R4NUT, core group conference and ENNs, once a year. Peer review, two at the end of year three.

#### **6 TIME FRAME**

Key milestone, achievement or result (maximum 10 rows)	Activity(ies)	Completion date
1. Protocol Development	The following activities will initially be financed by OFDA and ECHO funds:  Appoint partners, write protocol and Ethics Committee	October 2019
	- Appoint partners, write protocol and Ethics Committee validation	
	- Set up Technical Committees and Steering Committees	
	- Presentations to the authorities, regional workshops to start study	
	- Coverage assessment	
	- Training of Healthcare Centre Directors (HCD), Unarmed Civilian Peacekeeping force (UCP, or ICP, Comité Francáis por l'Intervention Civile de Paix) and substitute HCDs) and work placement post-training of CHWs.	
2.Admission of RCT	- Care of children and admission of RCT children	September 2019
children	- Monitoring research activities	
	- Meetings with Health District (HD) and INRSP in Mali, LARTES in Senegal as well as Technical and Steering Committee meetings.	

3. Endline	<ul> <li>Data Collection</li> <li>Survey on the quality of the care received by CHWs</li> <li>Final coverage survey</li> <li>Retrospective cost-effective analysis</li> </ul>	December 2020
4. Data Analysis	<ul> <li>Processing and analysis of data</li> <li>Final assessment report and preparation of recommendations</li> </ul>	May 2021
5. Presentation of results (National and Regional)	- Workshops with consortium partners at country and regional level - Publication of the report and "lessons learnt" paper	August 2021
6. Participation in regional and international conferences	- Presentation of main results, communication and dissemination of the results	January 2022
7. Peer review submissions	- Drafting of articles - Submission and validation	September 2022

#### **REFERENCES**

<sup>1</sup> UNICEF, WHO & WBG. (2019). Levels and trends in child malnutrition. Key findings of the 2019 edition. Available at: https://www.who.int/nutgrowthdb/estimates2018/en/

<sup>&</sup>lt;sup>2</sup> Rogers et al. (2015). Coverage of Community-Based Management of Severe Acute Malnutrition Programmes in Twenty-One Countries, 2012-2013. PLoS ONE, 10 (6): e0128666.

<sup>&</sup>lt;sup>3</sup> Puett & Guerrero (2015). Barriers to access for severe acute malnutrition treatment services in Pakistan and Ethiopia: a comparative qualitative analysis. Public Health Nutrition, 18 (10), 1873-1882.

<sup>&</sup>lt;sup>4</sup> Young et al. (2012). World Health Organization/United Nations Children's Fund Joint Statement on Integrated Community Case Management: An Equity-Focused Strategy to Improve Access to Essential Treatment Services for Children. American Journal of Tropical Medicine and Hygiene, 87 (suppl 5), 6-10.

<sup>&</sup>lt;sup>5</sup> Ibrahim et al. (2017). Impact of childhood malnutrition on host defense and infection. Clinical Microbiology Reviews, 30 (4), 919-971.

<sup>&</sup>lt;sup>6</sup> Friedman & Wolfheim. (2014). Linking nutrition & (integrated) Community Case Management. A review of operational experiences. Available at: <a href="https://www.ennonline.net/linkingnutritionintegratedcommunitycasemanagementareviewofoperationalexperiences">https://www.ennonline.net/linkingnutritionintegratedcommunitycasemanagementareviewofoperationalexperiences</a>

<sup>7</sup> Bailey et al. (2018). Combined protocol for acute malnutrition study (ComPAS) in rural South Soudan and urban Kenya: study protocol for a randomized controlled trial. BMC Trials, 19: 251

- <sup>8</sup> López-Ejeda et al. (2018). Can Community Health Workers manage uncomplicated severe acute malnutrition? A review of operational experiences in delivering SAM treatment through community health platforms. Maternal and Child Nutrition, in press. DOI: 180.1111/mcn.12719
- <sup>9</sup> Save the Children (2015). Review of current Community Management of Acute Malnutrition (CMAM) practice and outcomes in 12 countries using the Minimum Reporting Package. Available at: <a href="https://www.elrha.org/wp-content/uploads/2015/01/Appendix-1-MRP-analysis-report-2015-Final.pdf">https://www.elrha.org/wp-content/uploads/2015/01/Appendix-1-MRP-analysis-report-2015-Final.pdf</a>
- <sup>10</sup> Morgan et al. (2015). Community case management approach to SAM treatment in Angola. Field Exchange, 49, 3. Available at: <a href="http://www.ennonline.net/fex/49/angola">http://www.ennonline.net/fex/49/angola</a>
- <sup>11</sup> Maust et al. (2015). Severe and moderate acute malnutrition can be successfully managed with an integrated protocol in Sierra Leona. The Journal of Nutrition, 145 (11): 2604-9.
- <sup>12</sup> Blanchet et al. (2015). An evidence review of research on health interventions in humanitarian crises. ELRHA and The Harvard School of Public health and the Overseas Development Institute. Available at: http://www.elrha.org/r2hc/research/humanitarian-health-evidence-review/
- <sup>13</sup> Álvarez-Morán et al. (2018a). Quality of care for treatment of uncomplicated severe acute malnutrition delivered by community health workers in a rural area of Mali. Maternal and Child Nutrition, 18, e12449.
- <sup>14</sup> Álvarez-Morán et al. (2018b). The effectiveness of treatment for Severe Acute Malnutrition (SAM) delivered by Community Health Workers compared to a traditional facility based model. BMC Health Services Research, 18 (1), 207.
- <sup>15</sup> Rogers et al. (2018). Cost-effectiveness of the treatment of uncomplicated severe acute malnutrition by community health workers compared to treatment provided at an outpatient facility in rural Mali. Human resources for Health, 16, 12.
- <sup>16</sup> Charle (2018). Comparison of the three models of training and supervision with community health workers providing treatment of children with severe acute malnutrition in Mali. Available at: <a href="http://www.isrctn.com/ISRCTN14990746">http://www.isrctn.com/ISRCTN14990746</a>
- <sup>17</sup> CARE International (2018). Suffering in silence. The 10 most under-reported humanitarian crises of 2017. Available at: <a href="https://www.care-international.org/suffering-in-silence/">https://www.care-international.org/suffering-in-silence/</a>
- <sup>18</sup> Conseil National de Sécurité Alimentaire (2019) .Analyse nationale du Cadre Harmonisé Résultats préliminaires. Mars 2019
- <sup>19</sup> Ministère de la Santé et de l'Action Sociale, Republique du Senegal (2019). Enquête nutritionnelle nationale utilisant la méthodologie SMART. Rapport Avril 2019.

<sup>20</sup> De Onis et al. (2019). Prevalence thresholds for wasting, overweight and stunting in children under 5 years. Public Health Nutr. 22 (1): 175–179.

- <sup>22</sup> ICF (2018). Demographic and Health Surveys Standard Recode Manual for DHS VII. The Demographic and Health Surveys Program. Available at: <a href="https://dhsprogram.com/pubs/pdf/DHSG4/Recode7">https://dhsprogram.com/pubs/pdf/DHSG4/Recode7</a> DHS 10Sep2018 DHSG4.pdf
- <sup>23</sup> FAO (2012). Guidelines for measuring household and individual dietary diversity. Available at: <a href="http://www.fao.org/docrep/014/i1983e/i1983e00.htm">http://www.fao.org/docrep/014/i1983e/i1983e00.htm</a>
- <sup>24</sup> Myatt M et al. (2012). Semi-Quantitative Evaluation of Access and Coverage (SQUEAC)/ Simplified Lot Quality Assurance Sampling Evaluation of Access and Coverage (SLEAC) Technical Reference. USAID Food and Nutrition Technical Assistance (FANTA III). Available at: <a href="http://www.coverage-monitoring.org/wp-content/uploads/2013/01/SQUEAC-SLEAC-Technical-Reference-Oct2012.pdf">http://www.coverage-monitoring.org/wp-content/uploads/2013/01/SQUEAC-SLEAC-Technical-Reference-Oct2012.pdf</a>
- <sup>25</sup> Bratt, J. H et al. (1999). A comparison of four approaches for measuring clinician time use. Health policy and planning, 14(4), 374-381.
- <sup>26</sup> Harvey, A.S. and M.E. Taylor (2000). Time use, in *Designing Household Survey Questionnaires for Developing Countries: Lessons from Fifteen Years of LSMS Experience*, M. Grosh and P. Glewwe, Editors. World Bank: Washington, D.C

<sup>&</sup>lt;sup>21</sup> Hayes, R.J. & Bennett, S. (1999). Simple sample size calculation for cluster-randomized trials. International Journal of Epidemiology, 28: 319-326.