Community Management at-risk Mothers & Infants aged under 6 months (cMAMI)









Executive Summary

The challenge

Over the last 15 years, Community Management of Acute Malnutrition (CMAM) has revolutionized care for malnourished children aged 6-59 months. Rather than treatment in all too scarce, distant, difficult to access hospital settings as before, they are now treated as outpatients in easy to access local clinics. This enables programmes to: enroll many more children; to enroll them early (since access to outpatient care is much easier). Thus CMAM save lives: many children previously would never even have gotten treatment.

Since their needs are more complex, malnourished infants aged under 6 months (infants u6m) have been left behind. Equivalent community packages of care are not currently available and treatment capacity is limited. Their needs are rarely met. Sometimes, malnutrition in infants u6m is not even recognized as a problem. Yet globally, some 8.5 million are acutely malnourished.

Since 2008, determined advocacy by an international collaboration, the MAMI (Management of At-risk Mothers & Infants) Special Interest Group has helped catalyse progress for infants u6m. For the first time there was a chapter on infants in WHO 2013 guidelines on severe malnutrition. Despite some promising programmes run by NGOs (Non Governmental Organizations) this guidance has sadly not filtered through to front-line policy and practice in countries where infants u6m malnutrition is common. The major reason for this is a lack of evidence that programmes for infants u6m work and concerns about potential costs and scalability.

Proposed Innovation

Our vision is that:

"Every infant u6m, at every healthcare / community-level contact point is nutritionally assessed and appropriately supported to survive and thrive".

Towards that vision, we propose a project to test a 'Community Management of at-risk Mothers & Infants' (cMAMI) package of care. This includes two components.

First, the MAMI Care Pathway. This is an integrated care pathway which healthcare workers can use to identify at-risk mothers and infants. It offers a guide to identification and management and is thus particularly valuable to non-experts, enabling them to better care for affected infants. It was first developed as the C-MAMI tool in a multi-agency collaboration to meet the immediate needs of front-line practitioners who previously had been struggling to manage infant malnutrition. The C-MAMI Tool was piloted at small scale in Ethiopia and Bangladesh and was updated in 2018. It is now being updated as a MAMI Care Pathway will be piloted in early 2021 to make it even more user-friendly and ensure it fits with and complements other parts of the healthcare system. Thus to be as effective as possible.

Second, we will examine the use of simpler and more effective ways of identifying at-risk infants. Current guidelines recommend weight-for-length measures: these are difficult to conduct, are often done poorly if at all and do not even identify the most vulnerable infants. We will thus explore alternative measures: weight-for-age and MUAC (mid-upper arm circumference). MUAC especially is far easier and quicker to measure and could enable far more children to be identified and treated at an early stage, before they become very malnourished and thus ill and at-risk of dying from underlying malnutrition.

There is also potential for *community-based support* (e.g. in women's groups and other support groups) to complement health care worker-delivered cMAMI care. Thus to improve outcomes for small and sick infants u6m. Through interviews and feedback from both policy makers and local communities will explore what community activities might work and how they might fit within wider health / social care systems. If logistics allow, we will directly examine the additional value of such groups over and above healthcare worker-delivered cMAMI alone.

Reflecting the above, our study questions are:

- 1) Does outpatient-care using a 'cMAMI package of care 'work' to improve the growth and health of at-risk infants <6m?
- 2) Does support via cMAMI also improve the mental health & wellbeing of mothers/carers?
- 3) Are MUAC and weight-for-age good ways of identifying high-risk infants u6m
- 4) What is the added value of community support over & above healthcare worker cMAMI? We will also assess the cost and economic implications of our innovations.

Proposed methodology

The research will take place 2019-2023. We will first conduct baseline surveys: these will give us key data to fine tune and optimize our main study. This will be a cluster randomized controlled trial (cRCT). In a cRCT, clusters (in our case health centres) rather than individual patients are randomly allocated to one of two possible study groups.

We will recruit patients across two sites in Ethiopia: Jimma Zone (a stable area overseen by Jimma University) and Deder Woreda (a more vulnerable area overseen by GOAL).

All infants aged 0 to <6 months will be eligible for enrolment into the study.

Health centres will be randomly allocated to either:

- **Intervention sites** where trained nurses use the **cMAMI tool** to help them identify and mange infants u6m
- **Control sites** where **usual care** is offered (this involves assessment by weight-for-length alone and referral to inpatient care if needed)

Our main (primary) outcome will be assessed at age 6 months. We will look for improved weight-forage and MUAC in infants in the intervention groups. There will be a further assessment at age 12months to see if there are any sustained benefits. Secondary outcomes include breastfeeding status, and episodes of severe illness. Possible benefits to mothers will also be explored: improved mental health and improved wellbeing / perceptions of social support.

In Jimma, a total of 28 health centres will be split between the two groups: 14 cMAMI vs 14 controls. In Deder it will be 4 vs 4 (8 total). We will aim to recruit 75 infants per health centre. Details will be confirmed following initial formative work but these numbers should be sufficient for a high quality, scientifically robust study which has adequate statistical 'power' to answer our study questions. Ethical approval will be secured at institutional and national levels in accordance with standards set by Jimma University and LSHTM.

Coordination

We are a collaboration of four partners: The London School of Hygiene and Tropical Medicine (LSHTM) (UK); Jimma University (Ethiopia); GOAL (Ethiopia) and ENN (UK).

All partners all have a strong track record of high quality research and public health practice. LSHTM as lead agency will be overall responsible and oversee the programme and coordinate partner inputs. Activities will be coordinated using in-person team meetings and field visits to project areas (including regular visits by UK-based team to Ethiopia), conference calls and online project management resources.

As well as our core project team we will also draw on the expertise of our wide networks of contacts and collaborators to enhance the research by engaging with key stakeholders and advisors: ranging from technical specialists at WHO and the Ethiopian Federal Ministry of Health to local communities and community leaders.

Monitoring, Evaluation & Dissemination

The ultimate goal of our cMAMI project is to effect national (Ethiopian) and international policy guidance change to ensure access to community based care for at risk infants and their mothers. Central to this is generating high quality evidence on an intervention that is feasible, effective, scalable and sustainable. Our project thus invests heavily in a formative period to secure a shared vision with international, national and sub-national stakeholders and to establish the most robust research protocol possible. We will ensure that our project design resonates with and reflects national and sub-national needs and that our research is aligned with key global processes at WHO. We will work in close collaboration with an in-country Technical Advisory Group, and with international stakeholders including WHO, other UN agencies and international NGOs.

Monitoring, evaluation, dissemination and learning are integral to this research. In addition to research related M&E processes and generated data, a dedicated work package will monitor and evaluate the research process itself. Experiences and lessons learnt will be documented. Outcome, output and impact indicators are detailed in an M&E framework; methods and systems to capture monitoring information will be established in the formative phase. To ensure quality outputs, a data manager will

be located at LSHTM. In Year 1 a communication plan and implementation learning plan, in consultation with country teams and overseen by ENN. Ultimate impact on national and international policy change will be appraised by ENN. Our objective to generate a totality of quality evidence will overseen by the LSHTM and Jimma University academic teams.

Scalability & Sustainability

Scale up of the cMAMI intervention is a prime consideration in this Phase 1 research. Our intial formative work will develop a shared vision and set the tone for strong, multi-stakeholder collaboration. This cocreation and co-ownership is key to future success. Our vision for scale is integration of cMAMI within existing health facility and community services. This is why we are testing cMAMI within existing government systems, in close collaboration with government, in two different locations to explore effect in different contexts.

We will commit to systematic ongoing monitoring, evaluation and learning throughout; examine cost and cost effectiveness; publish our results in high impact peer review journals with Ethiopian lead authors; critically appraise the package of evidence generated through a government lens. We will maximise on existing strong engagement by Jimma University and GOAL in national networks, and policy guidance development.

Conclusions

There is currently strong national and international appetite to secure solutions for infant u6m malnutrition. What is lacking is high quality evidence: through our project we propose to fill some of those critical data gaps. Our proposed research is long overdue and is optimally positioned for impact. In the nutrition field, Ethiopia is widely known for being a country which pioneered the now global CMAM 'revolution' for older malnourished children. Through this work we hope that in future it will be similarly well known for having pioneered the 'cMAMI revolution'.

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