LESSONS FROM RESEARCH UNDER THE INTERMINISTRIAL SAM ALLIANCE

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Venue: India International Centre (Multipurpose Hall)

A multi stake holder consultation was held to disseminate findings of studies comparing dietary options for home treatment of uncomplicated SAM and appropriate cut-off for MUAC to identify children 6mo-5yrs age with severe acute malnutrition for purpose of home /community based rehabilitation.

The participants including representatives of relevant ministries of the central government, representatives of several state governments, researchers, technical and development experts. The research was conducted under oversight of an Interministerial Steering Committee supported by a technical advisory group, constituted by Ministry of Health, Department of Biotechnology of Ministry of Science and Department of Health Research. A detail meeting report is under preparation. In this executive summary are provided key lessons from research and the guiding principles for future that emerged from these, the state experiences and commitment. It will require further work by the Ministry of Health and its relevant partners in government, to shape these into specific recommendations taking into account practicalities of program implementation. A list of participants is provided as Annex I.

Study 1

This was a multicentre, individually randomized, controlled trial to compare three dietary regimens, namely augmented home prepared food (AHPF), commercially procured ready to use therapeutic food (RUTF-C) and locally prepared ready to use therapeutic food (RUTF-L). In a post-hoc analysis, study also provided insights into value of peer supporters in enhancing recovery, and benefits of a maximum treatment duration of 16 weeks rather than 8 week as originally planned. The composition of diets used and co-interventions are given as Annex II.

Key lessons from Study 1

Key findings of this multi-center trial: The recovery rates overall was 43% in AHPF, 48% in RUTF-C and 57% in RUTF-L. The difference between RUTF-L and AHPF in recovery rate was 13% (P=0.002). Viewed in another way, a third more children recovered with RUTF-L compared to AHPF. The time to recovery was significantly shorter in RUTF-L and RUTF-C compared to AHF group.

The peer supported subgroups in general had higher recovery rate in all feeding groups; the absolute difference was 7% in AHF, 17% in RUTF-C and 13% in RUTF –L. As these are sub group data, interpretation should be cautious.

Peer supporters were neighboring mothers with healthy children who visited homes several times a day to motivate, support and assist the mothers. Peer supporter engagement with incentives seem to enhance rate of recovery.

The daily weight gain per kg initial body weight was 2.6 (AHF), 3.1 (RUTF-C) and 3.5 (RUTF-L).
It was seen that non-recovered children also gain from the intervention but less so than the recovered children. Median weight gain in children who recovered was 1100g (SD 360) as against 600g (SD) in children who did not recover. Given similar energy content of RUTF-c and RUTF-L, the possible reason for somewhat better performance of RUTF-L may be related to its high acceptability due to presentation, taste or texture.

Factors associated with non-recovery as against recovery among those receiving either type of RUTF were daily energy intake, inter-current morbidity (diarrhea, pneumonia or fever) and rate of weight gain.
Accordingly peer support to mothers to achieve high energy intake, and measures to prevent and treat inter-current morbidity are critical to recovery.
Daily weight gain of ≤ 10g per day over initial 2 weeks of treatment predicted treatment failure with sensitivity of 92% and specificity of 95%. This subgroup requires quick monitoring and support to enhance recovery rates.

Study 2

Study 2 assessed MUAC at different cutoff and the balance of sensitivity and specificity in detecting children 6 mo-5 yrs of age with SAM as identified by weight for height criteria of ≤-3SD.
The WHO recommends to use WFH ≤ –3SD or MUAC < 11.5cms as the criteria for identifying children with SAM for purposes of rehabilitation.

Key lessons from study II

The key findings from the study are, use of MUAC <11.5cms only identifies about a third of the children in a community out of those who have WFH ≤ –3SD. In other words, use of MUAC with this cut-off would miss out a large proportion of children with WFH ≤ –3SD. The study examined multiple cut-offs for MUAC and its findings suggest that a cut-off of 13.4cms would identify around 80% of all target children with WFH ≤ –3SD. It also raises the concern of low specificity meaning that for every 1 child identified as SAM by this MUAC cut-off, an additional 8 to 9 children would be identified who do not have WFH ≤ –3SD.
The investigators have been requested to analyze whether the false positives are children only with MAM or a mix with MAM and normal weight for height Z scores.

The cut-offs between 11.5cms and 13.4cms as expected progressively increased sensitivity and decreased specificity. It was suggested that a group be constituted to assess the data further and provide final recommendation.

Consensus Guidelines Emerging From Research

1. **Identification of children for purposes of treatment in a community**
   It was felt that both WFH and MUAC criteria could be considered while designing programs and when both measurements are available then WFH ≤ –3SD or MUAC <11.5cms could be used to select children for home treatment, if there are no complications
   In programs where screening is done at the anganwadi centres, the recent decision to make infantometer or stadiometer available, should make measurements of weight, height and MUAC, all possible.
   For children selected on the basis of MUAC ≤11.5 cms, recovery should be defined as MUAC ≥12.5 cms. The length of treatment to achieve recovery is uncertain and was not assessed in the trial.

2. **Dietary Regimens**
   Research evidence under SAM Alliance has excellent quality and it is possibly the largest trial of treatment of SAM children in the world. This multicentre trial suggests that RUTF gives higher recovery rates than augmented home prepared food under study conditions where full support and monitoring are available. About 30% more children recovered in RUTF-L than AHF fed children. RUTF should be one of the options available for state programs where SAM is an important problem. Locally produced RUTF appears to be somewhat more efficacious than commercial RUTF.

3. In general engaging peer supporters as mothers from neighborhood who have healthy children when given suitable incentives and through multiple home visits in a day, clearly contribute to enhancement of recovery rates in all feeding regimens and also enhance the mother's motivation and capability. The benefit would depend on careful selection of the peer supporters and supervision by AWWs and our ANMs. Wherever routine use of peer supporters is not considered feasible, it may be possible to sub-select a group at high risk of non-recovery by tracking weight gain within the first week or 2 weeks. Appropriate criteria can be suggested if desired.

4. The duration of treatment of SAM children should be until recovery or a minimum of 16 weeks, whichever is earlier. SAM in India is predominantly marasmic and experience in the Indian

multicentre trial as well as earlier studies in Africa show that longer duration of treatment is required for marasmic children. It was emphasized that guidelines derived from Africa cannot be implemented in this country

5. **Program design issues**

   There was consensus that program for treatment of SAM should be embedded in comprehensive nutrition program. These would include, better delivered current interventions of maternal nutrition and care, timely initiation of breast feeding, exclusive breast feeding, nutritionally adequate complementary feeding, infection prevention measures such as hand washing and sanitation and as important, earliest detection, effective treatment and referral of sick children, special support to children with MAM to prevent them from becoming SAM and effective implementation of current government supplementation program for anemia and vitamin A.

6. **Product Registration Process**

   A simplified process of registration of RUTF by FSSAI on the basis of a rapid assessment by an accredited MOH established technical resource center or group is desirable for commercial RUTF. For RUTF prepared locally standard guidelines and manuals and technical support for local production would be critical to rapid scale up.

7. A variation in the prevalence of SAM was noted in the study sites ranging from 0.5% in Vellore, 1.5% in Delhi and 5% in Udaipur. Prioritizing states and districts with high SAM burden would be an efficient strategy.

8. Several measures were considered important for scale up of program but the most important are to establish technical resource group for assisting state governments in program designing and early implementation and for facilitating local production of RUTF whenever this approach is adopted. In choosing source of RUTF, the modest differences between RUTF formulations must be balanced with availability, access and feasibility.

9. **Sustaining remission after initial treatment**

   Sustaining the acceleration in growth achieved through home treatment is more likely where SAM treatment is embedded within well functioning community nutrition programs. In addition, an algorithm for home treatment should include components of how to link the concerned child with the ICDS program and follow up by ASHAs and Anaganwadi workers, to see that participation in the routine feeding support is both high in coverage and equitable. It is noted that a proportion of SAM children may relapse to MAM and the linkage as above to retain in nutrition program is

important. In a similar manner children discharged prematurely from NRCs should be recruited into the home based treatment once free from complications through efficient linking mechanisms

10. As the adverse consequences of SAM are the highest for youngest children, focusing on children less than 3 years of age will be more cost effective.

11. Finally, treatment of SAM requires integrated intervention and monitoring and mobilization of additional help for those responding less well and treatment and referral for inter-current illnesses on a prioritized enabled way, akin to what is recommended for neonates. The obsessive focus on the type of diet used often dilutes attention from the critical aspect of caring. Home treatment of SAM children should be mother and family centric and not food centric.

    Within the overall framework, stigmatization of short term use of energy rich formulations for home treatment of SAM is also not justified by the study results.

    Nearly half of the mothers of SAM children in this trial had BMI ≤18.5. Here is an opportunity to support mothers as well.

    Early monitoring of state and district programs should ensure a documented recovery rate of atleast 50% for the implementation approach and efficiency to be considered acceptable

    A technical group may be constituted by MOH to quickly draft out an algorithm characterized by clinical and decision making excellence and practicality. This can be adopted by state governments.