BRIEFING PAPER

ACF positioning and answers to major criticism on RUTF

Questions and Answers- December 2014

Objective of the document

- Equip ACF staff with answers to major criticism on RUTF based on the latest research and recommendations of the international nutrition and health community
- Assist missions with their advocacy efforts in countries where RUTF use is being questioned

SUMMARY

Major criticism on RUTF

A number of criticisms on RUTF have been raised in different countries, including that:

- Using RUTF creates dependency on a product
- Efforts should be diverted from treatment to prevention
- RUTF undermines breastfeeding

Answers on major criticism

ACF is highlighting the importance of treating the life threatening condition of uncomplicated severe acute malnutrition in children with a ready to use therapeutic food (RUTF) in light of the general lack of evidence of the efficacy of other proposed home-based methods today.

RUTF has never been promoted by ACF for **any other use than the nutritional recovery, at home, of uncomplicated cases of severe acute malnutrition.** ACF doesn't support RUTF as a stand-alone solution. Solving the issue of undernutrition is a much wider goal, which would in fact require a number of curative strategies while developing an ambitious **multisectorial preventive strategy** tackling the underlying causes of undernutrition.

Like any medicine required to treat a medical condition, RUTF is only needed until the child is cured from severe acute malnutrition. Locally produced RUTF that meets WHO specifications already exist in different countries indicating the opportunity for local production to also be undertaken in other countries.

As a treatment for SAM, ACF does not consider that the use of RUTF undermines breastfeeding. No RUTF should be given to infants below 6 months. For children aged 6-24 months, breastfeeding is actively encouraged before the child is offered RUTF. ACF fully supports and agrees that exclusive breastfeeding for infants less than 6 months of age is essential for optimum child health. ACF actively promotes this best practice, as well as advocating for sustained breastfeeding for children aged 6-24 months and beyond.

ACF position

Overall ACF considers that, given its proven results in saving children's lives, the benefits of using RUTF for the treatment of severe acute malnutrition substantially outweighs some remaining concerns.

TOP 10 CRITICISMS ON RUTF

1. **RUTF is not a "magic bullet"** that can solve the issue of undernutrition
2. The **commercially produced RUTF is an unaffordable option for many countries** and for most people who live in poverty
3. Some resources are directed to procure RUTF when they could possibly be used to improve access to food and help prevent undernutrition for poor and vulnerable people
4. **The use of RUTF entails a risk of a high dependence on foreign companies**
5. **The use of commercialized RUTF entails the risk of commercializing the fight against acu**te malnutrition
6. **RUTF is an unnecessary product** as home cooked food when fed in adequate amounts can cure severe acute malnutrition
7. **RUTF is not a sustainable solution**
8. **RUTF shouldn't be used for the prevention of malnutrition.**
9. The promotion of **RUTF may undermine breastfeeding**: both exclusive breastfeeding, up to 6 months of age, and sustained breastfeeding, for children of 6-24+ months of age
10. RUTF contains no water and **may cause dehydration**. Extra water intake will be essential and is not without risk

ANSWERS TO TOP 10 CRITICISMS ON RUTF

1. RUTF IS NOT A "MAGIC BULLET" THAT CAN SOLVE THE ISSUE OF UNDERNUTRITION.

✓ **RIGHT.**

Like all the international organizations dealing with Health and Nutrition (UNICEF, WFP, WHO) we do agree with this.

First, it should be noted that **RUTF has not been promoted by ACF for any other use than the nutritional recovery, at home, of uncomplicated cases of severe acute malnutrition (SAM)** between 6 months and 5 years of age, following in recommendations from the relevant United Nations agencies[1].Solving the issue of undernutrition is a much wider goal, which would in fact require a combination of curative

DEFINITIONS

1. **Malnutrition** = undernutrition + overnutrition
2. **Undernutrition** = wasting (acute malnutrition), stunting (chronic malnutrition) and underweight
3. **Wasting = moderate acute malnutrition and severe acute malnutrition**

[1] Joint statement by World Health Organization/World Food Programme/United Nations System Standing Committee on Nutrition/The United Nations Children's Fund, Community-based Management of Severe Acute Malnutrition, 2007.

strategies (for complicated SAM cases, moderate acute malnutrition cases, chronic malnutrition cases, and micronutrient deficiencies) while developing an ambitious **multisectorial** preventive strategy tackling the underlying causes of undernutrition, in order to significantly reduce the appearance of new cases.

Second, regarding the management of uncomplicated SAM cases itself, **ACF doesn't support RUTF as a stand-alone solution** but supports widespread uptake of the community based management of acute malnutrition (CMAM) approach by health facilities and communities through government management, and the local production of RUTF to meet the demand. This health system based approach will also ensure that associated diseases are tackled.

ACF recognizes that there are multiple factors that contribute towards recovery of patients from SAM. Whilst therapeutic products, including Ready to Use Therapeutic Foods (RUTF), have been a proven key element of success, hence promoted by international stakeholders dealing with global health and nutrition, it is important to note at the outset that CMAM comprises many components and is absolutely **not restricted to the supply of a product**, requiring a very comprehensive follow-up system, including**:**

- A medical protocol is used to tackle underlying infections and to respond to new or worsening symptoms appropriately.
- Within outpatient care, weekly follow-up is essential, with criteria of how to respond to patients who are not recovering properly. Inpatient care requires continuous observations by qualified medical personnel.
- Continual emphasis is placed on the role of appropriate infant and young child feeding (IYCF) within sustainable recovery.
- A number of ACF missions have found it helpful to introduce focus groups, individual counseling and home follow-up of non-responders and defaulters as ways of improving recovery rates and reducing the proportion of defaulters.

2. THE COMMERCIALLY PRODUCED RUTF IS AN UNAFFORDABLE OPTION FOR MANY COUNTRIES AND FOR MOST PEOPLE WHO LIVE IN POVERTY.

✓ RIGHT BUT TO BE MITIGATED: RUTF IS EXPENSIVE BUT COST-EFFECTIVE. FURTHERMORE THE COSTS CAN BE REDUCED.

Although the price of RUTF could seem expensive compared to a wide range of food commodities, it has been recommended by UN agencies[2] dealing with Global Health and Nutrition as well as by the scientific community[3] for its effectiveness as well as for its cost-effectiveness in curing children from SAM, a deadly condition. It should therefore be compared with the wide range of expensive medical products whose procurement and use is required to save lives.

Indeed, one should remember that much more than a simple food commodity, RUTF is a type of nutritional support which is **a key component of a medical treatment**, whose efficacy has been demonstrated in a wide range of settings. For ACF, the use of any available RUTF is essential, as long as no sound (scientifically proven and operationally effective) alternatives are available.

- According to the only three publications on the subject as of today , the cost per child cured within a CMAM program ranges from $180 and $250, on which 30 to 40% relies on the use of RUTF[4]
- **Cost-effectiveness of SAM management programs including out-patient management using RUTF has been shown to largely overcome cost-effectiveness of** in-patient SAM management without RUTF.
- It is **not more expensive than other treatments used to cure a life-threatening disease.** For instance, in 2013, the average cost of first-line antiretroviral treatment (ART) for LMICs was $115 per patient per year (PPY) and $330 PPY for second-line ART[5].

2 Ibid.
3 Bhutta et al., 'Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost?', The Lancet Series on maternal and child nutrition, 2013.
4 Linda S Adair, Caroline H D Fall, Clive Osmond, Aryeh D Stein, Reynaldo Martorell, Manuel Ramirez-Zea, Harshpal Singh Sachdev, Darren L Dahly,Isabelita Bas, Shane A Norris, Lisa Micklesfi eld, Pedro Hallal, Cesar G Victora, for the COHORTS group. Associations of linear growth and relative weight gain during early life with adult health and human capital in countries of low and middle income: findings from five birth cohort studies. The lancet Vol 382 August 10, 2013
5 http://www.avert.org/antiretroviral-drug-prices.htm

Costs can be reduced with local production of RUTF:

- The technology to produce RUTF can be introduced in developing countries with minimal industrial infrastructure and is already in use in several countries. Since the cost of many RUTF products is highly linked to fluctuating skimmed milk powder prices, ACF welcomes continued research into lower cost alternatives using locally available products.
- ACF also recognizes that locally-made RUTF products may not be inexpensive, due to lack of subsidies for key ingredients as found in some developed countries. However, the **added benefit to the local economy** brought about by local factories should be factored into any cost-benefit analysis when choosing products, and suggests that quantitative research into such local benefits is continued and published. It promises hopes of reduced prices and transportation costs and of more responsive delivery times.
- In theory the increased demand for RUTF combined with the existing proliferation of good quality RUTF products on the market will increase competition and bring prices down.

It is the State's responsibility to **ensure that children under-five have a free access to SAM treatment,** especially for marginalized and most vulnerable groups: free access to treatment implies a free consultation at the point of use but also coverage of all the related costs such as the transport and the medicines (including RUTF).

3. SOME RESOURCES ARE DIRECTED TO PROCURE RUTF WHEN THEY COULD POSSIBLY BE USED TO IMPROVE ACCESS TO FOOD AND HELP PREVENT UNDERNUTRITION FOR POOR AND VULNERABLE PEOPLE

✓ RIGHT

Treatment and prevention of acute malnutrition must not be viewed as competing activities but as concerted efforts, much like the treatment of any other illness (malaria, HIV, tuberculosis) where it is inconceivable to focus only on prevention without treating already affected people and prevent them from dying. The treatment of millions of malnourished children from this life-threatening disease that is severe acute malnutrition is as pressing a need as the prevention of further undernutrition through a holistic and integrated approach.

4. THE USE OF RUTF ENTAILS A RISK OF A HIGH DEPENDENCE ON FOREIGN COMPANIES

☒ WRONG

Dependence on foreign companies can be avoided by locally producing RUTF as per WHO specifications by local factories.

A new recipe can be created and for already existing recipes, some measures have been taken at international level to make the patent more accessible to local producers and thus decrease the risk of a high dependence to foreign companies.

The government can adopt a clear position on the production of RUTF and ensures that multiple producers and supplies are supported to prevent monopolization of the RUTF market by foreign companies.

5. THE USE OF COMMERCIALIZED RUTF ENTAILS THE RISK OF COMMERCIALIZING THE FIGHT AGAINST ACUTE MALNUTRITION

✓ RIGHT BUT SAFEGUARD MEASURES EXIST

Severe acute malnutrition is a life threatening condition that requires treatment, and the risk of commercialization for its treatment through RUTF exists, as it does for **any other disease requiring treatment**.

However, some safeguard measures already exist or can be developed both at national and international level:

- Development of standards and guidelines both at international and national level to control the promotion and marketing of RUTF should be developed. These rules could embrace relevant aims, principles and provisions contained in the WHO International Code on the Marketing of Breastmilk Substitutes.

- At national level, the government can ensure that public health system is the sole procurement agency with a specific strategy that ensures purchase from multiple producers.
- At international level, RUTF production is strictly certified by non-profit and non-commercial organisations (Médecins sans Frontières and UNICEF), which would further prevent conflicts of interest.

6. RUTF IS AN UNNECESSARY PRODUCT AS HOME COOKED FOOD, WHEN FED IN ADEQUATE AMOUNTS, CAN CURE SEVERE ACUTE MALNUTRITION

☒ WRONG. WE DISAGREE AS TO OUR KNOWLEDGE THIS ASSERTION HAS NEVER BEEN DEMONSTRATED.

ACF acknowledges that theoretically, home cooked foods could reach nutritional adequacy for the treatment of SAM. This is in practice **a very difficult task** and **evidence is still lacking so far regarding successful food-based approaches to SAM management and how they compare with RUTF.**

Though there is a strong need for more research into food-based alternatives to RUTF, it should be noted that besides nutritional adequacy and clinical efficacy, the operational effectiveness of such alternatives in real life programs should be carefully analyzed.

Indeed, the international recommendation to use RUTF relies on a wide range of **pragmatic considerations, which might not be met by food-based alternatives.**

Note that a local recipe could be either or:

1/ prepared and packed in a local factory
2/prepared and distributed daily on site by health staff
3/ prepared by mothers at home

Note that a local recipe is unlikely to meet WHO specifications for RUTF when cooked daily at home or in a health center

Following operational evidence that ACF has been observing for years, it appears that RUTF presents the following advantages:

- If it is compared to a recipe that is to be mixed at home:
  a) RUTF use reduces the risk of over or under dilution,
  b) saves resources and time to the mother at it requires no additional utensils, cooking or preparation
  c) Reduces the risk of unhygienic preparation in unhygienic settings (i.e. urban slums, refugee camps, displaced settlements, populations with very limited resources, etc.)
- If it is compared to a recipe prepared in the health center:
  a) RUTF allows treatment to be given by a minimal number of staff,
  b) RUTF saves time to existing staff in the centers,
  c) Allows the mother not to attend the health center daily to receive the ration and therefore saves time to the mother, and
  d) Reduces the risk of unhygienic preparation in centers based in unhygienic settings (i.e. urban slums, refugee camps, displaced settlements, populations with very limited resources, etc.)
- RUTF is easier to transport and easier to use at home when compared to either the raw ingredients transported to be cooked at home or the center made local recipe that is not ready packed.

7. RUTF IS NOT A SUSTAINABLE SOLUTION

✓ RIGHT BUT IT IS AS TRUE FOR THE TREATMENT OF SAM AS IT IS FOR THE TREAMENT OF ANY OTHER DISEASE.

As for any other disease, treatment is not a sustainable solution and must be accompanied by preventive interventions. A **multi-sector approach** involving food security, water and sanitation, integration of HIV management and addressing care practices is needed to make a lasting impact, prevent the development of acute malnutrition and reduce the caseload of SAM patients in the first place.

Some mitigation measures can be taken to increase the sustainability of access and availability of SAM treatment through RUTF:

- The **development of local production of RUTF**, through an improved acceptance and lower costs of production, should overall greatly increase the sustainability of CMAM programs.
- True sustainability of treatment will only be achieved when **CMAM is integrated into existing and functioning health structures**. Governments must be supported to ensure that treatment is and will remain regularly available and accessible over the long term as part of routine national health services. To date there is compelling evidence from Malawi, Ethiopia and Zambia to show that scaling up CMAM through integration into national health systems is feasible and achievable. NGOs and external donors have a strong role to play in supporting governments to strengthen their health system.

8. RUTF SHOULDN'T BE USED FOR THE PREVENTION OF MALNUTRITION.

✓ RIGHT ACF DOES NOT PROMOTE THE USE OF RUTF FOR THE PREVENTION OF CHILD MALNUTRITION

ACF considers that RUTF **is a medical treatment** for uncomplicated severe acute malnutrition, not a cure-all for all forms of childhood undernutrition. As any other medicine, RUTF is a medicine whose distribution and use must be strictly regulated. The scale-up of CMAM should be alongside (and not replaced) initiatives which look at all forms of undernutrition.

Prevention of all forms of undernutrition is best undertaken through well-established interventions: optimal infant and young child feeding practices, expanding access to high quality foods, quality health care, improved water sources and sanitation facilities; and better knowledge of nutrition, health and hygiene practices in communities.

9. THE PROMOTION OF RUTF MAY UNDERMINE BREASTFEEDING

☒ WRONG

ACF fully supports and agrees that exclusive breastfeeding for infants less than 6 months of age is essential for optimum child health. ACF actively promotes this best practice, as well as advocates for sustained breastfeeding for children aged 6-24 months and beyond. As a treatment for SAM, ACF does not consider that the use of RUTF undermines breastfeeding, but acknowledges that careful follow-up should monitor this risk. **International protocols clearly state that no RUTF should be given to infants below 6 months**. **For children aged 6-24 months, breastfeeding is actively encouraged before the child is offered RUTF.**

10. RUTF CONTAINS NO WATER AND MAY CAUSE DEHYDRATION. EXTRA WATER INTAKE WILL BE ESSENTIAL AND IS NOT WITHOUT RISK

✓ RIGHT BUT SAFEGUARD MEASURES EXIST

Every child needs to drink water- whether it is due to RUTF intake or heat or diarrhea. Drinking water is not a risk directly linked with RUTF. However, while consuming RUTF, a child requires more water and it is essential that safe water access is ensured where RUTF is used (Journal of the World Public Health Nutrition Association February 2010). ACF emphasizes that it is essential to integrate efforts to provide clean water supplies with under-nutrition programs.

ACF POSITION ON MAJOR CRITICISM TO RUTF

Overall ACF considers that, given its proven results in saving children's lives, the benefits of using RUTFs for the treatment of severe acute malnutrition substantially outweigh some remaining concerns. Our overriding priority is to save children's lives with proven, efficacious and cost effective solutions.