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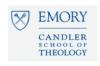
Severe Acute Malnutrition Strategy in the Oromiya Region, Ethiopia

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BACKGROUND STORY

One year old Aamina lives with her widowed mother and four siblings in Ethiopia's Oromiya region. Aamina's mother struggles to feed her family on the income she makes from selling baskets in the market.

Today Aamina sits listlessly at her mother's feet. She is small for her age and her mother has noticed that her verbal and motor skills are not as advanced as other children her age. She no longer shows any interest in interacting with her family; she does not play. Aamina is dying. Without money, time, and resources to access treatment, her mother has little hope for her daughter's survival.

OBJECTIVE

The Phil and Linda Bates Foundation is seeking strategies for how to invest US \$1 million to sustainably reduce the burden of uncomplicated, severe acute malnutrition in Oromiya Region, Ethiopia. The regional government of Oromiya is unable to spend enough funds on childhood nutrition; therefore, in the near term, any investments towards this topic would require the support of private donors.

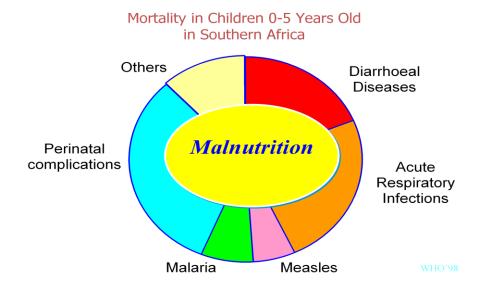
The World Health Organization (WHO) currently recommends that all cases of severe acute malnutrition be treated following a facility-based treatment strategy but have not discounted that community-based strategies providing ready-to-use therapeutic foods (RUTF) may be at least as effective. Other vested groups also support a wider scope of this intervention's impact, but no impartial evidence is currently available.

Given the controversies and complexities involved in the issue, the Bates Foundation has requested project proposals from a select group of teams within a short time-frame. As one of the chosen teams of consultants, your objective is to provide the Foundation with the most appropriate, up-to-date, and effective recommendation on how to spend the Foundation's money in the effort to reduce uncomplicated, severe acute malnutrition in the Oromiya region. Each team member has different expertise and abilities to incorporate information and methodologies from their disciplines, which will contribute to the range of perspectives ultimately presented in the recommendations. The Bates Foundation has traditionally accepted proposals that are based on strong evidence, are derived from an interdisciplinary perspective, and that consider sustainability, feasibility, and social returns on the investment.

¹ Community-Based Management of Severe Acute Malnutrition, A Joint Statement by the World Health Organization, the World Food Programme, the United Nations Standing Committee on Nutrition and the United Nations Children's Fund, 2007.

CASE RATIONALE & BACKGROUND

Malnutrition is a serious global health problem, especially for children in developing countries. Malnutrition is a major underlying and *preventable* factor in more than 5 million child deaths under the age of five ^{2,3}. Globally there are 2.2 million deaths and 91 million disability-adjusted life years (DALYs) lost due to nutritional deficiencies annually. It is estimated that 32% of all children (178 million) are stunted, with the highest prevalence found in Africa, South-, and South-east Asia. In Africa alone, 24% of children are underweight, and 35% are stunted. Although poor nutritional status may encompass both under- and over-nutrition, developing countries face overwhelming burdens of inadequately nourished children, which is compounded by lack of access to clean water supplies and sanitary hygiene practices. Malnutrition also hinders economic growth, which prevents progress toward the Millennium Development Goals (MDGs) which target poverty reduction and social upliftment for all.



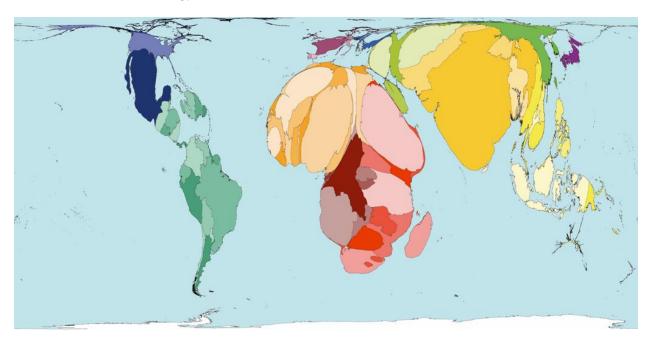
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² Black, Robert E, et al. Where and why are 10 million children dying every year? *The Lancet*. 2003, 361 (9376).

³ Collins, Steve et al. Management of severe acute malnutrition in children. *The Lancet*. 2006, 368 (1992-2000).

Severe acute malnutrition is defined by WHO as a child having "very low weight for height...by visible severe wasting, or by the presence of nutritional edema," which is a form of body swelling caused by severe protein deficiency in the body. Considering that the window of opportunity for improving childhood nutrition is relatively limited before irreversible damage to a child's growth and development occurs, nutrition-based interventions must target the first two years of a child's life.

Deaths from Protein-Energy Malnutrition⁵



CONTEXT: NUTRITION IN ETHIOPIA

According to one survey, 11% of children under-five are wasted (thin for their height),
 and 38% are underweight in Ethiopia.⁶

⁴ World Health Organization. Severe Acute Malnutrition. Accessed February 21, 2009. http://www.who.int/nutrition/topics/malnutrition/en/index.html

⁵ Taken from worldmapper.org. Territories are sized in proportion to the absolute number of people who died from protein and energy malnutrition in one year.

⁶ Ethiopia Demographic and Health Survey, 2005. ORC Macro, September 2006.

- In Oromiya Region, in particular, 34.4% of all children under-five are classified as underweight.⁷
- According to the Global Hunger Index 2008, a ranking system of 88 countries that
 assesses levels of under-nutrition and child mortality in its metric, Ethiopia's rating
 categorized it as the sixth worst country in terms of nutritional outcomes worldwide.⁸
- UNICEF estimates that 126,000 children are in need of urgent therapeutic care for severe malnutrition in Ethiopia, and this number is likely to climb.
- In 2004, health expenditures in Ethiopia were shared between (1) the Ethiopian government contributed 28% (equal to US\$1.99 per capita), (2) households 31% (US\$2.19 per capita), and (3) donors 37% (US\$2.63 per capita). The WHO's recommended target expenditure is US\$30–40 per capita⁹. Though this budgetary data refers specifically to Ethiopia's health expenses, many other predominantly-rural, lowincome, developing countries experience similar financial challenges.

TREATMENT OF UNCOMPLICATED SEVERE ACUTE MALNUTRITION

Facility-Based Treatment

WHO recommendations for treatment of uncomplicated, severely undernourished children in developing countries have traditionally favored facility-based care, focusing on in-patient case assessment and clinical management of malnourished children^{10,11}. According to the WHO, the management of a child with severe malnutrition is divided into three phases:

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⁷ Ibid.

⁸ BBC World News. *Global Hunger Index in Full*. 2008. Accessed March 15, 2009. http://news.bbc.co.uk/2/hi/in depth/7670229.stm

⁹ Save the Children Report, 2003.

¹⁰ Ibid.

- The *initial treatment phase* requires identification of life-threatening problems (severe infections, diarrheal disease, hypothermia, etc.) within the context of a hospital or residential care facility, followed by subsequent therapy, feeding, and deficiency corrections.
- 2) During the *rehabilitation phase*, intensive feeding is implemented within the facility to replace lost weight, and the caretaker or mother is trained to continue the care regimen at home, before preparations are made for discharge.
- 3) The *final follow-up phase* takes place after discharge, an important period for preventing relapse and ensuring the child's physical, mental, and emotional development. ¹²

The WHO-endorsed standard of treatment for severe malnutrition during the rehabilitation phase is typically the consumption of large quantities of F-100, which is a high-energy and high-protein milk powder, fortified with several minerals and vitamins. The formula is used in therapeutic feeding centers where children are hospitalized for treatment. The typical amount of time spent at the hospital is 30 days¹³, and the total cost of this treatment can range from \$50 to \$200 per patient.

Ready to-use Therapeutic Foods (RUTF)

An alternative approach to recuperative care from severe malnutrition is community-based therapy utilizing ready-to-use therapeutic foods (RUTF). Due to their unique ability to offer a form of treatment for severely malnourished children on an out-patient basis, RUTFs have been touted to reduce nutrition-related hospital admission. This strategy's strongest

¹¹ World Health Organization. *Management of the child with a serious infection or severe malnutrition: Guidelines for care at the first referral level in developing countries*. 2000. Accessed February 21, 2009. http://whqlibdoc.who.int/hq/2000/WHO_FCH_CAH_00.1.pdf

¹² World Health Organization. *Malnutrition: A Manual for Physicians and other Senior Health Workers.* 1999. Accessed March 15, 2009. http://www.who.int/nutrition/publications/severemalnutrition/en/manage severe malnutrition eng.pdf

¹³ Management of severe acute malnutrition in children, Collins et al. 2006

features include: fewer communicable illnesses acquired through facility-based interaction with other children carrying infections and rapid weight gain.

The evidence regarding the effectiveness of ready-to-use therapeutic foods on mortality is limited. No adequately designed randomized controlled trials have investigated this intervention, but some observational studies have shown RUTFs to be successful (please see Appendix 2).

Challenges Associated with Treatment Strategies

Among the challenges associated with facility-based treatment are: the dearth of skilled health workers and health infrastructure; poor accessibility (physical and economic) to these facilities; and opportunity and travel costs incurred by the mother (or caregiver) getting to, and staying at, the health center with her child.

Like oral rehydration therapy (the common treatment for diarrhea patients, which replaces lost water and electrolytes through the consumption of a specific solution), F-100 treatment, which is given in treatment facilities, was not patented because it was created for humanitarian nutrition purposes. Some of the newer RUTFs, however, are patented by private companies. One widely used RUTF company has come under intense scrutiny regarding patent enforcement. Some say that private companies entering the RUTF field should relinquish patents or at least negotiate favorable licensing agreements with governments. See Appendix 6 for a description of an RUTF patent.

The urgency and moral impetus for acting are often in conflict with the need for scientific evidence-based intervention, without which, one may cause more harm than good.

Furthermore, there is very little anecdotal and/or scientific data regarding the cultural aspects and community perceptions of the treatment strategies discussed. Indeed, the social, environmental, political, and economic considerations of such a complex problem are sobering, as these intricately-woven factors aggravate the challenge confronting our globalized world.

ACQUISITION OF THERAPY

The cost elements of any intervention for malnutrition need to be considered. RUTF can be imported as a prepackaged good of produced locally. Experiences with local production have generally involved outsourcing to a local food producer (refer to Appendix 4 for more details). A child being treated for severe acute malnutrition will need 10–15 kg of RUTF, given over a period of six to eight weeks. The total amount of time required at the treatment facility is still 5 to 10 days. The primary expenditure associated with RUTF production is the cost of the ingredients, since the production process itself is relatively simple. In Malawi, the cost of milk powder represented over half the cost of the final product, as the milk powder must often be imported. Furthermore, "RUTF production in Ethiopia has been hampered by the difficulty of importing ingredients not available locally, particularly dry skimmed milk and the mineral—vitamin mix" 17.

By comparison, F-100, the supplement typically used in treatment facilities, can be prepared from basic ingredients, is available in powder form, and requires only a few minutes of cooking. If F-100 is going to be stored for more than 2 hours, it should be refrigerated after cooling. It can also be produced locally and only requires rudimentary equipment to process. It

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¹⁴ According to Collins, Steve et al. in "Key Issues in the success of community-based management of severe malnutrition", one brand of RUTF typically costs US\$3,500 per metric ton to import (shipping costs excluded). You can assume that international shipping into Addis Ababa will cost \$1,000 per ton and within the country shipping will cost \$5 per 80 kg per 100 miles on paved roads and 5 times that on unpaved roads.

¹⁵ Community-Based Management of Severe Acute Malnutrition, A Joint Statement by the World Health Organization, the World Food Programme, the United Nations Standing Committee on Nutrition and the United Nations Children's Fund, 2007.

¹⁶ Management of severe acute malnutrition in children, Collins et al. 2006.

¹⁷ Collins, Steve et al. "Key Issues in the success of community-based management of severe malnutrition. SCN Nutrition Policy Paper No. 21.

can cost up to \$3,000 per metric ton¹⁸¹⁹, though F-100 can still be considered cost-effective, as the rate of recovery is faster than with other foods.

SUMMARY OF ASSIGNMENT

The Bates Foundation has declared an interest in reducing the burden of nutritional deficiencies in the Oromiya Region, Ethiopia. They have pledged US \$1 million to address this issue in Oromiya Region, Ethiopia. However, given the uncertainties, they have hired teams of consultants to provide them with the most appropriate, up-to-date, effective, clear, and high-value recommendation of how to invest their money to address severe acute malnutrition in Oromiya region. Specific and targeted recommendations will be delivered and defended consecutively on Saturday April 4th. Among other aspects, teams should consider social returns, feasibility, and sustainability of the investment. The two best proposals will be considered for investment and the teams responsible will be awarded accordingly.

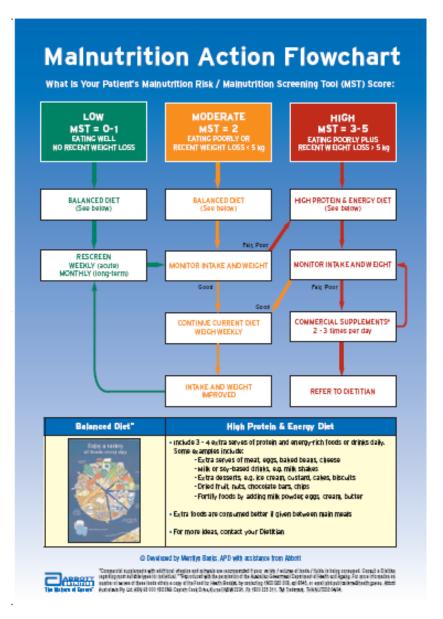
Specific questions you might consider:

- How are severe acute malnutrition cases found and identified?
- Have you considered the legal ramifications and cultural acceptability of your proposal?
- Has your strategy addressed the potential political and social sentiments towards your recommendations?
- Have you considered all of the components necessary for implementation of your strategy?

¹⁸ The cost of F-100 does not need to be added to the cost of facility-based care, as it is already included in the cost per patient given earlier.

¹⁹ Emergency Nutrition Network. Foods for the Treatment of Malnutrition: Summary of Conference Presentation 1997. http://fex.ennonline.net/2/foods.aspx

APPENDIX 1: WHO MALNUTRITION ACTION FLOWCHART



http://www.health.qld.gov.au/patientsafety/pupp/documents/malnu.pdf

APPENDIX 2: EXCERPT FROM LANCET ARTICLE ON MALNUTRITION TREATMENT STRATEGIES

"Community management of severe acute malnutrition with ready-to-use therapeutic foods has been shown to induce weight gain in emergency settings and has been recommended by WHO, UNICEF, and the UN World Food Programme. We could not find any randomized clinical trials that had investigated the effect of ready-to-use therapeutic foods on mortality. However, observational data from field programmes suggest that management of severe malnutrition at home with pre-prepared balanced food can achieve high coverage and low case fatality. The overall case-fatality rate in 23,511 unselected severely malnourished children treated in 21 programmes of community-based therapeutic care in Malawi, Ethiopia, and Sudan between 2001 and 2005 was 4.1%, with a recovery rate of 79.4% and default of 11.0%. This compares favorably with case-fatality rates that are typically achieved with facility-based management. However, this comparison must be interpreted cautiously since the severity of cases in the facility-based trials and the community-based observational studies might differ."

²⁰ Bhutta, Zulfiqar A et al. What works? Interventions for maternal and child undernutrition and survival. *The Lancet*. 2008, Feb 2 371 (9610).

APPENDIX 3: EXCERPT FROM LANCET ARTICLE ON MALNUTRITION TREATMENT STRATEGIES

Bhutta, Zulfiqar A et al. What works? Interventions for maternal and child undernutrition and survival. *The Lancet*. 2008, Feb 2 371 (9610).

- 1. The current WHO guidelines are effective in reducing case fatality rate of children with severe acute malnutrition.
- 2. Because of the relatively new concept, electronic as well as hand search revealed not many papers on RUTF and its role in the management of severe malnutrition.
- 3. RUTF seems to play an important role in the management of severe malnutrition in disaster and emergency settings. A supplementary feeding program providing food rations to families of the affected child should be in place. So should be a stabilization centre for taking care of acutely ill severely malnourished children who need facilitybased care based on WHO guidelines.

APPENDIX 4: EXAMPLE OF PRODUCTION COSTS FOR RUTF IN MALAWI

In one example of a locally produced RUTF in Malawi, the cost per kilogram of RUTF was as follows: milk \$0.63, sugar \$0.17, peanut butter \$0.18, oil \$0.18, vitamins/ minerals mixture \$0.26, for a total of about \$1.40/kg. These costs include the transport of the ingredients to the factory. Packaging is also a significant cost, in Malawi about \$0.50/kg (plastic bottles and cardboard boxes). Additional costs include labor, facility rental, and utilities. ²¹ In this example the total cost of producing RUTF is about \$2.60/kg, ²² which includes all of the variable costs mentioned earlier (milk, sugar, through packaging and labor). To license a patented RUTF would amount to an additional \$0.28 per kg. To contract with a local food producer, assume the costs are the same except the local producer requires production runs of at least 500 kilograms per week and a 30% profit margin.

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²¹ The cost of utilities and commercial rent can be around \$1 per square foot per month in Addis Ababa.

²² Manary, Mark J. Technical Background Paper. "Local production and provision of ready-to-use therapeutic food for the treatment of severe childhood malnutrition."

APPENDIX 5: MINERAL AND VITAMIN CONTENT OF RUTF IMPORTED MIX¹

Vitamins:

Vit A (57 mg)

Vit D (1 mg)

Vit E (1.25 g)

Vit K (1.30 mg)

Vit B1 (37.5 mg)

Vit B2 (116mg)

Vit B6 (37.5 mg)

Vit B12 (110 mg)

Vit C (3.3g)

Biotin (4.1 mg)

Folic acid (13 mg)

Niacin (332mg)

Pantothenic acid (194 mg)

Minerals:

Potassium (36 g) Magnesium (587 mg) Iron (704 mg) Zinc (717 mg) Copper (92 mg) Iodine (5 mg) Selenium (1.54 mg)

APPENDIX 6: PATENT DESCRIPTION

The Clinton Foundation HIV/AIDS Initiative describes the RUTF patent to encompass all nutritional products characterized by the following features²³:

- Product Complete food or nutritional supplement which contains at most 10% by weight of water comprising at least one lipid rich substance derived from oleaginous seeds and enriched in vitamins, mineral salts, enzymes or mixtures thereof
- Process Process for the preparation of a complete food or food complement
- Use
 Use of the complete food or nutritional supplement according to any of claims, in nutritional programs for renourishment or nutritional supplementation, or for correcting deficiencies of vitamins or mineral salts

²³ Sources: WIPO, CHAI analysis