Malawi

Malawi
Preparatory survey on BOP Business for Innovative Ready to Use Therapeutic Food (RUTF)

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Index

Executive summary

List of abbreviation

- SAM：Severe Acute Malnutrition
- RUTF：Ready to Use Therapeutic Food
- CMAM ：Community-based Management of Acute Malnutrition
- VN：Valid Nutrition
- P-RUTF（PM-RUTF）：Existing commercial product of RUTF which is based on skim milk and peanuts paste
- SMS: Soy, Maize and Sorghum
- SMS-RUTF：Prior developed new RUTF product by VN which is based soy maize sorghum (SMS)
- FSMS-RUTF：Current developing new RUTF product which is based SMS and amino acids
- MSMS-RUTF：Current developing new RUTF product which is based SMS, low level of skim milk and amino acids
- CBCC：Community Based Child Care Centers
- UNICEF：United Nation Children's Fund
- WFP：World Food Program
- WHO: World Health Organization
- SADC：Southern Africa Development Community
- MUAC：Middle Upper Arm Circumstance
- CCFNSDU： Codex Committee on Nutrition and Foods for Special Dietary Uses
- MSEA: Metabolic Set Enrichment Analysis
- LP：Linear Programing
- DIAAS：Digestible Indispensable Amino Acid Score
- PDCAAS：Protein Digestibility Corrected Amino Acid Score
- GIF：Global Innovation Fund
- CIFF：Children's Investment Fund Foundation

EXECUTIVE SUMMARY

1.1: Back ground and Objective

50 million children aged 6-59 months suffer from acute malnutrition, and 16 million the children is severely acutely malnourished. Most of them live in sub-Saharan Africa and south Asia. In addition, severe acute malnutrition (SAM) remains a major killer of children under five years old. The aged 6-59 months is including "first thousand days", and malnutrition of these days extremely affects their growth and is associated with their future productively. Therefore, it is quite important to supply enough and suitable nutrition. Previously, the treatment for SAM had been restricted to facility based approach such as infusion treatment in hospital, which is limiting its coverage and impact. From 2000, new therapy is developed, which is called "Ready to Use Therapeutic Food (RUTF)". Compared with the facility based approaches, new treatment by RUTF is a community based approach, which involves timely detection of SAM in the community and supply nutritious food, RUTF at community or home. RUTF treatment is cheaper than the facility approach in total cost to recovery, and implemented on a large scale and area, and could prevent the deaths of hundreds of thousands of children. Procurement of RUTF by UNICEF is 35,000 MT per year in 2016, and market is growing 10% per year, but potential volume is 10 times higher than that. To save more SAM children, United Nations is anxious to supply more cheap and good quality RUTF.

RUTF is used to recover from SAM, therefore, nutritional effect is most important, and safety of product is also quite important to prevent diarrhea. In addition, cost reduction is one of the key issue because budget for RUTF treatment is limited. And also, local production is one of the answer to reduce the time to supply RUTF after ordered because extra 1~2 months is necessary for logistics and custom clearance if the product will be imported from abroad such as Europe. From these reason, UNICE expect the following to RUTF, 1) adequate nutritional effect, 2) safety, 3) low price and 4) local production.

Current commercialized RUTF is based on skim milk, peanut paste, oil, sugar and vitamins and minerals which is satisfied with nutrition requirement. This product was developed by Nutriset SAS (France) which main product is called PlumpyNut's®. Skim milk is known as good quality protein, but there is little food habit and production in Africa, therefore, the price of skim milk is expensive. Peanut is also good quality protein source among plant protein, and taste preference is higher in Africa. But, there is high Aflatoxin risk compared with other plant source, therefore, it is difficult to manage this safety issue in Africa. On the other hand, grans such as maize, soy, sorghum are staple food in many African countries and are cheaper than animal source such as meat, fish and eggs. But protein quality is not so good. Protein quality is defined by amino acid composition and availability. If plant protein and amino acid will be combined, protein quality will be improved. More inexpensive, acceptable RUTF compared with current RUTF may be provided if grain based effective RUTF will be developed.

Valid Nutrition (VN) which is NGO in Ireland developed grain based RUTF (Soy-Maize-Sorghum: SMS) from 2008 to 2014. In the comparison clinical study with skim milk-peanut paste type RUTF (P-RUTF), SMS-RUTF showed the same recovery rate over 2 years old children, but less effect under 2 years. In addition, physicality of grains is not smooth and is low fluidity which should be improved to take it easily for infant.

Ajinomoto is a food company with seasoning, processed food and amino acid, which has advantage of food technology, quality assurance and amino acid nutrition. In addition, Ajinomoto developed "KOKO Plus" characterized by protein/amino acid nutrition in Ghana. "KOKO Plus" is nutritious supplement used with traditional wearing food "Koko", and respected local preference and food culture. VN established a concept of RUTF and treatment method of RUTF called Community based Management of Acute Malnutrition (CMAM).

In addition, they have an experience developed SMS-RUTF and have some connection to UNICEF and NGOs.

We, Ajinomoto and VN combine each strength to solve the above issues of RUTF, and developed new RUTF in this research in Malawi. Main objective of this study is to develop new RUTF used local available ingredients and to investigate value-chain for commercialization.

1.2: Region

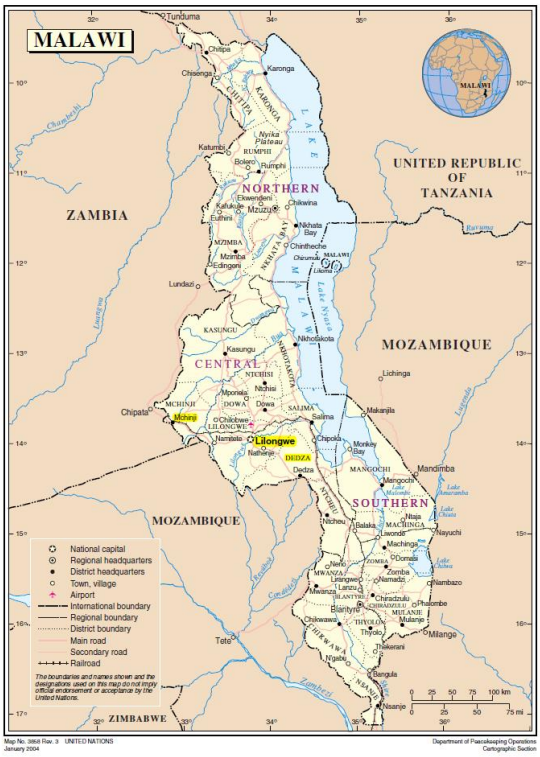


Fig. 1 Map of Malawi

This research was conducted in Malawi. Because malnutrition is still big issue in Malawi. And also, joint research partner, Valid Nutrition has a RUTF test factory and operation capacities such as RUTF production, product development and clinical study in Malawi, and also has a good relationship between Malawi government and UNICEF Malawi.

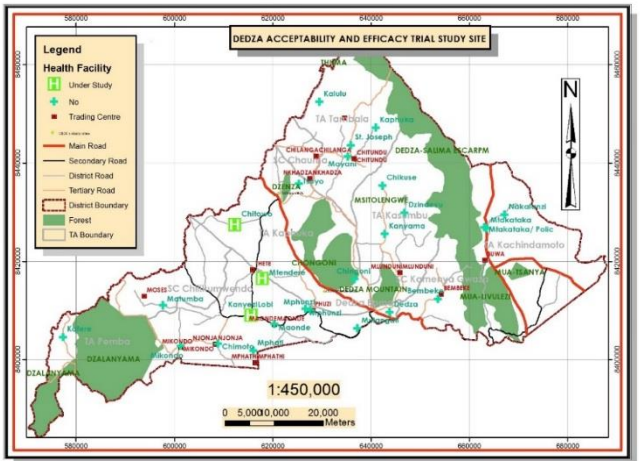
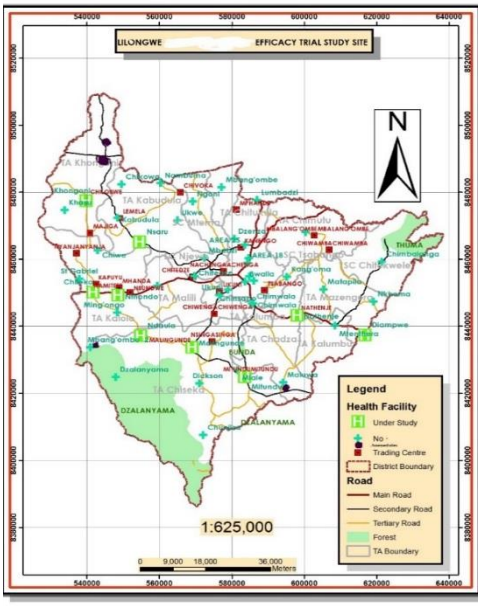


Fig2. Dedza district for acceptability and efficacy study



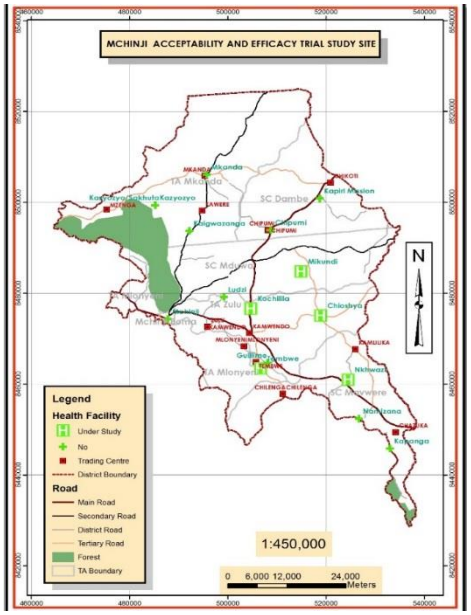


Fig. 3 (left): Lilongwe district for efficacy study

Fig. 4 (light): Mchinji district for acceptability and efficacy study

1.3: Target and method of the research

Research items	Method and term
Local	・ Local economics, related law, market, needs, social dimension and logistics survey:

logistics, and food habit	Conducted by bibliographic, field surveys, and interview to Ministry of Health in Malawi and JICA Malawi office etc. (term: 2014 Sep ~ 2016 Aug) Malawi is one of the poorest counties over the word. Economic growth is around 5 % but, 40% of annual revenue is dependent on aid money. Most common industry is agriculture. High expensive transportation cost which reason is inland state and poor infrastructure, is one of the key issue in Malawi for economics. Poverty index is high even Lilongwe area, so, nutrition improvement is important subject. ・ Survey of local food habit and needs: Conducted by visiting community and local market (term：2014/Sep~2016/April) Traditional and modern markets were visited around Lilongwe area, and also communities in northern area which is activity site of Japanese NGO, ISAPH was visited (2014/April). Compared with urban area such as Lilongwe and Blantyre, northern area is very poor and there is no food diversity. And there is no choice for kind of raw ingredients and for processed foods compared with Ghana. Taste of food is very simple, just salty taste, not spicy compared with western Africa.
Product development	<Formulation> Investigation of RUTF formulation which the characteristics are low cost and high protein/amino acid nutrition used local available ingredients as main source (term: 2014/Sep~2014/Dec) To improve protein quantity and quality from SMS-RUTF (see1.1), formulation was calculated by linear programing analysis using soy, maize, sorghum and crystal amino acids. The analysis was one of the best tool to calculate best nutritious composition with best price. <Value chain survey> Survey good quality local ingredients and development of production process to achieve high preference RUTF (term: 2014/Nov ~ 2016/Dec) ・ Local ingredients survey: Visited local suppliers and conducted test production using the local grains. High quality ingredients is necessary because RUTF is therapeutic food. Now, we use the grains from S company. (Kenya) which was used for previous SMS-RUTF, but it is better to use Malawian company for the future if the product is produced in Malawi. In this time, grain ingredients of E company (Malawi). which is introduced by Japanese trading company, Itochu company that trade soy bean with E company, was tested whether the quality is good. The quality was compared with that of S company. Crude protein and lipid concentration of grain mixture in several batch was measured. Coefficient of variation value in E company sample was high compared with S company sample, and also it is difficult to mill the mixture continuously in the current facility. As a result, it is difficult to use grains of E company at this time. Further improvement will be requested for the future production. ・ Production process: The texture such as smooth and fluidity are one of the issue for grain based RUTF. Therefore, production process was developed at Institute of Food Sciences and Technologies of Ajinomoto for basic process and at VN Malawi factory for actual production process. As a result, developed product became smooth and fluid texture.

	・ <Clinical study> <Test products used for clinical study> Test products were the existed RUTF and current developed two RUTF 1: P-RUTF (Control: 25% skim milk, 26% peanuts paste, mainly) 2: FSMS-RUTF (developed product 1; soy, maize, sorghum, mainly) 3: MSMS-RUTF (developed product 2; soy, maize, sorghum and 9.4% skim milk) <Acceptability trial> Investigated an acceptability of the developed products (term: 2015/April ~ May) ●Area: Community Based Child Care Centers (CBCC) at Linthipe、Chimwemwe district ●Subject: 3～5 years children with moderate acute malnutrition ●Method: Cross over study between control RUTF and developed two RUTF (n=20 in each) Subjects was divided two groups, and in 2 separate phases of two weeks each (5 days per week), each group alternatively received one of the study food (FSMS-RUTF or MSMS-RUTF) and the control (P-RUTF). Wash-out period was 2 weeks between phases. ●Measurements: Intake monitoring (intake volume, preference, eating pattern, request additional amount, etc.) Morbidity (fever, diarrhea, cough, dyspnea, etc.) Anthropometric measurements (MUAC, weight) ●Result: Basically, acceptability of developed two RUTF was almost same level as that of control RUTF. The texture of FSMS-RUTF was slightly bad because particle size was big compared with others. This issue had been improved by production process development. As a result, these developed two RUTF was permitted to use the efficacy study. <Efficacy study)> Investigated the effect of the developed RUTF on recovering form (term: 2015/Oct ~ 2016/June) ●Area: Lilongwe, Linthipe and Chimwemwe district ●Subjects: 6 ~ 59 months old SAM children ●Number of subjects: PM-RUTF (control: n=380/454), FSMS-RUTF (n=340/458), MSMS-RUTF (n=355/435) (n=study complete/recruitment number) ●Method : Non-blinded, parallel group, simple randomized, controlled was conducted, and non-inferiority hypothesis was tested among 3 test group. Subjects stayed at the specially built “say care sites” at each health centers from 8 am to 4 pm every day, and fed RUTF only under free access to water and breast milk. Recovery was decided by the change in body weight, MUAC, infection, edema. ●Measurements: Anthropometric measurements (MUAC, weight, height)

	Morbidity (fever, diarrhea, cough, dyspnea, etc.) Breast milk feeding and body composition (double labeled water method, impedance method) Blood variable (hemoglobin, amino acid, etc.) Fecal calprotectin (Inflammatory bowel disease, commercial kit) Follow up study ●Results: The developed two RUTFs are not inferior recovery rate compared with PM-RUTF. This result indicated that grain based RUTF with amino acids has same recovery effect of current commercial milk-peanut based RUTF.

1.4: Probability of the business plan

Value chain of RUTF model is based on raw material, production and UNICEF procurement. Issue of raw material and production is shown in 1.3. For the UNICEF procurement, it is necessary to receive endorsement from WHO/UNICEF. The process of endorsement is different from kind of items, quality and quantity of evidence, and also, endorsement of new RUTF is first time for RUTF type product. Therefore, it is difficult to decide probability of the business plan at this moment. One of the example, Olyset®Net (Sumitomo Chemicals, Co., Inc.) spent 6 years to collect the data and more 3 years to receive UN recommendation. To launch the product after 2019, establishment of evidence and approach to each organization will be continued.

The confirmed items until now

- Development of new grain based RUTF which main ingredients are local available, low risk of aflatoxin and more low cost.
- The new RUTFs have acceptability and efficacy to recovery SAM as same as milk-peanut based RUTF

The remaining challenges

- Establishment of evidence (publication, pilot program)
- Endorsement from WHO/UNICEF
- Endorsement from local government
- Permission as RUTF supplier (when new factory will be established)
- Establishment of stable production process of new RUTF at VN Malawi factory and procurement of local grain ingredients in Malawi
- More research for commercialization in high demand countries

1.5: Reason of the business probability

New RUTF should be shown efficacy and effectiveness according the guideline from UNICEF, and also be endorsed by WHO/UNICEF. In addition, the permission of Food safety authority/regulatory in local government will be needed, and permission ad RUTF supplier by UNICEF. We had already had the meeting with UNCIEF Malawi and UNICEF supplier division. At this moment, UNICEF highly estimates and has interest with our project because the new product use local available ingredients as main source, is low risk of aflatoxin, has a potential to reduce a cost. At the beginning, we will work to establish the evidence as immediate priority. In addition, cost impact of this business model is procurement of materials and production among the value chain. It is necessary to establish business structure to make a profit.

1.6: Additional survey plan for commercialization

High priority is to receive the endorsement from WHO/UNICEF by shown the evidence of the new RUTF for

commercialization. Most important point is shown the evidence of the efficacy. Further publication such as remaining data of clinical study, reason of the formulation and product development will be shown. In addition, pilot program which the new RUTF will be used in actual RUTF treatment program, CMAM, will be conducted during hunger season 2017. Furthermore, we will try to establish stable product process of new RUTF in VN Malawi factory and start to survey for commercialization in high demand countries in East and West Africa.

1.7: Schedule for the commercialization

To do	Method and term
Product development	<Establish the evidence> ・Scientific reports: Results of the efficacy study such as recovery from SAM, blood variables, and the concept of the RUTF formulation such as the result of animal study, secondary analysis of human study, and the product development. Total 5~6 paper will be published by the end of March 2018 ・Pilot program: Start the field study in 2017. Number of subjects will be 1,500~2,000 <Stable production process> ・To confirm the production process in VN Malawi factory. In addition, investment of milling machine will be done in September 2017, and will conduct test production <Raw materials procurement in Malawi> High quality mixed grain ingredients will be researched. VN will handle it.
Advocacy	<WHO、UNICEF> After publication, we will really communicate with WHO/UNICEF. Before that, we will update the situation to them continuously, and will join some meeting organized by UN to update information of RUTF. <Codex guideline> RUTF guideline will be discussed by Codex committee. We will provide evidence/information to them to prevent against our product. <NGOs> After publication, we will really communicate with NGOs such as Medicins Sans Frontieres (MSF) <outside funds> We will try to obtain outside funds from donors such as GIF（Global Innovation Fund）、Power of Nutrition, etc. This activity was started.
Survey in high demand countries	We will start the survey in high demand countries and/or its neighbor countries for fully commercialization in 2017. The survey such as politics, situation, economics, infrastructure, raw materials, tax, local partner, etc. in the countries will be conducted by desk review and field investigation.