

Ready-to-Use Therapeutic Foods Scale-Up



Evaluation of Innovation in UNICEF Work Case Study: Ready-to-Use Therapeutic Foods Scale-Up

© United Nations Children's Fund, New York, 2019
United Nations Children's Fund
Three United Nations Plaza
New York, New York 10017
November 2019

The purpose of publishing evaluation reports produced by the UNICEF Evaluation Office is to fulfil a corporate commitment to transparency through the publication of all completed evaluations. The reports are designed to stimulate a free exchange of ideas among those interested in the topic and to assure those supporting the work of unicef that it rigorously examines its strategies, results, and overall effectiveness.

The contents of the report do not necessarily reflect the policies or views of UNICEF. The views expressed in this report are those of the evaluators. The text has not been edited to official publication standards and UNICEF accepts no responsibility for error. The designations in this publication do not imply an opinion on the legal status of any country or territory, or of its authorities, or the delimitation of frontiers.

This case study report for the Ready-to-Use Therapeutic Foods (RUTF) Scale-Up is one of thirteen innovation case studies which were conducted as part of a global evaluation titled 'Evaluation of innovation in UNICEF work'. The case study component of the evaluation was conducted by Deloitte LLC. The RUTF case study report was prepared by Edward Thomas, Katherine Arblaster, Ariel Kangasniemi, Laura Maxwell and Adarsh Desai. Beth Plowman, Senior Evaluation Specialist, Evaluation Office, led and managed the overall evaluation process in close collaboration with UNICEF Supply Division and Ethiopia Country Office.

The copyright for this report is held by the United Nations Children's Fund. Permission is required to reprint/reproduce/photocopy or in any other way cite or quote from this report in written form. Unicef has a formal permission policy that requires a written request to be submitted. For non-commercial uses, the permission will normally be granted free of charge. Please write to the evaluation office at the address below to initiate a permission request.

See innovation case studies at: https://www.unicef.org/evaldatabase/index_103533.html.

For further information, please contact:

Evaluation Office
United Nations Children's Fund
Three United Nations Plaza
New York, New York 10017
evalhelp@unicef.org

Copyright of photos:

Cover photo: © Ariel Kangasniemi
Page 29: © Ariel Kangasniemi

ACKNOWLEDGEMENTS

This case study report was commissioned by the UNICEF Evaluation Office. This case study report is the result of the commitment, efforts and contribution of a large number of individuals and institutions. The Evaluation Office wishes to thank the many colleagues who gave freely of their time for this evaluation. In particular, the team thanks the UNICEF Supply Division for their assistance in coordinating meetings and guidance throughout the data collection process. In addition, acknowledgement is given to all stakeholders who took time out of their day to share invaluable feedback on the innovation process. This includes representatives from the UNICEF Supply Division, the UNICEF Ethiopia Country Office, Nutriset, GAC Rieber Compact, Meds & Food for Kids, STA Niger, Valid International, Mediciens Sans Frontières, World Health Organization and United States Agency for International Development. Thanks to Celeste Lebowitz, Geeta Dey and Dalma Rivero of the Evaluation Office for administrative support and Laura Gagliardone for support in finalizing the report.

TABLE OF CONTENTS

List of acronyms	5
1. INTRODUCTION	8
2. INNOVATION AT A GLANCE.....	9
3. CONTEXT FOR DEVELOPMENT AND SCALE-UP OF RUTF	11
3.1 Development/humanitarian context	11
3.2 Innovation context	11
3.3 UNICEF programme context	12
4. THE INNOVATION JOURNEY FOR RUTF.....	13
5. RUTF FIELD TESTING.....	23
5.1 Use of RUTF at UNICEF globally.....	23
5.2 A glimpse into the use of RUTF: Ethiopia.....	26
5.3 Lessons learned	27
6. FINDINGS	30
6.1 Approach dimension	30
6.2 Organization dimension	33
6.3 Resources and capabilities dimension	36
6.4 Incentives and outcomes	37
7. CONCLUSIONS AND CONSIDERATIONS	40
Annex A: Methodology.....	42
Annex B: RUTF stakeholders	44
Annex C: The context for innovation at Supply Division	46
Annex D: Sustainable development framework.....	47
Annex E: Supply division workplans.....	48

LIST OF ACRONYMS

ACF	Action Contre la Faim
CMAM	Community-based Management of Acute Malnutrition
FAO	Food and Agriculture Organization of the United Nations
IRB	Innovation Review Board
IRD	L'Institut de Recherche pour le Développement
LTA	Long-Term Agreement
MAM	Moderate Acute Malnutrition
MSF	Médecins Sans Frontières
MSFIC	Markets, Supplier Financing and Innovations Centre
MNC	Medicines and Nutrition Centre
RFP	Request for Proposal
RUF	Ready-to-Use Food
RUSF	Ready-to-Use Supplementary Food
RUTF	Ready-to-Use Therapeutic Foods
SAM	Severe Acute Malnutrition
SDG	Sustainable Development Goal
UNSSCN	United Nations System Standing Committee on Nutrition
USAID	United States Agency for International Development
WFP	World Food Programme
WHA	World Health Assembly
WHO	World Health Organization

EXECUTIVE SUMMARY

Since 2014, UNICEF has embraced innovation as one of its key strategies to achieve results for children. That commitment is reaffirmed in its current Strategic Plan, 2018-2021, and is evident in the organization's programming and institutional architecture. Indeed, since 2014, significant progress has occurred in a relatively short period of time, backed by clear strategic intent and targeted investment. With the increased foothold of innovation in UNICEF, it is important and timely to take stock of these efforts through high quality evidence to inform decision-making, learning and accountability. In keeping with the need for this evidence, UNICEF conducted an global evaluation of innovation in 2018.

The objective of the global evaluation was to assess UNICEF's 'fitness for purpose' to employ innovation as a key strategy to achieve the outcomes and goals defined in its strategic plans covering the period 2014-2021. A set of innovation case studies was a key element of this global evaluation, along with an organizational assessment and a synthesis project. The case studies were guided by three objectives:

- To provide detailed descriptions of a set of innovations across stages of the development continuum inclusive of contextual influences
- To assess the application of innovation principles or other standards for a set of innovations with particular attention to issues of ownership and scale
- To produce clear conclusions and considerations for policy, strategy and management decisions to further enhance innovation as key change strategy.

Case studies were conducted by Deloitte LLP over the period February 2018-January 2019. Mixed methods were utilized for data

collection including key informant interviews, document review and observations in the field.

The innovation case examined in this report concerns the Ready-to-Use Therapeutic Foods (RUTF) Scale-Up. The objectives of the case study are the following:

- Inform organizational learning about ready to use therapeutic foods
- Enhance organizational accountability for innovation processes
- Strengthen and support the innovation processes to increase effectiveness.

Nearly half of all deaths in children under 5 years old are attributable to undernutrition, associated with weakened immunity, increased susceptibility to long-term developmental delays and risk of death.¹ Although moderate and severe wasting are conditions that can change throughout the course of the year (e.g., due to drought), UNICEF/World Health Organization (WHO)/World Bank Group Joint Child Malnutrition Estimates indicate that in 2017, an estimated 50.5 million children were wasted, of which 16.4 million were severely wasted.² Prior to development of RUTF, treatment of severe acute malnutrition (SAM) was completed in clinical settings, which limited the number of affected children health authorities were able to reach and created a resource burden on health systems.³ Responding to these challenges, RUTF is an energy-dense, micronutrient-enhanced product used in therapeutic feeding in clinical and community settings for children with SAM.

The original formulation of RUTF was invented through a collaboration between Nutriset and L'Institut de Recherche pour le Développement (IRD). Following completion of a field trial by Action Contre la Faim (ACF) in

¹ United Nations Children's Fund, World Health Organization and World Bank Group Joint Child Malnutrition Estimates, *Levels and Trends in Child Malnutrition*, WHO, Geneva, 2018.

² Ibid.

³ Greiner, Ted, 'The Advantages, Disadvantages and Risks of Ready-to-use Foods', *Breastfeeding Briefs*, no. 56/57, International Baby Food Action Network, Geneva, September 2014.

1997, the UNICEF Supply Division identified the need to scale and improve affordability and local availability of RUTF, and has been instrumental in scaling the procurement and distribution of a quality-assured product.

UNICEF is now the primary procurer of RUTF for community-based treatment of SAM, a model through which children receive treatment for caregivers (e.g., parent) rather than in a clinical setting.

1. INTRODUCTION

The world is changing faster than ever before, and so too are the challenges facing its most vulnerable. Conflict and displacement, disasters and climate change, urbanization and disease outbreaks are growing increasingly complex and inter-related, demanding new strategies and approaches. Innovation for development – exploring new ways of delivering programmes, with new partners and new technologies – is increasingly recognized as crucial to meeting the Sustainable Development Goals and the promise of the 2030 Agenda for Sustainable Development.

Since 2014, UNICEF embraced innovation as one of its key strategies to achieve results for children. That commitment is reaffirmed in its current Strategic Plan, 2018-2021, and is evident in the organization's programming and institutional architecture. Indeed, since 2014, significant progress has occurred in a relatively short period of time, backed by clear strategic intent and targeted investment. A number of formal structures have evolved, and new milestones achieved.

With the increased foothold of innovation in UNICEF, it is important and timely to take stock of these efforts through high quality evidence to inform decision-making, learning and accountability. In keeping with the need for this evidence, UNICEF conducted a global evaluation of innovation in 2018. The evaluation comes at a time when the organization is considering how best to maximize its resources for innovation and is intended to inform those decisions in an impartial manner, backed by credible evidence.

The objective of the evaluation was to assess UNICEF's 'fitness for purpose' to employ innovation as a key strategy to achieve the outcomes and goals defined in its strategic plans covering the period 2014-2021. It also sought to provide insights on how innovation contributes to UNICEF's goals and objectives, as well as how innovation might contribute to increasingly effective organizational responses in the coming years. The global evaluation was

designed with three core components including: an organizational assessment, a set of innovation case studies and a synthesis project.

The case studies are intended to serve organizational learning by unpacking and examining the multiple pathways and dynamics which underpin innovation within the organization. In addition, the case studies contribute to accountability by assessing the manner in which innovation work in practice reflects the strategies and principles which UNICEF has developed to guide these efforts.

Three objectives guided the work:

- To provide detailed descriptions of a set of innovations across stages of the development continuum inclusive of contextual influences
- To assess the application of innovation principles or other standards for a set of innovations with particular attention to issues of ownership and scale
- To produce clear conclusions and considerations for policy, strategy and management decisions to further enhance innovation as key change strategy.

Cases are defined as *the processes an innovation was identified, developed, tested, implemented and taken to scale along with contextual factors such as underlying organizational and partnership arrangements*. The primary audience for the case studies is internal to UNICEF including senior management and programme managers at HQ, regional and country level. Its uses include informing the implementation of the Strategic Plan 2018-2021 particularly the change strategy focused on innovation. UNICEF commissioned Deloitte LLP to conduct thirteen case studies to examine innovation across the spectrum of innovation types, country contexts and internal (UNICEF) and external (partner, supplier) actors.

All case studies were structured around a modified version of the Deloitte Dublin Framework for Innovation. Within this

framework, four thematic dimensions (i.e. approach, organization, resources and capabilities and metrics and incentives) are seen as necessary to enable successful innovation. Case studies employed a mixed methods approach to build a complete picture of the innovation process and identify findings related to these four thematic dimensions. The evaluation team collected qualitative and quantitative data through desktop review, case study informant interviews and field visits. More information on the methods used appears in Annex A. A listing of stakeholders and interviewees appears in Annex B.

The innovation case examined in this report concerns the Ready-to-Use Therapeutic Foods (RUTF) Scale-Up. RUTF is an energy-dense, micronutrient-enhanced product used in therapeutic feeding in clinical and community settings for children with SAM.

2. INNOVATION AT A GLANCE

This section provides a brief description of what the innovation intends to achieve, its application in the field, and an overview of users.

Ready-to-use therapeutic foods

Nearly half of all deaths in children under 5 years old are attributable to undernutrition, associated with weakened immunity, increased susceptibility to long-term developmental delays and risk of death.⁴ Although moderate and severe wasting are conditions that can change throughout the course of the year (e.g., due to drought), UNICEF/World Health Organization (WHO)/World Bank Group Joint Child Malnutrition Estimates indicate that in 2017, an estimated 50.5 million children were wasted, of

The original formulation of RUTF was invented through a collaboration between Nutriset and L'Institut de Recherche pour le Développement (IRD). Following completion of a field trial by Action Contre la Faim (ACF) in 1997, the UNICEF Supply Division identified the need to scale and improve affordability and local availability of RUTF, and has been instrumental in scaling the procurement and distribution of a quality-assured product. UNICEF is now the primary procurer of RUTF for community-based treatment of SAM, a model through which children receive treatment for caregivers (e.g., parent) rather than in a clinical setting.

This report includes information on the context for the development of RUTF (Section 3), the innovation journey (Section 4), field testing (Section 5), findings (Section 6) and considerations for UNICEF and conclusions (Section 7).

which 16.4 million were severely wasted.⁵ Prior to development of ready-to-use therapeutic foods (RUTF), treatment of severe acute malnutrition (SAM) was completed in clinical settings, which limited the number of affected children health authorities were able to reach and created a resource burden on health systems.⁶ Responding to these challenges, RUTF is an energy-dense, micronutrient-enhanced product used in therapeutic feeding in clinical and community settings for children with SAM.

Intended innovation outcomes

The original formulation of RUTF was invented through a collaboration between Nutriset and L'Institut de Recherche pour le Développement (IRD). Following completion of a field trial by Action Contre la Faim (ACF) in

⁴ United Nations Children's Fund, World Health Organization and World Bank Group Joint Child Malnutrition Estimates, *Levels and Trends in Child Malnutrition*, WHO, Geneva, 2018.

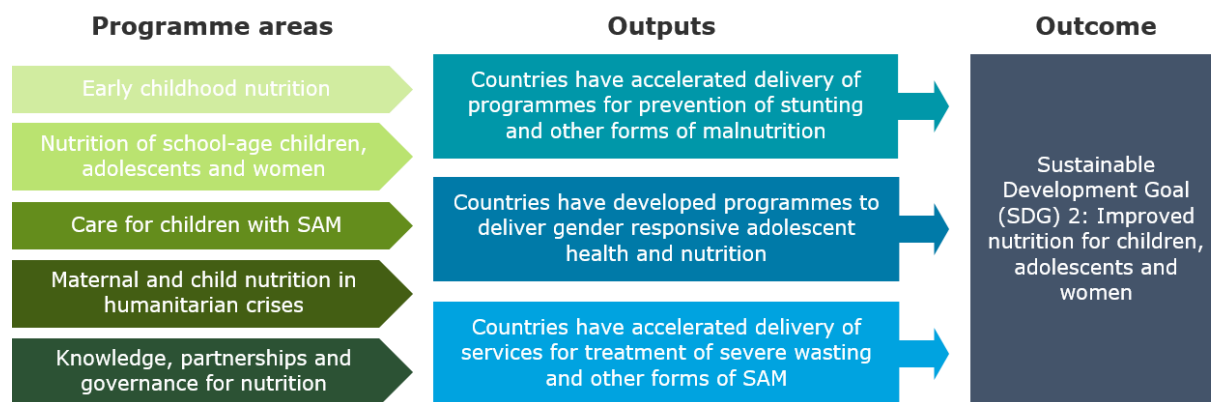
⁵ Ibid.

⁶ Greiner, Ted, 'The Advantages, Disadvantages and Risks of Ready-to-use Foods', *Breastfeeding Briefs*, no. 56/57, International Baby Food Action Network, Geneva, September 2014.

1997, the UNICEF Supply Division identified the need to scale and improve affordability and local availability of RUTF, and has been instrumental in scaling the procurement and distribution of a quality-assured product.

UNICEF is now the primary procurer of RUTF for community-based treatment of SAM, a model through which children receive treatment for caregivers (e.g., parent) rather than in a clinical setting.

Figure 1. UNICEF Nutrition Strategic Plan 2018–2021⁷



The Supply Division established the first long-term agreement (LTA) for 100 metric tons of RUTF, enough to treat 7,200 children (1 metric ton contains 72 cartons of RUTF; 1 carton per child treated) with Nutriset in 2000. Since then, the supplier base has grown to 19 manufacturers, 17 of which are located in programmatic countries (i.e., countries in which UNICEF is active), with procurement levels reaching 52,850 metric tons in 2017. The intended outcomes of RUTF scale up to several programme areas and outputs defined in UNICEF's Strategic Plan for Nutrition 2018–2021 (Figure 1). As the Supply Division continues to scale production and procurement of RUTF and invest in new product innovations, RUTF

could provide valuable lessons for scale-up of innovations at UNICEF, including improvements to supplier capacity, local procurement and product specifications.

Innovation users

The primary targeted users of RUTF are children 6 to 59 months old with uncomplicated cases of SAM, to be used as part of a medical protocol of community-based management of acute malnutrition (CMAM). As part of CMAM, caregivers who administer RUTF treatment are the secondary targeted users of RUTF.

⁷ United Nations Children's Fund, '[UNICEF's Approach to the Double Burden of Malnutrition](#)', UNICEF, New York, 4 October 2017.

3. CONTEXT FOR DEVELOPMENT AND SCALE-UP OF RUTF

Key takeaways

- Childhood **wasting and stunting is steadily declining** globally, but at current progress rates, it is unlikely that the international community will meet World Health Assembly (WHA) or Sustainable Development Goal (SDG) targets
- RUTF is an energy-dense, micronutrient-enhanced food product used in **therapeutic feeding for children with SAM**
- The UNICEF Supply Division **accelerates development and scale of product innovations** that encourage health markets and diversify the supplier base; recognizing the potential to reach more children with SAM, the Supply Division decided to play a market-shaping role **in RUTF scale-up**.

3.1 Development/humanitarian context

Good nutrition is associated with lower burden on national health systems and on improving GDP growth (estimated US\$16 return for every US\$1 invested);⁸ however, malnutrition can cause long-term developmental delays and/or increase the risk of death in children. The UNICEF, WHO and World Bank Group global and regional child malnutrition estimates monitor the various ways in which childhood malnutrition can manifest, including stunting, wasting and overweight.⁹

- **Wasting**, also referred to as **acute malnutrition**, is a condition in which children are measured as too thin for their height, due to rapid weight loss or failure to gain weight. Moderate wasting is defined as moderate acute malnutrition (MAM), while severe wasting is defined as severe acute malnutrition (SAM). Children with acute malnutrition are at increased risk of death due to weakened immunity and long-term developmental delays, but treatment to recovery is possible.
- **Stunting** refers to linear growth retardation due to chronic or recurrent malnutrition, which often coincides with failure of a child to grow cognitively. This results in children measuring as too short for their age; often the conditions associated with stunting are largely irreversible.

- **Overweight** refers to being too heavy for one's height, due to over consumption of calories compared with levels of activity. Overweight puts children at increased risk of noncommunicable diseases (e.g., diabetes) later in life.

Childhood malnutrition is steadily declining globally; however, current levels of progress towards reducing global levels of wasting and stunting will not be sufficient to meet World Health Assembly (WHA) targets in 2025 or the SDGs set for 2030. Further, Asian and African countries account for 96 per cent of wasted children (69 per cent in Asia, 27 per cent in Africa) under age 5 globally, demonstrating an uneven distribution of this form of malnutrition. The scale of global malnutrition challenges will require long-term efforts, and could benefit from partnership between government, international organizations and the private sector. The Supply Division's role as a convener of these groups makes it well suited to drive scale-up of RUTF.

3.2 Innovation context

In 1996, nutritionists developed RUTF, a product intended to improve upon the formulation of therapeutic milk (F-100), which required inpatient care and additional inputs from the end user to prepare the formulation on site. The novel formulation of RUTF presented several advantages over therapeutic milks

⁸ Development Initiatives, *Global Nutrition Report 2017: Nourishing the SDGs*, Development Initiatives, Bristol, UK, 2017.

⁹ UNICEF/WHO/World Bank Group Joint Child Malnutrition Estimates, *Levels and Trends in Child Malnutrition*.

(Table 1). Following field trials completed by ACF in 1997 and large-scale application by Medecins Sans Frontières (MSF) in the Sudan, the international community began to look

more favourably upon implementation and scale-up of RUTF.

Table 1. Uses and characteristics of therapeutic milk and RUTF



Therapeutic milk (F-75 and F-100)

Ready-to-use therapeutic food

Year developed	1993	1996
Benefits	Provides all nutrients needed to recover from SAM	Provides all nutrients needed to recover from SAM with added iron
Preparation	Product reconstituted by caregivers by mixing with heated water	No preparation required
Risks to children	Mixing the product with unclean water presented health risks	Low risk of contamination (lipid-based; long shelf life; no refrigeration required)
Taste	Children did not like the taste	Sweet and peanut-based flavour that children generally prefer
Treatment method	Clinical setting	At home
Cost (per carton)¹⁰	F-75: US\$61.51 F-100: US\$59.20	US\$54.00

3.3 UNICEF programme context

Innovation at UNICEF is most often defined as doing “anything that is new or different that adds value and has concrete impact”. The UNICEF Supply Division, based in Copenhagen, drives external product innovation to prompt and/or accelerate development of fit-for-purpose (i.e., appropriate to achieve the intended results) and value-for-money (i.e., optimal combination of cost, quality and sustainability that meets end-user needs) products with potential to positively affect UNICEF programmes. The unit is able to leverage UNICEF's procurement power (UNICEF procured approximately US\$3.86 billion worth of supplies and services for children in 2017, including US\$219.9 million in nutrition

products) to drive product innovation, initiated when there is an unmet product need in UNICEF programmes and/or emergency response.

The Supply Division accelerates the development and scale of product innovations that encourage healthy markets (the Supply Division Market Dashboard assesses market health based on availability, affordability, competition, quality, acceptability, delivery and funding security)¹¹ and diversify the supplier base; this complements UNICEF's position to understand global needs for new or improved product offerings, convene stakeholders, and drive scale. The RUTF scale-up will contribute to UNICEF's Nutrition Strategic Plan 2018–2021 (Figure 2) and its commitment

¹⁰ United Nations Children's Fund, *UNICEF Nutritional Supply Chain Integration Study: Volume 3 – Annexes*, 2015.

¹¹ UNICEF Supply Division, *'Market Dashboard – December 2017'*, 2017.

to the WHA target to reduce and maintain childhood wasting to less than 5 per cent by 2025. In 2014, the estimated percentage of children with SAM receiving treatment was less than 15 per cent.¹² Scaling production and use

of RUTF to treat children with SAM will therefore play an important role in achieving WHA targets by 2025.

4. THE INNOVATION JOURNEY FOR RUTF

Key takeaways

- After identifying the need to improve treatment of children with SAM, researchers (external to UNICEF) began to explore formulations, and **RUTF was invented in 1996**.
- The Supply Division issued the first LTA for RUTF with Nutriset in 2001 and, as demand for product began to grow, the Division began considering how to **improve capacity of the supplier base** to meet global demand.
- In 2007, UNICEF, WHO, the World Food Programme (WFP) and the United Nations System Standing Committee on Nutrition (UNSSCN) released a **Joint Statement on CMAM**, advocating for a community-based approach to treatment of SAM using RUTF; as CMAM was implemented globally, demand for RUTF experienced significant growth.
- Following a **supply chain analysis** in 2009, the Supply Division continued to diversify the supplier base through a competitive RFP process, positioned buffer stock in strategic locations, and developed a demand forecasting tool to accurately predict annual procurement volumes.
- Developing a **strong regulatory system for RUTF** has been an important aspect of scale-up, since the regulatory environment in programmatic countries tends to be less strict.
- The Supply Division will **accelerate the development of alternative formulations of RUTF**, which are expected to improve local acceptability, reduce costs and increase production capacity, particularly in programmatic countries.

The start of the innovation process typically begins with identification of a problem, for which possible solutions are explored until an ideal solution emerges and can be refined and scaled across an organization. This section describes how and by which processes UNICEF conceptualized and designed the RUTF project.

Figure 2. Progression of the innovation process for RUTF



Needs identification

Improving on existing therapeutic milk

From the 1970s to the early 2000s, therapeutic milks were the preferred treatment option to rebuild wasted tissues and catch up weight of children recovering from SAM. Therapeutic milks were a major step forward from previous nutritional products used to treat wasting in children in terms of effectiveness, coverage and convenience; however, there was growing interest among nutritionists and development practitioners to develop a novel product to improve acceptability and enable at-home treatment of SAM. This was due to the need for additional resources from the end user (who must reconstitute the formula using

¹² World Health Organization, 'Global Nutrition Targets 2025: Wasting Policy Brief', WHO, 2014.

local water supplies, which may be contaminated and unsafe for use), lack of refrigeration, and need for burdensome and costly inpatient care.¹³

Invention of Plumpy'Nut and recognition of RUTF potential

Researchers began to explore formulations to address these challenges to create a product that was easy to use and whose implementation would be superior in emergency situations where SAM is widespread, local food is unavailable, and resources are strained. In 1996, Dr. André Briend and Michael Lescanne invented a new therapeutic food product, replacing the milk powder in F-100 with peanut butter, which resulted in the first formulation of RUTF. Development of the formulation, which was named Plumpy'Nut, was a joint effort between Nutriset and L'Institut de Recherche pour le Développement (IRD) in France. The formulation was a lipid-based spread made of milk powder, sugar, peanut butter or paste, vegetable oil, and vitamin and mineral premix.

Following the completion of the first field trial in Chad conducted by ACF and the Chadian Ministry of Health in 1997,¹⁴ evidence began to emerge regarding the efficacy and benefits of using RUTF instead of previous therapeutic foods.^{15, 16} Further, the compact nature of the energy-dense product reduced ration size, volume consumed, and distribution and storage costs. International organizations including UNICEF began to recognize the potential of RUTF to improve treatment of SAM and change the landscape of therapeutic foods. In particular, the Supply Division recognized the need to scale production and distribution of RUTF.

Scaling up

Growing interest in RUTF

The Supply Division issued the first LTA for RUTF in 2001 with Nutriset, the only qualified supplier manufacturing the product at the time. In 2004, interest and demand for RUTF began to grow, as its efficacy was demonstrated in the field. At this time, SD began considering new sources of the product, in order to improve the capacity of the supplier bases to meet growing global demands. The Supply Division began to work with manufacturers in programmatic countries with the potential to produce RUTF for local use in 2006. Manufacturers in the Niger and Ethiopia were the first to be approved for procurement; however, quality of RUTF production was low in both countries and production capacities were not sufficient to meet local demand, leading to a continuing reliance on imported product. In response, expanding the supplier base, production capacity and quality of RUTF became key components of the Supply Division's contribution to scaling the novel product.

The Joint Statement Community-based management of acute malnutrition (CMAM) was officially endorsed by WHO, UNICEF, UNSSCN and WFP in 2007. The purpose of the Joint Statement was to adopt an approach that would allow for greater numbers of children with acute malnutrition to receive appropriate treatment and recover.¹⁷ The statement described a community-based approach through which children presenting uncomplicated cases of SAM would receive RUTF or other nutrient-dense foods at home. SAM is confirmed in children under age 5 with visible severe wasting, nutritional oedema, or mid-upper arm circumference of less than 115 millimetres measured using a simple coloured plastic strip. Under the CMAM model, uncomplicated cases of SAM can be treated

¹³ Bazzano, Alessandra N., et al., 'The Life Course Implications of Ready to Use Therapeutic Food for Children in Low-Income Countries', *International Journal of Environmental Research and Public Health*, vol. 14, no. 4, April 2017.

¹⁴ Briend, André, et al., 'Ready-to-Use Therapeutic Food for Treatment of Marasmus', *The Lancet*, vol. 353, May 1999.

¹⁵ Briend, André, 'Highly Nutrient-Dense Spreads: A new approach to delivering multiple micronutrients to high-risk groups', *British Journal of Nutrition*, vol. 85, suppl. 2, 2001.

¹⁶ Manary, M. J., et al., Home Based Therapy for Severe Acute Malnutrition with Ready-to-Use Food, *Archives of Disease in Childhood*, vol. 89, 2004.

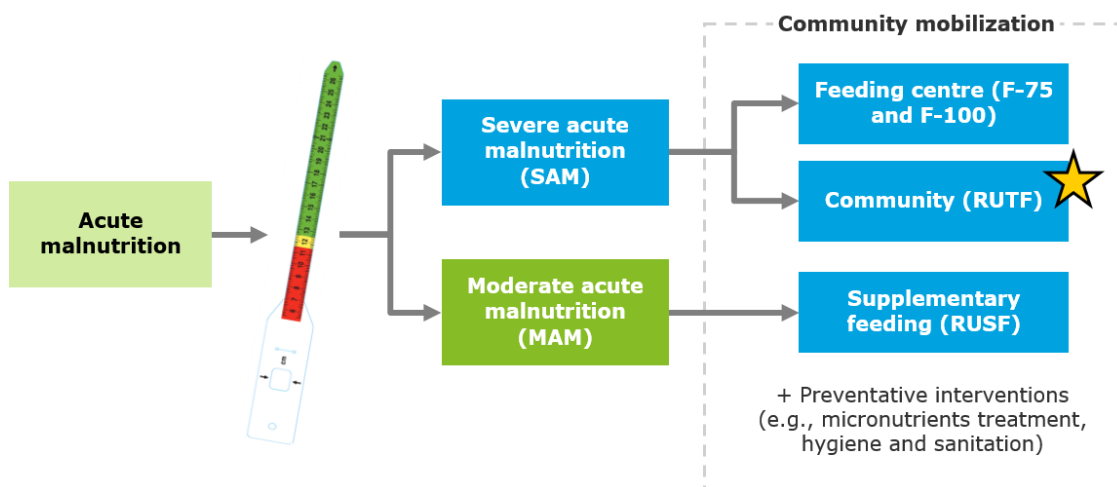
¹⁷ WHO, WFP, UNSSCN and UNICEF, 'Community-Based Management of Severe Acute Malnutrition', 2007.

at home or in the community using RUTF, while cases of SAM that include medical complications or no appetite require inpatient care using therapeutic milk (Figure 3).¹⁸

One of the advantages of CMAM is that Ministries of Health assume coordination and leadership, building on existing health systems and Integrated Management of Childhood Illness guidelines. UNICEF's role in the implementation of CMAM has been to support national efforts to treat SAM, including procurement of therapeutic goods, medicines and equipment, and government capacity-building. Supply Division activities supporting

availability of product have included expanding the supplier base and prepositioning stocks of RUTF closer to programmatic countries; assuring product quality; building the capacity of national governments to procure, import and distribute product; and strengthening in-country supply chains.

Figure 3. Community-based management of acute malnutrition (CMAM) model



International adoption of the CMAM model has contributed significantly to increasing the use of RUTF (demand nearly doubled the year following the Joint Statement)¹⁹ as the preferred means for SAM treatment. Although the Joint Statement included provisions of 'other nutrient-dense foods' in community-based treatment of SAM, international agencies have focused on implementing and scaling RUTF due to its availability and ease of

use. However, advocacy for use of RUTF to treat SAM may have hindered (and may continue to hinder) the use and scale-up of potentially more cost-effective and sustainable alternatives. Further, the use of locally produced and/or enriched foods, while requiring greater upfront effort to train community members, may have positive long-term results and greater food security in non-emergency situations.

¹⁸ Bazzano, 'The Life Course Implications'.

¹⁹ United Nations Children's Fund, *A Supply Chain Analysis of Ready-to-Use Therapeutic Foods for the Horn of Africa: The Nutrition Articulation Report*, UNICEF, May 2009.

Barriers to scale: The case for community-based solutions to SAM

In 2009, at the request of two state-level governments, UNICEF imported a large quantity of RUTF from Nutriset for use in nutrition rehabilitation centres in India. The Government of India stated that the action was unauthorized, following which the supplies were moved to surrounding countries.¹ While RUTF is used in emergency and non-emergency settings, only approximately 20 per cent of product is procured for emergency response, and some argue against its use in response to chronic malnutrition. Policies of the Indian Government advocate for decentralized and community-based solutions favouring indigenous foods to prevent and respond to acute malnutrition; internationally produced and processed RUTF products are viewed as ignoring the underlying causes of malnutrition. Further, concerns exist that importation of RUTF to treat SAM could undermine food security and create unnecessary dependence, whereas use of locally produced products promotes local agriculture and livelihoods.¹ Since 2009, the Government of India has maintained its stance against importation of RUTF in preference of a variety of locally procured therapeutic food products.

The Indian example highlights the importance of government buy-in during scale-up, and provides contrasting perspective on what constitutes appropriate use of RUTF in cases of chronic malnutrition versus emergency contexts (e.g., refugee camps where children often lose access to normal supply of food). In cases of widespread chronic malnutrition, alternative recipes using local ingredients may provide a more sustainable solution, whereas RUTF is better suited to nutritional emergencies. Further, the advantages of products based on indigenous foods (e.g., stimulating local economies, greater acceptability and affordability) present a compelling argument for development of alternative formulations to provide buyers of RUTF greater variation in options from which to choose according to local context.

Supply chain strengthening

In 2008, UNICEF was not able to meet global demand for RUTF, which rose as a result of famine in the Horn of Africa. During the emergency, only 27 per cent of deliveries to the Horn of Africa arrived on time, and deliveries to other regions were delayed an average of three months. Based on the inability to meet growing global demand, the Supply Division made the decision to open the market to new RUTF manufacturers through a competitive RFP process. The Supply Division also commissioned a study to identify gaps and opportunities for the RUTF supply chain in Ethiopia, Kenya and Somalia.²⁰ The analysis considered the entire supply chain, including planning, production, procurement and delivery. Findings of the study identified several bottlenecks for procurement of supplies, including transportation duration and cost (e.g., air transport can reduce time but increases cost per kilogram from US\$0.17 to US\$2.40), accurate demand forecasting, and limits to production capacity.

Supply chain strengthening (Figure 4) undertaken, following the study conducted by the University of North Carolina and Duke University, included:

- Continuing to diversify the supplier base through a competitive RFP process through which the Supply Division establishes LTAs with companies that meet the technical requirements.
- Pre-positioning buffer stock in strategic locations through a dual supply sourcing strategy to increase the responsiveness and flexibility of procurement in response to sudden spikes in demand.
- Developing an Excel-based global demand-forecasting tool that makes more accurate predictions based on monthly admissions of children into feeding programmes, provided by country offices.

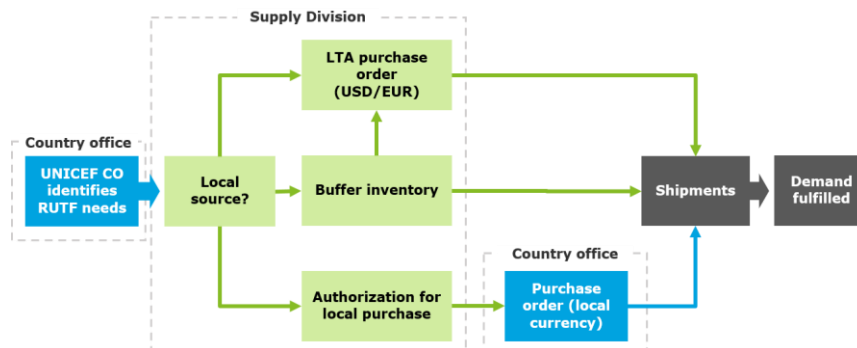
The Supply Division has worked closely with suppliers to increase production capacity, which has improved its ability to respond to emergencies. In 2011, the Supply Division was able to meet a sudden increase in demand caused by a severe drought in Africa, while maintaining uninterrupted global supply. Although the UNICEF Financial Rules and Regulations do not allow investment or loaning of money to suppliers, one of the key barriers to support development of domestic capacity and markets, it provides communication and

²⁰ UNICEF, *A Supply Chain Analysis of Ready-to-Use Therapeutic Foods*.

networking opportunities between suppliers and financing partners through the Manufacturer Financing Database.²¹ The database provides a suite of financing options (e.g., through banks, cooperatives, foundations) for activities that will generate

positive financial and social returns. Annual industry consultations also provide opportunities for suppliers and potential financing partners to make connections and better understand financing requirements.

Figure 4. Strengthened RUTF supply chain following identification of bottlenecks



Enablers of scale: Evolution of the RUTF patent

In 1997, Nutriset registered a patent for the process and method of production of RUTF. The existence of the patent could have limited local production of the product; however, following initial interest and buy-in from international agencies, Nutriset established the PlumpyField network, a franchise model through which manufacturers are licensed to produce Plumpy'Nut; in 2017, Nutriset's global production capacity had increased 7.5-fold since its establishment, to 114,000 metric tons.¹

In 2010, IRD and Nutriset released its patent online, opening RUTF production to independent producers (through a Patent Usage Agreement through which beneficiaries contribute 1 per cent of annual revenue to IRD to fund research and development) in developing countries in which the PlumpyField network does not operate.¹ This followed increasing public pressure after publication of an article in the *New York Times*¹ criticizing the ethics of holding a patent for life-saving products, which could lead to a monopoly and inflated prices (at the time, treatment of one child with Plumpy'Nut cost approximately US\$60). While the existence of the patent has limited production of RUTF in Western countries, so far it has not presented a significant issue for production in programmatic countries.

One of the objectives of the RUTF project in the Supply Division is to reduce cost. Several factors have influenced the unit price of the product over time, particularly those manufactured in programmatic countries (Figure 5), where the weighted average price is more expensive than offshore procurement. This is especially true for small-batch manufacturers in programmatic countries,

which typically have to pay higher prices for raw materials than larger companies that can buy materials in bulk. While cost reduction has been an important component of RUTF scale-up, the Supply Division is often willing to accept slightly higher prices for locally produced product, balanced by the advantages of such procurement.

²¹ United Nations Children's Fund, 'Sources of Financing for New and Growing Manufacturers', 2018.

Figure 5. Advantages and challenges to locally procured RUTF

Advantages of locally procured product



Cost efficiency

Supply chain management cost efficiency gained due to close proximity to the source



Lead time

Reduced lead time from the time an order is submitted to the time it is delivered



Acceptability

Better acceptability and/or government endorsement of locally produced product



Development

Local production of RUTF contributes to development objectives (e.g., creating jobs)

Challenges with locally procured product



Increased cost

Importation of ingredients (e.g., milk powder, peanuts, vitamin-mineral mix) and materials (e.g., packaging) more expensive



Tax exemptions

Imported finished RUTF products are tax exempt due to their programmatic purpose



Production capacity

Challenges attracting investment capital to expand production; high interest rates on capital loans



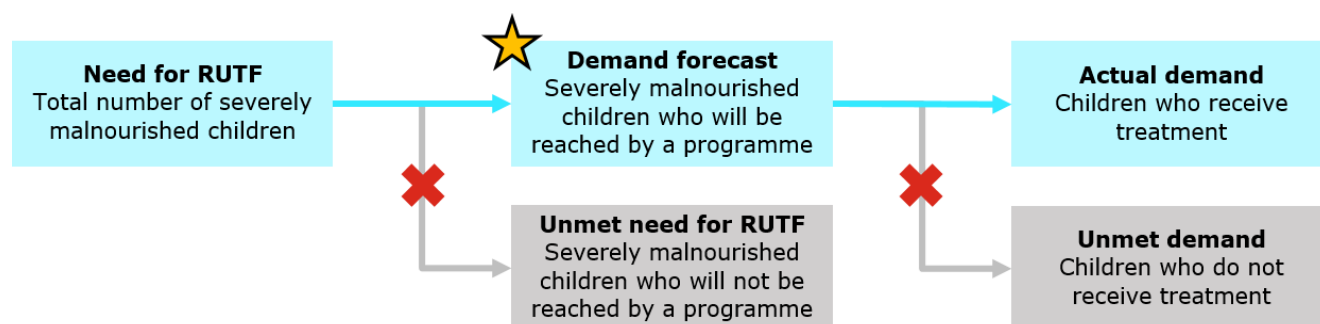
Regulations

National standards may not be sufficient; access to quality testing labs for quality assurance may be limited

In order to allow manufacturers to plan for short- and long-term procurement and associated investment in production capacity, SD prepares annual demand forecasts. However, demand forecasting is not based on the global need for RUTF to treat cases of SAM, but rather the number of children with SAM who will be reached by a program in a given year (Figure 6). Annual demand forecasts are

informed by input from COs, and are reviewed by PD prior to finalization; key trends such as funding availability, supply-chain improvements, and new countries introducing CMAM are also considered. Nutrition programme information collected and shared by partners through the Nutrition Dashboard (NutriDash)²² complements this information, increasing forecast accuracy.

Figure 6. Need versus demand for RUTF



²² United Nations Children's Fund, 'NutriDash: Facts and figures – Nutrition programme data for the SDGs (2015–2030)', UNICEF, New York, 2017.

Since the number of children reached by nutrition programmes globally is limited by the resources available across the spectrum of nutrition-related interventions (e.g., preventive, curative, emergency response), funding availability has limited the rate at which scale-up of RUTF can occur. The RUTF scale-up process has taken a market-driven approach and is part of the Supply Division's regular procurement processes. However, the majority of RUTF is procured using donor funding (e.g., in 2015/16, the United States Agency for International Development (USAID) provided an in-kind donation of 10,000 metric tons of RUTF, accounting for 12.8 per cent of the total volume procured through UNICEF). In order to improve scale-up and sustainable procurement of RUTF, the Supply Division is exploring co-financing options for RUTF. Ideally, national governments would accept greater ownership and include a budget for procurement of RUTF for treatment of SAM. To facilitate this movement, project team members from the Supply Division Medicines and Nutrition Centre (MNC) are working to have RUTF included on the WHO Essential Medicines List (EML)²³ to encourage the treatment of children with SAM through domestic health systems. Inclusion on the list would assist with long-term budgeting and planning and reduce reliance on donor funding, accelerating sustainable scale-up.

Improving quality standards

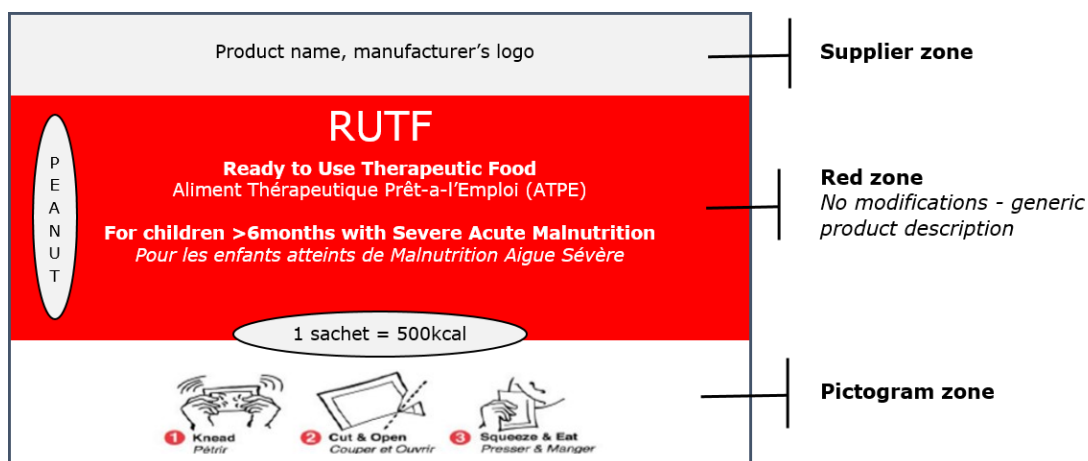
Since the regulatory environment in programmatic countries in which RUTF is produced can be less strict, fostering a strong regulatory system played a key role in scale-up; this was expressed by three interviewees (Supply Division, partner, manufacturer). Quality assurance is monitored for RUTF products using several different strategies. As a

condition of LTAs, all manufacturing sites must be approved by the Supply Division Quality Assurance Centre, or a selected representative (e.g., MSF). Good Manufacturing Practices inspections, in which local authorities are invited to participate, are intended to ensure compliance with UNICEF requirements. Quality control of direct shipments is also a component of quality assurance, as a third-party contractor performs pre-delivery inspections of product, including randomized microbiological and analytical testing, and aflatoxin (a toxin present in peanuts) testing. Combined, these processes have increased the rigour of the manufacturing process, protecting children from exposure to harmful pathogens.

A key strategy for diversifying the supplier base and increasing production capacity in programme countries has been incremental increases to quality assurance processes. Throughout the scaling process, UNICEF has held supplier conferences during which changes to specifications and ways to improve quality (e.g., aflatoxin management) have been communicated. For example, during a supplier conference in 2012, the Supply Division and MSF provided an update to industry on harmonized product specifications (Figure 7). The standardization of packaging was an important step in the quality-assurance process in order to (1) improve packaging standards among manufacturers and (2) avoid confusion between packaging of the same product, which was highly variable in terms of colour (red signifies that the product serves a medical purpose), size and materials. The approach taken by the Supply Division and its partners allowed manufacturers in programmatic countries a 'catch-up' period, during which product was procured while improving production capacity and processes.

²³ World Health Organization, *WHO Model List of Essential Medicines: 20th list*, WHO, 2017.

Figure 7. Standardized RUTF product packaging



Another key component for improving quality standards of RUTF has been through the Codex Alimentarius' Code of Hygienic Practice for Low-moisture Foods. The Codex, adopted in 2015, sets regulations to ensure safe foods for international trade and provides manufacturers with Food and Agriculture Organization (FAO) and WHO guidance on microbial safety of ready-to-use food (RUF) products.²⁴ Inclusion of RUF for acute malnutrition in the Codex required significant input and coordination from the Supply Division

MNC, which worked with the Codex Committee for Nutrition and Foods for Special Dietary Uses and the Codex Committee for Food Hygiene. Despite inclusion of RUF products in the Code of Hygienic Practice for Low-Moisture Foods, several quality-related challenges remain. These include lack of regulation in many programmatic countries, in response to which UNICEF and its partners have incrementally developed specifications and quality-assurance processes to which manufacturers must adhere.

Barriers to scale: Restoring trust after *Cronobacter sakazakii*

Cronobacter are a family of pathogens that are present in a wide range of food products, and have been linked to a variety of infections including meningitis, particularly in infants fed on powdered infant formula.¹ Recognizing that there may be a risk to children with SAM associated with *C. sakazakii* present in powdered milk, a key ingredient of RUTF, the pathogen was added to RUTF specifications in 2009. This decision led manufacturers to fail quality-assurance testing and, by March 2013, some 12 suppliers within the PlumpyField network were affected. Upon failing testing for the bacterium, manufacturers were required to destroy affected product, resulting in significant financial losses for manufacturers and a global shortage of RUTF.

In 2012, a FAO/WHO technical meeting was held in Rome to discuss the implications of the presence of *Cronobacter* in RUTF and ready-to-use supplementary food (RUSF). They found that while little was known of the epidemiology of *Cronobacter*, the risk was highest in high-risk infants, and its presence in RUTF and RUSF was therefore of low risk. However, the panel found that the specifications for *Salmonella* were weak and should be enhanced, in order to better protect children with SAM. Ultimately, the recommendations emerging from this meeting were to control for the larger group of *Enterobacteriaceae*, which includes *Cronobacter*. The supply-chain issues associated with *C. sakazakii* included the destruction and/or quarantine of RUTF supplies, leading to stock-outs for many programmes.¹ This has led two manufacturers of RUTF to question the Supply Division's scientific basis for decision-making and fear of reputational risk that ultimately resulted in children with SAM not receiving the treatment needed to recover.

²⁴ Food and Agriculture Organization and World Health Organization, *Code of Hygienic Practice for Low-Moisture*

Foods: Codex Alimentarius International Food Standards, 2015.

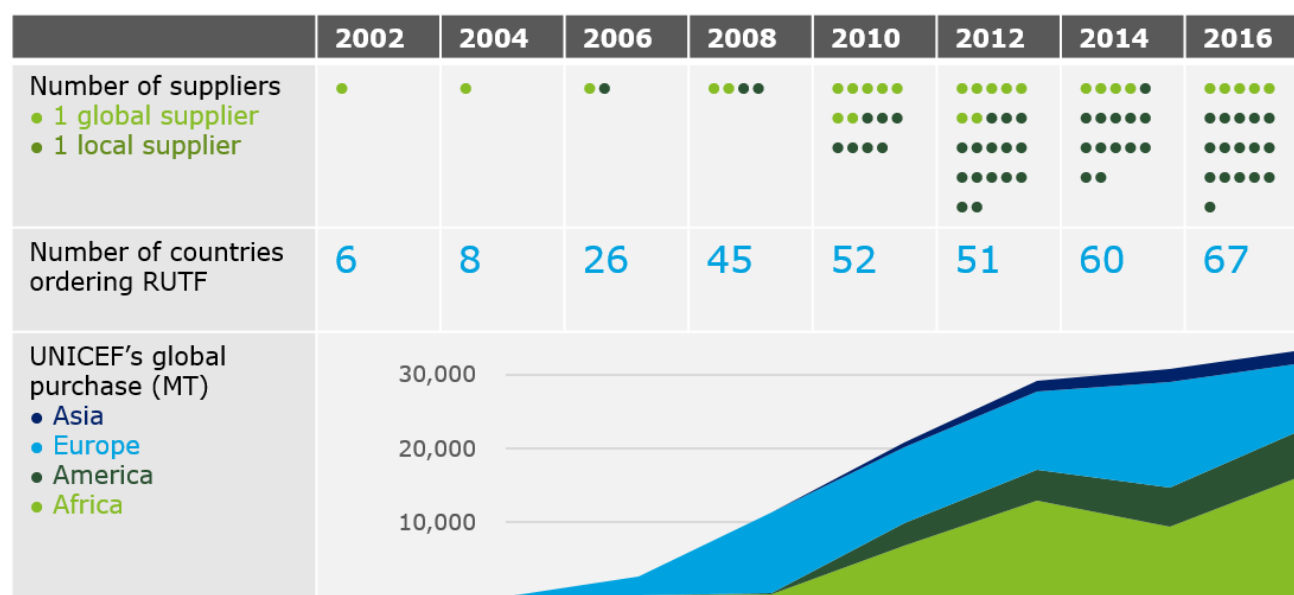
Outcomes

Outcomes of RUTF scale-up

The Supply Division's long-term procurement objective is to achieve affordability and local availability of RUTF. Outcomes of this strategy include building and maintaining a reliable supplier base to meet growing demands at a competitive price (including unit price, transportation and storage costs); and supporting development of a sustainable

supplier base in programmatic countries (including the objective to source 50 per cent from manufacturers based in programme countries by 2016). Since UNICEF became involved with the scale-up of RUTF, significant progress has been made towards these objectives (Figure 8).

Figure 8. Trends in RUTF procurement 2002–2016



Unintended consequences of RUTF scale-up

The scale-up process of RUTF has undoubtedly changed the landscape of how SAM is treated, particularly in emergency contexts (e.g., drought, refugee camps); however, the unintended potential and/or real consequences of expansion of RUTF production and use present several concerns.

- **Influence on taste preferences:** Research has demonstrated that exposure to foods

early in life can influence dietary habits when older, and nutrition products could therefore lead to obesity and chronic disease.²⁵ Providing sweet, fatty foods utilizing non-local ingredients to young children could negatively influence future food behaviours. Alternative formulations of RUTF reflecting local foods could minimize this risk.

- **Replacement of long-term nutritional services:** Prolonged availability of RUTF at

²⁵ UKAID and Human Development Resource Centre, 'The Use of Nutrition Products for the Prevention and Treatment of Undernutrition', 9 February 2011.

the community level could change nutrition behaviours and the availability of nutrition counselling services.²⁶ As countries mainstream treatment of SAM with RUTF through CMAM, it is important that preventive programmes remain a priority at the health-centre level, in order to reduce the future burden of SAM on health systems.

- **Replacement of indigenous food therapies:** Prolonged availability of RUTF at the community level could discourage the consumption of local foods and enriched local foods for therapeutic feeding (e.g., oil- and protein-enhanced 'super-wot' used in Ethiopia²⁷). While use of RUTF enables treatment of greater numbers of children with SAM, replacement of local alternatives previously used as treatment could change food behaviours (see above) and/or displace the benefits of local production (e.g., supporting the local economy and farmers, suited to local taste preferences, and greater acceptability).
- **Improper use:** In some contexts, studies have identified misuse of RUTF as an issue. In Chad, RUTF has developed a high commercial value at the community level, and has been diverted for adult consumption, and some health professionals suspect that caregivers intentionally lower the weight of children before bringing them to health centres.²⁸ The high value of RUTF used at the community level could lead to these types of behaviours, which could reduce effectiveness of treatment of severely wasted children.
- **Alternative formulations at a better unit price:** Several alternative formulations of RUTF been developed and tested by public and private organizations, utilizing locally available products that tend to be more cost-effective than milk powder and

imported peanuts. For example, a study in Ethiopia, Ghana, India and Pakistan tested RUTF formulated using only local ingredients; in all but Pakistan, acceptability of the alternative formulations was similar to that of RUTF, and 40 per cent less expensive.²⁹ The Supply Division's decision to procure and scale the original formulation RUTF may have limited the potential for commercial success (locally and internationally) of these products.

Recognition and exploration

The pursuit of alternative formulations

Since as early as 2010, the Supply Division has recognized the potential need for alternative formulations of RUTF, iteration being an important aspect of the innovation process. Based on feedback from eight interviewees (four Supply Division, one Innovation Review Board (IRB), one partner, one supplier), the primary benefits of new recipes would be cost reduction and use of local ingredients. Novel formulations of RUTF may:

- Lower cost of production (e.g., replace expensive milk powder)
- Encourage production in programmatic countries
- Replace problematic ingredients (e.g., regional taste preferences, aflatoxin content and peanut allergies)
- Favour use of indigenous ingredients (e.g., chickpeas, lentils), thereby reducing cost, avoiding reliance on imports, and generating positive social and economic impacts
- Improve acceptability of RUTF recipes.

By accelerating the development and commercial availability of alternative formulations, the Supply Division will be able to leverage its convening and procurement power to improve the current version of RUTF,

²⁶ UKAID and Human Development Resource Centre, 'The Use of Nutrition Products'..

²⁷ Bazzano, 'The Life Course Implications'.

²⁸ Grünewald, François, et al., 'Real Time Review of the DFID Funded Humanitarian Programmes in the Sahel 2013–2014', DFID, 2014.

²⁹ Weber, Jacklyn, et al., 'Acceptability of Locally Produced Ready-to-Use Therapeutic Foods in Ethiopia, Ghana, Pakistan and India', *Maternal and Child Nutrition*, vol. 13, no. 2, January 2016.

which has not changed since its invention. By reducing cost, increasing potential for local procurement and improving the cultural acceptability of a range of products, alternative formulations could better respond to user needs and improve the sustainability of procurement. While managing multiple formulations of RUTF will increase the

complexity of procurement for SD and its partners, this action presents an opportunity to manufacturers, researchers and other organizations to improve on the current formulation and better respond to the global challenge of acute malnutrition.

5. RUTF FIELD TESTING

Key takeaways

- RUTF are procured by country offices, which submit orders through the Supply Division; procurement has grown about 500 per cent since 2009, with the highest levels of procurement occurring in African country offices.
- Although a formal framework for demand forecasting of RUTFs was not available to case study investigators, stakeholders indicated that increased demand for RUTF supplies is linked to acute emergencies, leading to increased SAM and, also, to the increased availability of donor funding for supplies in the area of nutrition.
- In Ethiopia, the positioning of RUTF as a medicine (as opposed to food product) is clearly evident, although staff and health workers continue to face challenges with supply leakages and misuse, indicating a potential need for optimization of the supply chain at a local level.
- With increasing production capacities of local suppliers, lack of transparency on the policies for local and global procurement of RUTFs has the potential to contribute to strained relationships between local suppliers and UNICEF.

Ultimately, an innovation is taken by users and applied to meet their specific needs. At UNICEF, an innovation can move from concept to practice typically when it enters use by country offices and encounters the very real challenges associated with its use in complex in-country ecosystems.

In this section, the use of RUTF by country offices is discussed. This section identifies how the procurement of RUTF is managed by

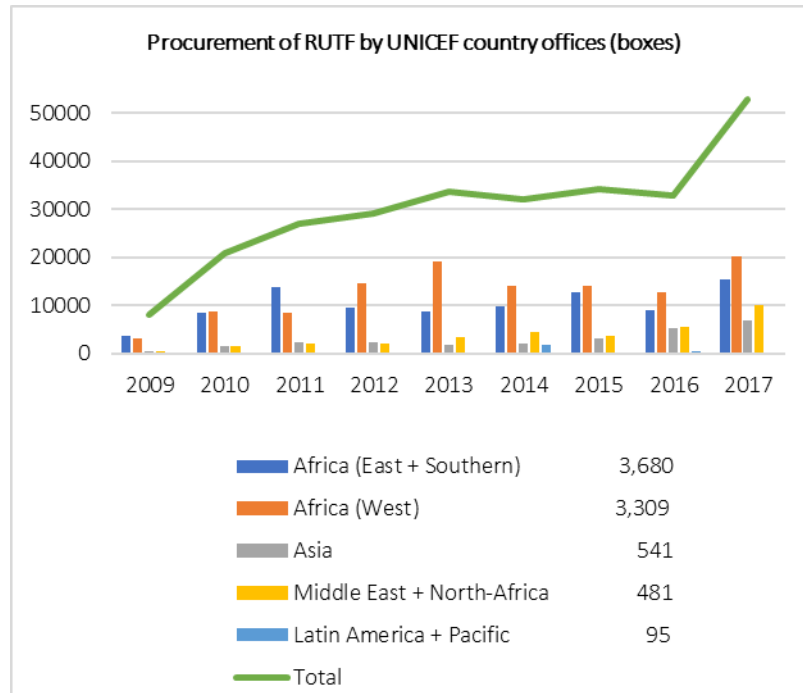
country offices and how they are deployed to reach malnourished children. This section describes how the innovation has met (or failed to meet) the expectations of users and shares lessons learned from the field. These lessons learned have implications on how to improve upon the design of the product, enhance procurement processes, and provide insight into considerations for the design and scaling of future product innovations.

5.1 Use of RUTF at UNICEF globally

Demand for RUTF globally has grown substantially since introduction in 2009, with the

highest levels of procurement occurring in African country offices.

Figure 9. UNICEF global RUTF demand



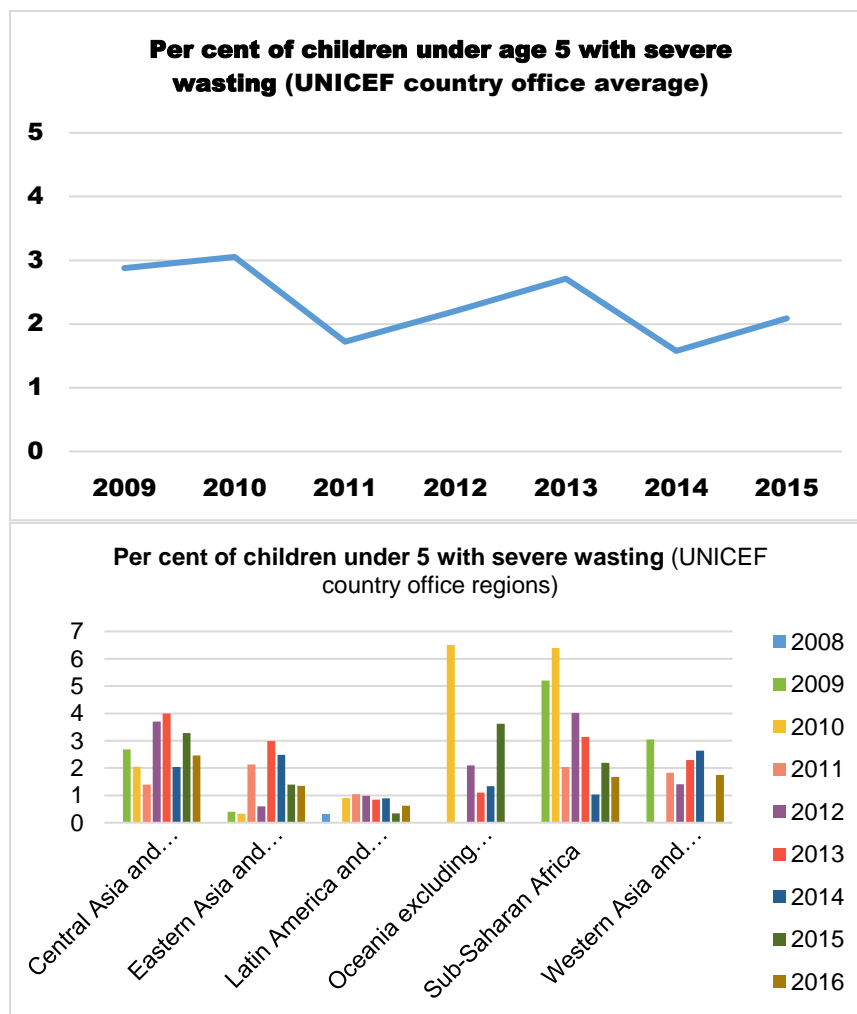
Estimating demand for RUTFs is a particular challenge, as RUTF are often deployed in emergencies, with levels of SAM driven by unpredictable political and environmental factors such as drought and conflict. In 2016, RUTF orders were significantly less than the programmatic estimates of a 30 per cent annual increase – with a 9 per cent overall decrease.

Based on discussions with case study informants and a review of strategic documentation, a number of drivers have been identified as potential factors in increasing demand globally, including:

- **Increased levels of SAM.** In some country offices, demand may be driven by increased need, with increased diagnosis of SAM due to emergencies or scaling up of CMAM to new regions. The extent to which demand is being driven by these factors requires further consideration.

Central Asia and South Asia currently have the highest levels of severe wasting in children under age 5, with relatively stable levels of SAM compared with sub-Saharan Africa, where significant fluctuations in wasting are notable. Procurement of RUTF by UNICEF in Asia remains relatively low compared with the African region, although demand increased throughout 2015–2017. Strategic documentation from 2015 indicates that the Supply Division is aware of the challenge of 'creating demand' for RUTF in Asian countries (particularly India), where levels of SAM are high.

Figure 10. Incidence of severe wasting in UNICEF regions and globally



- Increased funding for RUTF.** In some country offices, demand may be driven by availability of donor funding for procurement of RUTF. Based on discussion with one case study informant, country offices may be driven to purchase RUTF based on receiving donor funding earmarked for such supplies, as opposed to being based on a specific identified need in-country. The role of donor funding in contributing to demand for RUTF is partially reflected by references to delayed arrival of funding for orders in 2015 strategic

documents.³⁰ Further, while annual forecasts for supplies were not available to the case study team in order to reconcile estimates, it appears that Supply Division forecasts could be based on the availability of earmarked funding for purchase of RUTF, as opposed to specific need in the field. Orders are only placed once funding is received, which, according to one report, “suggests that annual order volume is less indicative of need than funding availability”.³¹

³⁰ United Nations Children’s Fund, ‘2016 Procurement Strategy RUTF’, UNICEF internal document, 2015.

³¹ United Nations Children’s Fund, ‘A Supply Chain Analysis of RUTF for the Horn of Africa: The Nutrition Articulation Project’, UNICEF commissioned study, 2009.

5.2 A glimpse into the use of RUTF: Ethiopia

Given the prevalence of severe acute malnutrition in Ethiopia, the country office has been one of the main users of the RUTF in UNICEF. Compared with other countries in the region, Ethiopia has seen slow progress in addressing of undernutrition and chronic malnutrition. This is particularly evident in eastern Ethiopia, where recurrent droughts beginning in 2015 have resulted in insufficient food production at a household level and global increases in food prices have resulted in food insecurity.³²

Who are the stakeholders involved?

- **Procurement of RUTF:** The Supply Division places orders based on requisitions from the Ethiopia Country Office.
- **Management of UNICEF country supply, including local supplier relationship management:** UNICEF Ethiopia Country Office Nutrition and Supply Divisions. The Ethiopia Country Office receives orders from the Regional Office and requests inventory from the Supply Division. The Ethiopia Country Office also works closely with a local Ethiopian supplier of RUTF, providing demand forecasting when available, to aid the local supplier in planning production. Based on discussion with one regional office, RUTFs were delivered on time and no shortages were experienced in Amhara between 2017 and 2018.
- **Management and storage of UNICEF regional supply:** The Regional Office submits orders to the Ethiopia Country Office based on demand from the Government and other partners. It also aids in managing storage, transport, and delivery. Based on discussion with two Regional Office informants in Amhara, the price of a box of RUTF was not known by the Regional Office.
- **Provision of RUTF and technical assistance to partners:** UNICEF Ethiopia Country Office and Regional Office nutritional specialists. The main partner of UNICEF in the treatment of SAM is the Government of Ethiopia. At multiple levels, the Ethiopia Country Office supports the Ministry of Health through order and delivery management of RUTF, training and oversight of health workers, monitoring of RUTF use, and policy support. The Regional Office also aids in identifying RUTF demand, the distribution of goods in the existing health-care system and parallel systems, such as feeding centres established for CMAM, and in providing guidance in the management of supplies once they reach their final destination.
- **Provision of RUTFs to mothers:** Front-line health workers, including local community health workers, nurses, and doctors, prescribe RUTFs when a child meets the criteria for SAM. This criteria have been set by the Ministry of Health, in consultation with the WHO. Local health offices also identify when there is need for more RUTFs and place orders with the Ministry of Health.
- **Feeding of children:** Mothers or other family members are responsible for feeding the malnourished child with the RUTF as prescribed.
- **Monitoring of RUTF quality:** Médecins Sans Frontières (MSF). MSF is involved in ground monitoring of the quality of RUTF and works directly with CMAM providers to impart good treatment practices.
- **Local production of RUTFs:** HILNA Enriched Foods. Based near Addis Ababa, HILNA primarily manufactures Plumpy'Nut and Plumpy'sup, although the company is beginning to expand to commercial peanut-based goods. The company is currently exporting RUTF to Kenya, Djibouti, Somalia and Yemen for use by UNICEF and other humanitarian actors. It is a member

³² Abdulahi, A., et al., 'Nutritional Status of Under Five Children in Ethiopia: A systematic review and meta-

analysis.', 2017, retrieved from www.ncbi.nlm.nih.gov/pmc/articles/PMC5440832/#R43.

of the PlumpyField network. High costs were associated with the purchase of manufacturing equipment for Plumpy'Nut. HILNA, with help from UNICEF, received funding for the purchase of the equipment from private donors, with the requirement that HILNA provided the value of the equipment in-kind to UNICEF in the form of product.

- **Technical assistance and patent ownership:** Nutriset is a joint owner of HILNA, based on the sale of shares. As part of this agreement, Nutriset provides technical assistance to HILNA in the area of manufacturing to ensure that a sufficient quality of RUTF is produced and enhance the capability of HILNA to meet demand.
- **Other RUTF buyers:** Humanitarian organizations and government. Nutritional products produced by the local supplier are also sold to other humanitarian organizations working in Ethiopia, including hospitals, NGOs and charities and directly to government associations, such as Public Health Ministries.

How is the innovation funded?

Procurement of RUTFs is primarily funded by donors, although regular UNICEF resources are also budgeted for supplies.

- **Donor funds:** Funding for provision of RUTFs is received by the ECO from donors in the form of in-kind donations or cash. Financial support is provided based on funding proposals submitted by the Ethiopia Country Office on a regular basis. At the time of writing this report, demand for RUTF has decreased in Ethiopia due to improved agricultural conditions. Thus, the level of funding currently available for procurement of RUTF is limited.

This case study did not attempt to estimate the cost associated with the management of the RUTF supply chain and management of RUTF treatment in Ethiopia.

5.3 Lessons learned

Based on discussions with UNICEF Ethiopia Country Office and Regional Office staff members, a community health worker and local supplier, and a review of existing literature from the Horn of Africa, a number of key challenges and opportunities related to the use of RUTF were identified:³³

- **There may be unintended consequences from the use of RUTF:** Supplies in a humanitarian and development context are often associated with unintended consequences. Further work should be done to uncover the potentially negative consequences of RUTF shared by case study informants. These include the misuse or misappropriation of RUTF; leakage of RUTF into unintended markets; environmental impacts of RUTF packaging and production processes; and unmet demand for RUTF (particularly hypoallergenic, non-peanut based product) in Ethiopia. Leakage was highlighted as a particular concern in Ethiopia. Several UNICEF programmatic staff members in the Regional Office and Ethiopia Country Office noted that mothers with several children may sell RUTF on the market in order to purchase food for *all* family members, including children who not been diagnosed with SAM but who may also be malnourished. In situations such as this, the Ethiopia Country Office may look for other supply management practices that empower mothers to care for all children while ensuring the acute needs of SAM children are met through RUTF.

Local health offices are also contributing to managing leakage, with one interviewee indicating requiring that mothers return empty packages of RUTF upon completion of one cycle of feeding. In addition, a deliberate effort is made to communicate that RUTF are a medicine, as opposed to a food supplement. The Ethiopia Country Office has deployed monitors to ensure quality and provide on the job training and

³³ It is important to note that the majority of these lessons learned are based on anecdotal evidence from a limited

number of stakeholders, except in cases where specific literature is referenced.

coaching to health extension workers with the goal of both improving diagnosis and treatment and reducing misuse and leakage. A 2013 study conducted by Ethiopia Country Office monitors indicated 12 per cent suspected leakage of RUTF (unintended diversion of RUTF), with short-deliveries identified as the primary contributor to loss (i.e., administration errors and theft). Ultimately, 4 per cent of RUTF supply was approximated as ending up for sale in shops.³⁴

- **Demand for product improvements to RUTF is evident.** Based on discussion with local programmatic staff members, there remains a continued opportunity to improve Plumpy'Nut. One health office worker indicated that the high peanut content increases thirst in children – in areas where access to clean water is a challenge, this presents issues to conformance with using RUTFs as prescribed. A health office worker, local suppliers, and local UNICEF nutrition staff member all agreed that increasing the diversity of the RUTF product line would be beneficial. This does not just mean improvements with the goal of enhancing outcomes for children directly, but also improvements to the packaging to benefit the environment and to the product to reduce appeal to adults and enhance the local perception of RUTF as a 'medicine'. Optimization of RUTF remains an area of study beyond UNICEF, with substantial research conducted by nutritionists in this area from 2015 onward.³⁵

- **Unclear requirements for local procurement of supplies place a strain on local suppliers.** It is not clear whether there is a UNICEF policy related to the global versus local purchase of RUTF. During discussions with the local supplier and Ethiopia Country Office, the issue of local versus global procurement was raised as a key challenge for both organizations. It appears that the Ethiopia Country Office does not have control over where product is purchased. Previously, the Ethiopia Country Office has suffered from stock-outs due to transportation issues and labour strikes in European firms. One senior Ethiopia Country Office case study informant indicated that the market potential for procurement of all RUTFs from the local supplier is high and that they do not understand why the Ethiopia Country Office does not receive all its products from a local supplier.

This lack of transparency on the drivers of local versus global procurement further impacts local suppliers. While visiting the factory in Ethiopia, it was evident that the supplier had taken significant steps to increase production capacity with the expectation that additional products would be procured by UNICEF. Storing large amounts of unpurchased RUTF costs local suppliers in storage fees and can ultimately contribute to wastage in the form of spoiling or consumption of the product by pests such as mice.

³⁴ United Nations Children's Fund, 'Reducing RUTF Leakage in Ethiopia: RUTF leakage and misuse survey of the CMAM programme supply chain in Ethiopia', UNICEF country office internal report, 2013.

³⁵ Based on scan of academic journals. One such article relevant to UNICEF could include: Briend, A., et al., 'Developing Food Supplements for Moderately Malnourished Children: Lessons learned from RUTF', *Food and Nutrition Bulletin*, vol. 26, no. 1, 2015.



6. FINDINGS

6.1 Approach dimension

1. How does this innovation contribute to UNICEF country and global strategies?

At the global level, scaling of RUTF contributes to UNICEF's **Nutrition Strategic Plan 2018–2021** (and contributed to previous versions) and the **WHA target to reduce and maintain childhood wasting to less than 5 per cent by 2025**. RUTF also contributes to country-level strategies related to treatment of SAM and emergency (e.g., drought, refugee camps) response during which children may lose access to normal supply of food.

2. What is this innovation doing in terms of scaling up and out or working at greater efficiency and economy?

This innovation intends to scale up, scale out, and work at greater efficiency/economy.

- **Scale up:** The Supply Division initiated scaling of RUTF to build on initial success demonstrated in effectiveness studies of RUTF, and increase affordability and local availability of product.
- **Scaling out:** The Joint Statement in 2007 defined what RUTF was and allowed UNICEF and its partners to provide direction on the use of RUTF for CMAM. The statement played a significant role in beginning the scale-up process for RUTF globally, and generated significant interest and demand.
- **Working at greater efficiency/economy:** Six interviewees expressed that a major challenge with the previous therapeutic nutritional products used (F-75 and F-100) was that the number of children that could be reached for treatment using the in-patient model was limited. RUTF helps to address this challenge by taking a

community-based approach to treatment of uncomplicated cases of SAM, increasing the number of children with access to treatment.

3. How are end-user needs identified and considered and how did they shape the innovation?

Since UNICEF's involvement with RUTF began during the scale-up process, it was **not involved in the design of the original formulation of the product**. The decision to procure and scale RUTF was based on demonstrated results of field trials, including two field trials completed by ACF in Chad that showed that children enjoyed the taste, and high acceptability and energy intake than F-100.³⁶ While studies in African countries showed that the peanut-based product had high acceptability, in other regions in which peanuts are not widely consumed studies have demonstrated lower acceptability among caregivers, and dissatisfaction with taste among children.³⁷ Had the Supply Division and its partners influenced the design of the formulation and/or completed a range of acceptability studies across geographies, low acceptability in certain contexts (e.g., Asian countries) may have been identified prior to scale, and a range of formulations developed for use depending on local preferences.

Insights: Development of **alternative formulations of RUTF is intended to improve acceptability of products in programmatic countries**. Three Supply Division interviewees stated that ideally, alternative ingredients (e.g., chickpea, soya, maize) will be more acceptable to the end user from a taste perspective (particularly in Southeast Asia, where the peanut content of the current formulation is less desirable) due to better alignment with local eating habits.

While accelerating market availability of alternative formulations is perceived as a

³⁶ James, Philip, 'Products are Not Enough: Putting nutrition products in their proper place in the treatment and prevention of global acute malnutrition', Briefing and Position Paper, Action Contre la Faim International, December 2011.

³⁷ Ali, E., et al., 'Peanut-Based Ready-to-Use Therapeutic Food: Acceptability among malnourished children and community workers in Bangladesh', *Public Health Action*, vol. 3, no. 2, 21 June 2013.

positive step forward, several organizations are already in the process of developing or have developed alternative formulations (including milk-free and/or peanut-free recipes) that use local ingredients and may be more culturally acceptable. Some have begun effectiveness studies necessary to confirm that products achieve results equivalent to the current formulation of RUTF; however, products that have already demonstrated results in the field have not yet been accepted for procurement by UNICEF. One manufacturer questioned whether the Supply Division was ready to back new innovations in RUTF due to its risk aversion.

4. What challenges were faced during the innovation process and what strategies were used to overcome barriers?

The cost of **locally procured RUTF is, on average, more expensive than imported product**. This is due to a variety of factors, including the need to import raw materials, higher taxation and access to finance. At the beginning of the scaling process, products produced in programmatic countries **also suffered from low quality**; to address this, the Supply Division held teleconferences over a period of two years to help manufacturers improve the quality of their products (e.g., fortification of product, ventilation of production areas, leaking sachets) (Four Supply Division, one Country Office, one manufacturer). The strategy to provide greater flexibility in terms of quality assurance at the beginning of the scaling process allowed manufacturers with the potential to meet requirements to increase compliance over time, facilitating expansion of the supplier base.

Three manufacturers expressed during evaluative interviews that the **Nutriset patent was a challenge to competitiveness of local procurement**. Without the backing of Nutriset as part of the PlumpyField network, one smaller manufacturer identified a perceived preference for the Supply Division to procure through the network of franchisees. The Nutriset patent was designed to facilitate production in programmatic countries and the company provides capacity-building support to

franchisees (e.g., monitoring, maintenance and audit); however, the structure of the patent dictates that non-patented product cannot be imported into countries in which a member of the PlumpyField network operates. This was flagged as a logistical challenge in the early stages of scaling RUTF, but as of June 2018 follows an established RUTF process (two Supply Division); in the case that non-patented product needs to be imported into patent countries, the Supply Division informs Nutriset and requests permission to increase transparency and improve response time to stock-outs and/or emergency situations. However, the patent may limit diversification of the supplier base in programmatic countries and small non-franchised production could present additional risks for the Supply Division (e.g., in terms of quality assurance processes), causing it to favour local supply through the PlumpyField network.

The Supply Division has had to **rebuild trust with suppliers/manufacturers of RUTF following the C. sakazakii 'scare'** in 2012, during which a significant amount of product was destroyed unnecessarily (Four Supply Division, one partner, two manufacturers). Following consultation with experts of the Inter-Agency Group, the technical specifications and standards for *Salmonella* and *Cronobacter* were updated. Following the identification of bacteria as a possible issue for low-moisture foods (which were previously assumed to be immune), the Supply Division began to provide training at industry conferences on topics including zoning, cleaning and raw materials in order to improve production processes.

Insights: Although the Supply Division currently procures more than 55 per cent of product through programmatic countries, **much of the product is manufactured in Kenya and South Africa**. Two interviewees (manufacturers) indicated that procurement from smaller and/or less developed countries remains a challenge.

Driving down the weighted average cost of RUTF has been a key aspect and indicator of the Supply Division's strategy to develop a diverse supplier base and healthy market for the product; however, **the focus on cost may limit manufacturers'**

ability to increase production capacity.

Coupling increasing standards with decreasing prices may limit the potential for investment in new equipment and/or personnel (one Supply Division, one manufacturer). Further, based on feedback from manufacturers, the main driver of cost reduction of finished RUTF products has been increased production to meet demands, which has allowed manufacturers to negotiate better prices for raw materials. The impacts of the expanded supplier base and greater competition on cost (other than saved transportation costs) is relatively unknown.

5. Was a proof of concept and business case developed for this innovation?

Prior to issuing the first LTA, a **cost-benefit analysis for RUTF was not completed**; however, the Joint Statement advocated that RUTF be added to the list of cost-effective interventions (approximately US\$3 per kilogram when locally produced in 2007) to contribute to the Global Strategy for Infant and Young Child Feeding endorsed by WHA in 2002.³⁸ Interest in implementing and scaling use of RUTF to treat SAM developed in reaction to emerging evidence of the efficacy of RUTF,^{39, 40} which acted as proof of concept for the product.

Insights: Since UNICEF became involved in scale-up of RUTF, several studies have attempted to complete cost-benefit analyses. Studies have demonstrated that CMAM is a highly cost-effective strategy for treatment of acute malnutrition, compared with health-care services without CMAM.⁴¹ However, completion of a cost-effectiveness analysis prior to scale-up of the product would have been preferable, and in line with SD best practices.

6. How does this innovation complement or build on existing knowledge and work conducted in the country and across programmes?

This innovation contributes to treatment of SAM in programmatic countries, in chronic and emergency situations. Use of RUTF in emergency and non-emergency contexts at the community level has enabled treatment of greater numbers of children with SAM, and reduced burden on health centres related resource requirements for in-patient treatment.

7. How have the local environment/market (including legal, regulatory and technological) considerations influenced the design of the innovation?

RUTF is a specialized food product intended for use in a very specific context, for treatment of SAM in children. The regulatory environment for food products is less stringent than for medicines, which has enabled UNICEF to more easily diversify the supplier base in programmatic countries. Based on guidance from FAO and WHO, at the global level manufacturers follow several international guidelines including the Codex Alimentarius, ISO 22000 and ISO 9001:2000. More recently, **quality standards have been improved through inclusion of RUTF in Codex Alimentarius' Code of Hygienic Practice for Low-Moisture Foods.** Local legal and regulatory considerations have significantly influenced the scale-up process for RUTF. Three interviewees (Supply Division, partner, manufacturer) expressed that the regulatory environments in programmatic countries are often less strict than desired; it was therefore **important that UNICEF provide a strong regulatory framework** for RUTF and assist manufacturers to incrementally improve their processes over time. This was also an important component of diversifying the supplier base and encouraging local production.

³⁸ WHO, WFP, UNSSCN and UNICEF, *Community-Based Management of Severe Acute Malnutrition*, 2007.

³⁹ Briend, André, 'Highly Nutrient-Dense Spreads: A new approach to delivering multiple micronutrients to high-risk groups', *British Journal of Nutrition*, vol. 85, suppl. 2, 2001.

⁴⁰ Manary, M. J., et al., 'Home Based Therapy for Severe Acute Malnutrition with Ready-to-Use Food', *Archives of Disease in Childhood*, vol. 89, 2003.

⁴¹ Wilford, Robyn, Kate Golden and Damian G. Walker, 'Cost-Effectiveness of Community-Based Management of Acute Malnutrition in Malawi', *Health Policy and Planning*, vol. 27, no. 2, March 2012.

⁴² Isanaka, Sheila, et al., 'Cost Analysis of the Treatment of Severe Acute Malnutrition in West Africa', *Maternal & Child Nutrition*, 2016.

Product specifications previously established for RUTF will **facilitate development of alternative formulations that meet procurement requirements**. Since RUTF is now included in the Codex, the quality assurance processes will remain the same for finished products; however, developers and manufacturers will be responsible for defining product specifications based on ingredients used. Since UNICEF and its partners have developed a formalized quality assurance process and new products will adhere to Codex Alimentarius' Code of Hygienic Practice for Low-Moisture Foods, the risk of pursuing alternative formulations is significantly lower than it would have been at the start of the scaling process.

8. *What value does UNICEF bring to this innovation and what makes UNICEF suitable to scale it?*

In the early 2000s, UNICEF played a key role in **driving adoption of RUTF for treatment of SAM**. Two interviewees (one partner, one manufacturer) noted that without UNICEF's involvement in scaling RUTF, the scale-up process would not have occurred as quickly. UNICEF also played a key role in **facilitating the enabling environment for scale-up of RUTF** through improvements to quality assurance standards, specifications, and diversification of the supplier base. UNICEF's role as a convener and **procurer of 80 per cent of RUTF supplies** has provided the organization significant influence over the scale-up process.

9. *What principles or standards have been applied and how?*

Application of the Principles for Digital Development are not applicable to this innovation.

10. *What are the steps taken or methods used to assess and mitigate risks to children, users, and markets?*

In order to mitigate risks to users, the Supply Division has **oversight of the quality assurance standards and processes** for RUTF. The Supply

Division has incrementally introduced product and process controls to improve the quality of RUTF produced across manufacturers. This allowed for simultaneous scale-up of RUTF and improvement to production capacity, maximizing response to acute malnutrition while improving protection of children with SAM with weakened immunity.

In response to concerns over presence of *C. sakazakii* in RUTF, suppliers were required to destroy product that tested positive. While decisions were made in order to minimize the risk of exposing children with weakened immunity to *C. sakazakii*, based on interviewee feedback this was largely based on reputational risk to UNICEF. The exposure and reputational risks were minimized; however, recovery rates with treatment of RUTF tend to be higher than other locally available treatment (e.g., one study demonstrated 56.9 per cent recovery with RUTF compared with 42.8 per cent recovery with locally enriched foods after 16 weeks of treatment in India).⁴³ Therefore, the decision to destroy product testing positive for *C. sakazakii*, leading to stock-outs, may have put children at greater risk to their health (i.e., due to delayed recovery or death) than exposure to *C. sakazakii*.

6.2 Organization dimension

11. *What type of support was received from the leadership to enable the innovation process?*

Support from leadership has enabled progress towards Supply Division outcomes and global scaling of RUTF over a relatively short period. The Supply Division provided support for overall management of global supply and demand. The Chief of the MNC holds overall responsibility for RUTF within the Supply Division. Further, the Director of the Supply Division supported the division to take an active role in scaling RUTF.

Development of innovative alternative formulations of RUTF will have support from leadership of the Supply Division Innovation

⁴³ Bhandari, Nita, 'Efficacy of Three Feeding Regimes for Home-Based Management of Children with

Uncomplicated Severe Acute Malnutrition: A randomised trial in India', *BMJ Journal*, 2016.

Unit, which brings experience driving product development through Product Innovation Projects (PIPs).

12. What type of support and leadership facilitated the enabling environment for innovation?

Effective communication of UNICEF and partner expectations to industry has been a key factor for success in the scale-up of RUTF. Annual industry conferences have provided an avenue to discuss objectives, targets and processes, and how manufacturers will be evaluated. This has improved transparency with manufacturers and facilitated an enabling environment for scale-up. Preference for local procurement of RUTF, even though products produced in programmatic countries tend to be more expensive, has also contributed to the enabling environment for scaling the product innovation (two SD, one Country Office).

Insights: Despite significant progress in scaling RUTF, two manufacturers expressed that UNICEF is more risk averse than it is scientific, and were unconvinced that the organization could be considered an innovator in this space. This was said to be reflected in the lack of progress on alternative formulations and negative impacts to business and treatment of SAM due to concerns over *C. sakazakii*. Further, opportunities to innovate are constrained by the constant drive for lower prices and questions surrounding whether patents can be established for alternative formulations (one partner, one manufacturer). The ability to innovate in the case of RUTF may be hindered by UNICEF's limited risk appetite, particularly for a product that is used to treat vulnerable children, often in emergency response situations. Thus, the resulting risks of innovation, which requires room to test and iterate, while posing an ethical dilemma, could also present reputational risk to UNICEF.

13. Who makes decisions with respect to the design and implementation of the innovation?

The Supply Division was not involved in design of the formulation of RUTF; however, during the scaling process it worked

collaboratively with MSF and WFP to develop specifications and quality assurance standards.

Insights: While recognizing UNICEF's key role in the scaling of RUTF, several interviewees (one partner, one manufacturer) expressed that there is a risk of power being consolidated primarily within one organization. This was of particular concern in the case of RUTF, as UNICEF is the procurer of 80 per cent of RUTF. One implementing partner noted that ACF and the International Committee of the Red Cross intend to join the Inter-Agency Group, which may facilitate more multilateral decision-making.

14. What factors were considered when making decisions about governance and ownership of the innovation?

Originally, UNICEF, MSF and WFP collaborated closely in order to develop specifications, avoid procuring product from the same manufacturer and improve efficiency; however, WFP is now a major procurer of RUSF, while UNICEF and MSF procure RUTF in greater volumes. Accordingly, the partners came to the decision that UNICEF and MSF would own the audit process of RUTF and RUSF products.

15. How has the governance and ownership model influenced the innovation process?

UNICEF is not a regulatory body, but has oversight of the quality assurance standards and processes for RUTF, which has contributed to diversification of the supplier base while ensuring a minimum standard for quality product. This is done in coordination with MSF for manufacturer approval, follow-up, and monitoring based on performance indicators. While the organizations often conduct audits together, if one is unable to attend, the results are shared. The Supply Division tracks supplier key performance indicators (e.g., responsiveness, lead times, delivery of full quantity), takes product samples on an ongoing basis (e.g., testing for consistency, taste) and has incrementally introduced product and process controls to gradually improve product quality while avoiding

exclusion of manufacturers in programmatic countries.

Insights: It is important to note that UNICEF and MSF are not regulatory and/or normative bodies, and that validation of the product is the responsibility of the manufacturer.

One manufacturer expressed frustration regarding lack of cooperation between UNICEF, MSF and WFP to standardize product packaging between RUTF and RUSF, as RUTF requires 92 grams of packaging while RUSF requires 100 grams of packaging. If RUTF and RUSF packaging was standardized, production costs for local manufacturers could potentially be reduced, contributing to the intended outcome to improve affordability of RUTF.

16. To what extent was sustainability considered in the plan for the innovation?

The Supply Division has developed a **framework for sustainable procurement of RUTF** (Annex D), which focuses on strategy, integration of sustainable procurement principles to the supply chain, expansion of financing, and promotion among partners and suppliers. The drive for a greater proportion of local procurement also contributes to the sustainability principles of economic (e.g., lower cost), social (e.g., jobs created) and environmental (e.g., more efficient transportation) benefits. It is noted that improving the sustainable procurement of raw materials will likely increase the average weighted cost of RUTF, so manufacturers may be reluctant to adapt in response to the sustainability framework to remain competitive on price.

Insights: Interviewees (One Supply Division, one partner) indicated that in addition to sustainable procurement of RUTF, coordinated response to SAM within UNICEF and with partners should also consider preventive interventions, to reduce the number of cases of acute malnutrition progressing to SAM, in countries in which SAM is an ongoing and long-term challenge. There is also potential for manufacturers to diversify their product

offerings (e.g., supplementary foods) in order to decrease dependence on UNICEF procurement of RUTF and improve the prospects for sustainability.

17. When will this innovation become mainstream and no longer considered an innovation? What steps has UNICEF taken to move towards that point?

Standard Supply Division PIPs (Annex E) are used to drive research, development, availability and scale, and the stage-gated process that is followed moves from the 'explore' through 'scale-up' phases. Although the RUTF project does not follow the typical PIP process, the perception persists that RUTF will no longer be considered an innovation when it reaches scale.

18. How, if at all, has the innovation team worked across UNICEF offices and divisions to leverage internal and external knowledge and expertise and share learnings?

The project team, Country Offices and various divisions within UNICEF have collaborated effectively to move RUTF towards scale. The RUTF project team sits within the Supply Division, and is led by MNC, which provides general oversight, technical expertise, and contracting functions. The project team also includes membership of the Supply Division Quality Assurance Centre, which monitors quality of manufacturing sites and ensures that products comply with specifications.

The Supply Division project team works very closely with Country Offices to identify RUTF needs in programmatic countries and manage the supply chain. Following identification of the need, if a local source is available Country Offices prepare purchase orders in the local currency; if a local source is not available, the Supply Division coordinates offshore procurement of product to meet demand. Further, annual demand forecasts are prepared based on input from Country Offices and reviewed with PD before they are provided to industry.

Finally, the Supply Division Markets, Supplier Financing and Innovations Centre (MSFIC; formerly Markets, Finance, and Strategic Data

Unit) also supports development and refinement of procurement strategies, and publication of product/market information (e.g., food price data).

6.3 Resources and capabilities dimension

19. How is the innovation funded?

Scaling of RUTF has taken a market-driven approach; however, the majority of RUTF is procured using donor funding, including USAID, which makes a large in-kind annual donation of product procured through United States manufacturers. MSF, ACF and the International Committee of the Red Cross procure RUTF; however, UNICEF procures approximately 80 per cent of all RUTF. Implementing partners therefore consider UNICEF as the reference point from where and which suppliers product should be sourced.

Insights: Based on feedback from 3 Supply Division interviewees, funding is a key constraint in scale-up of RUTF. The challenges with funding include that:

- Donor agencies are the main source of funding; and
- Domestic funding for RUTF supplies is limited.

In response, the Supply Division is in the early stages of exploring co-financing solutions with government. Currently, very few governments (such as Zimbabwe)⁴⁴ include RUTF in their budget. Domestic ownership and funding for use of RUTF for chronic issues of malnutrition (as opposed to emergencies) could improve sustainability of RUTF procurement.

20. How much time and how many resources were invested at different points in the innovation process?

The Supply Division procured US\$219.9 million in nutrition commodities in 2017, including 52,850 tons of RUTF.⁴⁵ However, resources invested in the project include primarily human resources from MNC, Quality Assurance Centre and

MSFIC. These individuals work on a number of projects within their respective units.

21. What ongoing resources (human, physical, and financial) are required from UNICEF to manage this innovation?

See above.

22. How, if at all, have partners external to UNICEF contributed to the innovation process?

Partners external to UNICEF (Annex B) have made significant contributions to scaling of the product innovation. Contributions include but are not limited to:

- **Joint Statement:** UNICEF, UNSSCN, WFP and WHO endorsed CMAM in a Joint Statement in 2007, which advocated an approach that would enable more children with acute malnutrition to receive community-based treatment.
- **Interagency Group for Food Aid Product:** Membership includes major purchasers of nutritional products (WFP, USAID, UNICEF and MSF) and collaborates on auditing, specifications and quality standards of common products procured. Oversight of quality assurance standards and processes is shared by MSF and UNICEF (and formerly WFP), including manufacturer approval and audits. The group also consults FAO and WHO when expert input is required.
- **FAO/WHO Expert Committee:** The Codex Alimentarius provides manufacturers with guidance on safe production of RUTF. The committee has provided input to RUTF at key points during scale-up, including recommendations for specifications in response to *C. sakazakii* concerns, and inclusion of RUTF products in the Code of Hygienic Practice for Low-Moisture Foods.
- **USAID:** Makes an annual in-kind donation, coordinated through UNICEF, including RUTF supplies, transportation and storage. USAID procures its product from United States-based manufacturers, and its donation in 2015/16 accounted for 12.8 per cent of RUTF procured through UNICEF.

⁴⁴ ACF, 2018. Ready to Use Therapeutic Food (RUTF) and the WHO Essential Medicines List. CMAM Forum.

⁴⁵ UNICEF, 2018. Supply Annual Report 2017.

23. How are partnerships designed to provide value to partners?

The technical competencies of partners are leveraged through various groups (e.g., FAO/WHO Expert Committee), which **strengthen the production and quality of RUTF** as a whole. Partnerships also **improve the efficiency** of the tender process (coordinated through the Supply Division) and industry standardization of specifications, quality and auditing. Finally, implementing partners (purchasers of product) benefit from reduced cost and lead time, and improved supply-chain management associated with collaboration.

24. What methods, approaches or tools are used throughout the innovation process?

In order to strengthen the RUTF supply chain, the Supply Division has continuously worked to **diversify the supplier base through a competitive RFP process through which LTAs are established** with manufacturers/suppliers. Manufacturers are selected based on a variety of factors, including product quality, patent status, and proximity to programmatic countries, as well as import procedures and price. RUTF suppliers can be grouped into three categories:

- Offshore suppliers: Export only (no consumption of RUTF within their country);
- Local suppliers: Located in programmatic countries; and
- Local and export suppliers: Located in programmatic countries and export product to other countries.

Insights: Use of **quantity-bound agreements**, through which forecasted procurement volumes are shared among suppliers/manufacturers, has allowed **greater flexibility** for the Supply Division within contracts, and has allowed UNICEF to be **more agile** in response to market changes (three Supply Division).

6.4 Incentives and outcomes

25. What incentives are encouraging/driving and discouraging/detering adoption of the innovation by users?

Due to its procurement policies, the Supply Division is **restricted in the ways through which it can interact with product developers and manufacturers**. The policies are in place to avoid perceived conflicts of interest and/or the appearance of endorsing one company over another, and apply to scale-up of RUTF; however, there are several strategies utilized by the Supply Division to drive scale:

- **Country Offices have played a role, in collaboration with the Supply Division, in developing the local supplier base.** A representative from SD and a manufacturer described in detail the process undertaken to encourage local production in Niger. This included signing an LTA, quick delivery of invoices to ensure cash flow, and playing a coordinating role among partners procuring product from the manufacturer (lack of coordination previously made planning difficult) in order to consolidate procurement with one organization. This process is not formalized across countries; however, Supply Division representatives from Niger supported replication of the process in Burkina Faso.
- **The opportunity to sign LTAs with UNICEF may assist manufacturers to secure external assistance.** For a manufacturer in the Niger, signing a one-year LTA helped the company to secure a loan to expand production capacity for local procurement.
- **Annual demand forecasts provided to suppliers of RUTF has facilitated investment in production capacity.** Demand forecasts are developed by the Supply Division based on the number of children with SAM who will be reached by a programme in a given year, using input from Country Offices and reviewed by the PD. The forecasts also account for trends including funding availability, supply-chain improvements, and country-level implementation of CMAM. Four interviewees (three Supply Division, one supplier) stated that more reliable demand forecasting for RUTF volumes to be procured in a given year have helped companies to structure and make investments, and develop long-term strategies for increasing production capacity; however, two manufacturers

expressed that orders from UNICEF are less predictable for smaller suppliers, and that accuracy of forecasts could still be improved. In 2017, the Supply Division procured 50 per cent greater than the demand forecast provided to suppliers; manufacturers did not struggle to produce the required volumes, providing an opportunity to confirm production capacity.

Insights: Accelerating development and commercial availability of alternative formulations of RUTF is an important next step in the iterative innovation process; however, there may be disincentives to manufacturer innovation. Over the course of the evaluation, five interviewees (one Country Office, one partner, three manufacturers) expressed that while development of alternative formulations is welcomed, companies must be motivated to dedicate the time, cost and effort needed to develop new recipes. In some cases, motivation to innovate is minimal due to lack of resources to invest in research and development, and risk for manufacturers investing in alternative formulations that (following commercial availability) may be replicated by competitors.

26. How were metrics designed and used to inform the development and scaling of the innovation?

The Supply Division has four procurement objectives to ensure sustainable and affordable supply of quality RUTF, against which key performance indicators are monitored over time to track progress. Although the metrics designed focus on supply-side outcomes (rather than human development, e.g., number of children with SAM treated), this is appropriate considering the Supply Division's specific role in scale-up of RUTF.

- Establish a **diverse supplier base with capacity to respond** to demand (including emergency response). Indicators include estimated global manufacturing capacity, and percent capacity utilized.
- Increase **market competition** to improve **value for money**. Indicators include

weighted average price (US\$ per metric ton).

- **Quality assurance** in line with international standards.
- Support sourcing of RUTF from **manufacturers located in programmatic countries**. In 2013, the Supply Division set a target that by 2016 local procurement would make up greater than or equal to 50 percent of total procurement of RUTF.

Insights: Through annual industry conferences, the Supply Division has facilitated development of a community of manufacturers. Through presentations and informal discussion, three interviewees (two Supply Division, one manufacturer) reported that UNICEF, manufacturers and partners are able to share information and lessons learned.

27. At what point were metrics considered? How was impact measured before scaling (or how is it intended to be measured)?

Supply Division metrics were designed to monitor its impacts on supply-chain strengthening over time. Metrics have been reviewed over the course of scaling of RUTF; however, several key performance indicators (e.g., number of suppliers, local and offshore procurement, metric ton procured) have remained consistent. Other key performance indicators, such as estimated emissions per metric ton procured, have been added over time.

28. What does the ideal future state of this innovation 'at scale' look like?

The ideal future state of this innovation at scale includes **limited reliance on donor funding, with national governments taking greater ownership and allocating budget for procurement** and integration of RUTF in their respective health systems. One strategy strongly favoured by the Supply Division (five interviewees) to facilitate greater government ownership over RUTF is to have the product included on the WHO Essential Medicines List, to treat children with SAM through domestic health systems. Inclusion on the list would assist with long-term budgeting and planning; however, RUTF would ideally remain a food product, as

pharmaceutical quality standards could triple the average weighted price due to requirements for more rigorous testing. However, RUTF supplies are more often needed in countries with limited resources, and the need for donor funding is likely to continue (one Country Office, three partners). Therefore, donor funding will likely still be required to support treatment of SAM when RUTF reaches scale, but with less reliance for countries able to allocate a portion of their budget towards procurement.

29. How has this innovation considered and demonstrated development outcome/impact objectives? To what extent does the innovation contribute (or have the potential to contribute) to equitable results for children?

Since it began to scale RUTF, the Supply Division has made **significant progress towards increasing production capacity and procurement, and meeting global demand.**

CMAM has enabled implementing partners to reach greater numbers of children with SAM, with associated positive impacts on health and reduced mortality. Demonstrated outcomes of the Supply Division include:

- Achieved 56 per cent local procurement in 2016, and maintained the objective through to April 2018, at which point 59 per cent of product had been procured from manufacturers located in programmatic countries.

- The Supply Division procures RUTF from more than 20 manufacturers, two thirds of which are located in Africa (almost 80 per cent are in programmatic countries).
- As of April 2018, the weighted average price of RUTF procured by UNICEF has decreased by 16.6 per cent since 2006.

Insights: UNICEF has contributed significantly to scale-up of RUTF; however, there is **potential for unintended negative consequences** of use of RUTF, including:

- Influence on taste preferences and food choice behaviours.
- Replacement of long-term nutritional services.
- Replacement of use of indigenous foods and ingredients to treat SAM.
- Discourage use of potentially less expensive alternative formulations.

The impacts of several of these consequences (e.g., taste preferences, use of indigenous ingredients, cost) will be minimized through acceleration of market availability of alternative formulations of RUTF; however, minimizing the unintended consequences such as replacement of long-term nutrition services will require continued collaboration with the PD to ensure that CMAM is implemented through a holistic approach, including preventive activities.

7. CONCLUSIONS AND CONSIDERATIONS

Table 2. Practical considerations for RUTF going forward

Consider appropriate use of RUTF	UNICEF should consider how the procurement strategy for RUTF responds to acute malnutrition under various scenarios, mainly in response to chronic and emergency situations. While the current formulation of RUTF is well suited to emergency response where normal access to food is disrupted, locally produced RUTF using indigenous ingredients and contributing to local economies may be more appropriate and sustainable in cases of chronic issues of malnutrition.
Engage more with smaller manufacturers	A significant portion of RUTF procured from programmatic countries comes from countries with higher levels of development (e.g., middle income), including Kenya and South Africa. Manufacturers operating at smaller scale and/or in less-developed countries reported challenges having their product procured through UNICEF. The Supply Division could consider ways to more meaningfully engage with these manufacturers, such as more targeted procurement or mechanisms to support investment in production capacity (e.g., funding, advance purchase commitments).
Ensure evidence- and science-based decision making	The Supply Division should use evidence- and science-based decision-making in cases where the quality and/or safety of RUTF is in question, such as concerns regarding <i>C. sakazakii</i> . This includes weighing the risks of decisions that may impact the availability of RUTF, as in the case of <i>C. sakazakii</i> stock-outs leading to children with SAM not receiving treatment with RUTF, which increases mortality rates. Technical experts and industry should be consulted in cases where product safety is in question, and cost-benefit analyses of potential decisions conducted.
Decentralize UNICEF control over RUTF	With oversight of quality assurance processes and development of specifications, and as procurer of 80 per cent of RUTF, power is highly concentrated with the Supply Division. Decision-making should continue through multilateral processes such as the Interagency Group, and the Supply Division should continue to publish documentation including key decisions and reasoning to maintain transparency. However, the innovation process could be strengthened through the decentralization of power, for example by certifying manufacturers through an independent process.
Incentivize manufacturers to innovate	Prior to initiating the innovation process for development of alternative formulations of RUTF, the Supply Division should consider how it will incentivize manufacturers, as private sector actors, to innovate. For manufacturers, there is risk of investing significant resources in research and development activities if their novel product is to be replicated by other manufacturers, limiting the potential return on investment. The Supply Division could consider allowing manufacturers to hold patents for a defined period of time, or providing small grants for investment in research and development.

Table 3. Innovation at UNICEF

Consider the reputational risk UNICEF is willing to accept	Feedback from manufacturers and partners indicates that some external actors believe that UNICEF is not well positioned to innovate due to limited risk appetite. UNICEF should consider the level of risk it is willing to accept in order to innovate and/or accelerate innovation, what constitutes an acceptable level 'failure' of innovation projects. In the case of RUTF, the response to concerns regarding <i>C. Sakazakii</i> contamination was driven in part by reputational risk and resulted in reduced access to RUTF treatment. The risk to children's health and organizational reputation that the Supply Division is willing to accept should also be considered related to alternative formulations, as testing and/or treatment of SAM using new products could impact children's health.
Complete a cost-benefit analysis prior to project start	A cost-benefit analysis could help to enhance research and development infrastructure, strengthening innovation and more efficiently directing resources towards projects with significant impact potential. The analysis could be updated at key stages of the project (e.g., project planning, launch, scale-up) to assess viability. While RUTF studies have retrospectively demonstrated cost-effectiveness, earlier analysis may have identified regional differences in efficacy and acceptability.

<p>Create project teams with diverse membership</p>	<p>Innovation project teams should have diverse composition in order to leverage greater diversity of ideas, experience and technical expertise. Although the project team for RUTF is mainly composed of individuals from the Supply Division, membership from various centres has provided the project team with the knowledge and skills needed to scale the product innovation. Consultation of project team members with other divisions within UNICEF, including the PD, has also provided opportunities to strengthen components of the project (e.g., demand forecasting).</p>
<p>Work closely with COs to drive scale</p>	<p>For RUTF, working closely with Country Offices on demand forecasting, product order placement, and capacity-building of local manufacturers significantly contributed to successful scaling of the product. In addition to coordinating on-the-ground activities and supporting development of manufacturer production capacity, Country Offices have provided valuable input on country context and needs. The expertise provided by Country Offices could be expanded to include local regulatory frameworks and identification of potential viable alternative formulations using local ingredients.</p>
<p>Utilize knowledge-sharing platforms to engage partners and industry</p>	<p>Platforms such as NutriDash have facilitated knowledge-sharing and strengthened innovation tools such as accurate demand forecasting to guide industry on scale-up of production capacity. Further, groups including technical experts and implementing partners (e.g., Interagency Group for Food Aid Product) should be leveraged to provide insight, share developments, and publish lessons learned to contribute knowledge to the field in which the innovation operates.</p>

ANNEX A: METHODOLOGY

Case study objectives

Innovation is perceived at UNICEF as a strategy to tackle complex challenges faced by children around the world. For this reason, UNICEF identifies, tests and uses innovations to **accelerate results** that reduce inequities for children.

Deloitte was engaged by UNICEF to conduct case studies to examine innovation across the spectrum of innovation types, country contexts, and internal (UNICEF) and external (partner, supplier) actors. Cases are **descriptive and explanatory**, identifying how the innovation process has played out in single instances and surfacing key issues, lessons, challenges and successes. During scoping and development of the Terms of Reference for this evaluation, cases were selected by the UNICEF Evaluation Office through a multi-step approach. Diversity across cases was considered as a factor for selection; however, the sample selected was not intended to be fully representative of innovation at UNICEF. The primary focus of this case is to understand the process of innovation for ready-to-use therapeutic foods (RUTF), including challenges and lessons learned.

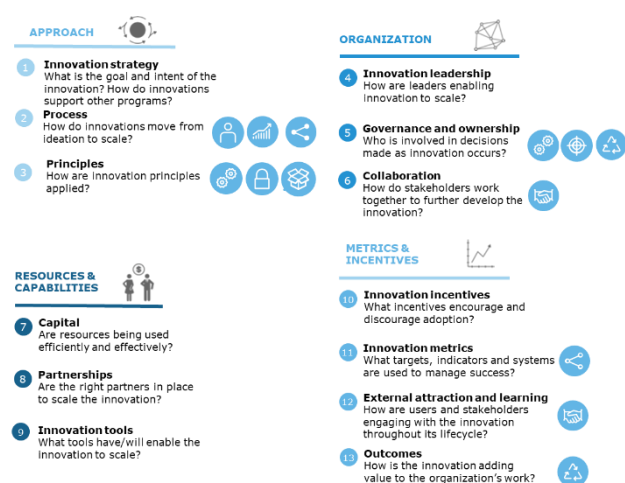
Evaluation framework

Evaluation questions were structured around a modified version of the Deloitte Doblin Framework for Innovation. Within this framework, the approach to innovation must be enabled through four thematic dimensions, including: approach, organization, resources and capabilities, and metrics and incentives. The four dimensions highlight the elements necessary to enable successful innovation.

Data collection approach

Deloitte employed a mixed methods approach to build a complete picture of the innovation process and identify findings related to the four thematic dimensions of the evaluation framework. The evaluation team collected qualitative and quantitative data through desktop review and case study informant interviews.

Figure 11. Deloitte Doblin Framework for Innovation



Desktop review	<ul style="list-style-type: none"> • Primary and secondary sources. Conducted review of demand forecasts, industry consultation documentation, presentations, workplans, Requests for Proposals (RFPs), and supply-chain analyses. • High-level organizational scan. Reviewed UNICEF Supply Division documentation related to product innovation.
Stakeholder engagement	<ul style="list-style-type: none"> • Interviews. Conducted semi-structured interviews, guided by interview protocols, with RUTF project team members, developers and manufacturers, implementing partners, and partner organizations. • Observations. Field mission to the Supply Division in Copenhagen, Denmark, to meet with key UNICEF stakeholders. Field mission to Ethiopia to meet with key UNICEF, manufacturer and community stakeholders.

Description of field visit activities

Two evaluation team members conducted a field mission to Copenhagen, Denmark, from 11 to 14 June 2018. Additionally, one evaluation team member carried out a field mission to Ethiopia from 6 to 10 August 2018. The UNICEF Supply Division scheduled both visits based on guidance documents from the evaluation team outlining the desired list of stakeholders for engagement. Activities included interviews with key stakeholders and observation of RUTF manufacturing.

Limitations of this case study

- **This case does not systematically assess the impacts or outcomes of innovation.** The case has captured perspectives on potential outcomes and impacts of innovations, when appropriate. However, given the early stage of development, limited scope of engagement and rapid approach to conducting the cases, the evaluation does not make objective conclusions on outcomes or impacts related to the RUTF.
- **A single case is not representative of the total population of innovations at UNICEF.** The sampling methodology for selection of cases (i.e., number, type and field visit locations) was not randomized and, due to the highly qualitative and contextual nature of case studies, findings from this case are not generalizable to innovation at UNICEF. As such, cross-case analysis performed by UNICEF should be done with consideration of this limitation.
- **Due to the nature of innovation, it is expected that some innovations will continue to evolve during case study implementation.** This case presents a reconstruction of the innovation process up to September 2018. Future activities and priorities shared by stakeholders will be captured, but cases will not strive to make forward-looking statements or conclusions.
- **Field visits were intended to reflect the innovation project, rather than the Supply Division.** As such, these case studies do not make inferences on the Supply Division's overall performance in innovation or on the impact of its innovation function.
- **Potential for bias in documentation received from the UNICEF Supply Division.** It is noted that the Supply Division has a strong process in place for documentation of progression of Product Innovation Projects. However, the majority of documentation received was developed and used by innovators and could be positively biased. Where possible, external sources were reviewed to validate findings from the document review.
- **Potential for bias from case study informants.** Due to the limited nature of this case study, perceptions of stakeholders who were not involved in the scale-up of RUTF were not engaged. As a result, perspectives of individuals with a stake in positively framing the innovation process are primarily presented.

ANNEX B: RUTF STAKEHOLDERS

The table below summarizes various stakeholder groups internal and external to UNICEF that were involved in the RUTF project

at various points along the innovation pathway.

Table 4. Organizations, role in ARIDA PIP, and status of engagement over the course of the evaluation

ORGANIZATION	ROLE IN RUTF SCALE-UP	ENGAGED?
FAO/WHO Expert Group	Provide technical expertise and recommend microbial specifications for RUTF and RUSF.	Yes
Innovation Review Board	Composed of Procurement Centre Chiefs (since 2018), the IRB is the decision-making body of PIPs and controls advancement through the stage-gated process of innovation.	Yes
Interagency Group for Food Aid Project	Membership includes MSF, UNICEF, USAID and WFP, which are major purchasers of nutritional products and collaborate on quality assurance matters of common nutritional products (e.g., specifications, shared audits).	Yes
Project Team	Responsible for day-to-day management and decision-making for the RUTF project. Membership includes the Supply Division, the PD and Country Offices.	Yes
Supply Division Innovation Unit	Provide support to the HTC in terms of project management, framework and resources for non-standardized activities. Representation on the Project Team.	Yes

Table 5. List of interviews completed for this case study

Name	Organization	Position
Stephane Arnaud	UNICEF Supply Division	Senior Emergency Supply Manager
Ismael Barmou	STA Niger	General Manager
Prince Boateng	USAID	Contracting Officer, Office of Acquisition & Assistance
Mathilde Bridier	Nutriset	Head of Quality Department
Andre Briend	WHO	Medical Officer for Department of Child and Adolescent Health and Development
Odile Caron	MSF	International Food Quality Assurance Coordinator
Steve Collins	Valid International	Director
Akthem Fourati	UNICEF Supply Division	Chief, Medicines and Nutrition Centre
Alison Fleet	UNICEF Supply Division	Technical Specialist, Medicines and Nutrition Centre
Kristoffer Gandrup-Marino	UNICEF Supply Division	Chief Innovation Unit
Gian Gandhi	UNICEF Supply Division	Chief Markets, Supplier Financing and Innovations Centre





Morten Hansen	GC Rieber Compact	CEO, GC India
Jonathan Howard-Brand	UNICEF Supply Division	Innovation Specialist, Innovation Unit
Peter Jacobsen	UNICEF Supply Division	Quality Assurance Specialist, Quality Assurance Centre
Natalie Jones	UNICEF Supply Division	Operations Officer
Jan Kormska	UNICEF Supply Division (former)	Pharmacist, Nutrition Unit
Ana Cristina Matos	UNICEF Supply Division	Evaluation Specialist
Nicolas Mayer-Rossignol	Nutriset	Executive Director Development
Riaan Oosthuizen	GC Rieber Compact	GC South Africa
Loraine Perraudin	Nutriset	Operations Director
Suvi Rautio	UNICEF Supply Division	Deputy Director Supply Programmes
Eric Sunde	GC Rieber Compact	Sales and Marketing Director
Regine Weber	UNICEF Supply Division	Chief Strategy, Change and Communications Centre
Patricia Wolf	Meds & Food for Kids	Executive Director

ANNEX C: THE CONTEXT FOR INNOVATION AT SUPPLY DIVISION

Scaling of RUTF did not follow the Supply Division process defined for innovation projects, but development of alternative formulations will follow the process more closely. Supply Division Product Innovation Projects (PIPs) are intended to create impact for women and children through UNICEF programmes, and follow a defined process that covers all stages of innovation, from idea to implementation and scale. The Supply Division designed the procedure to facilitate an iterative approach to innovation that is

valuable and flexible, with effective governance for each individual PIP.

Innovation process: The Supply Division has defined a stage-gated innovation process to cover all stages of the PIP life cycle, from exploration to scale. The process is meant to be highly iterative at the beginning of the PIP in response to new information and/or lessons learned, with decreasing levels of iteration as the project progresses.

	 Phase 0: Explore	 Phase 1: Concept	 Phase 2: Field trial	 Phase 3: Scale up
Description	In this phase, the project team will conduct research to assess relevance, complete a needs assessment and user analysis.	This phase explores and tests potential solutions to address the challenge, including detailed analysis of concepts and development of a draft TPP.	In this phase, the physical prototype(s) of the product is developed and tested in the field, and may involve multiple iterations.	In this phase, scaling of the solution(s) begins through increased procurement and close monitoring of implementation.
Level of iteration	High	Moderate	Little	Very little

To advance from one phase of innovation to the next, PIPs must meet the criteria required to pass through a stage gate. A PIP may start and be closed at any gate/phase of the innovation process.

Governance of the innovation process: In order to pass through Gate 0 and enter the exploration phase, the Innovation Chief and Centre Chief must approve a project as an innovation project. Following approval as a PIP, advancement to the next phase of the innovation process requires the project to pass through a stage gate after presentation of its status to the Innovation Review Board (IRB). The IRB is the sole decision-making body for PIPs, responsible for deciding whether a product should advance to the next stage of

innovation, remain in the same stage, or be abandoned. The project team presents the status of PIPs at meetings of the IRB at key points in the life cycle of the innovation; for example, to obtain resources for field-testing, or to receive input on significant decisions.

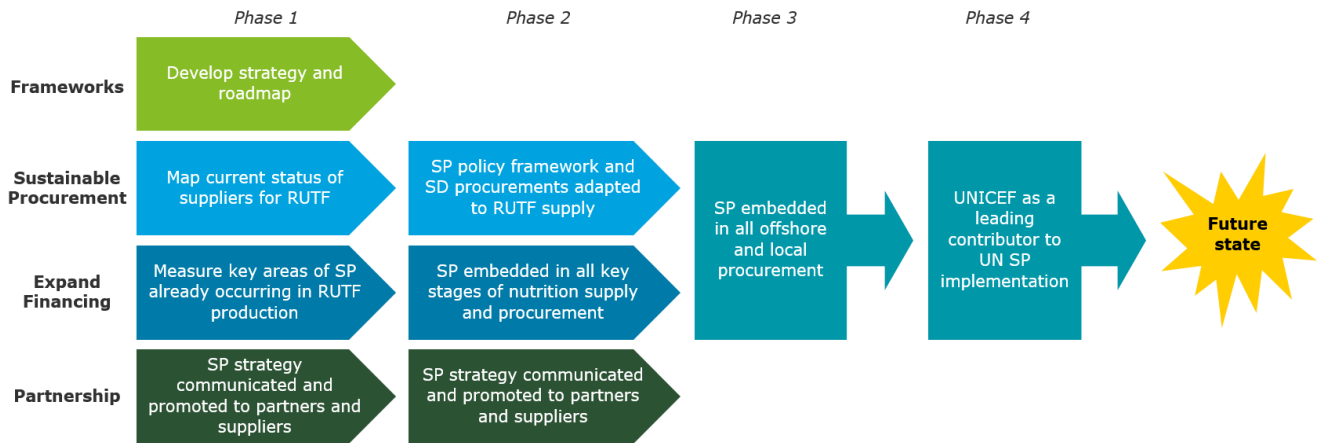
Documentation: Advancement through the phases of innovation is well documented at each stage of the project life cycle, and typically includes:

- Project Charter
- IRB Budget Template
- Project updates to the IRB
- Gate proposal (case for passage through each gate)
- IRB minutes.

ANNEX D: SUSTAINABLE PROCUREMENT FRAMEWORK

The framework for sustainable procurement of RUTF is intended to demonstrate how UNICEF will move from the current state to the future state in which sustainable procurement is embedded in all procurement of RUTF.

Figure 12. Framework for sustainable procurement of RUTF



ANNEX E: SUPPLY DIVISION WORKPLANS

Table 6. RUTF-related outcomes in the 2017 Supply Division workplan

UNICEF Strategic Plan outcomes	RUTF output	Supply Division leader
Health	<ul style="list-style-type: none"> Publish approved suppliers of RUTF Analyse the extent to which amoxicillin is available at service-delivery point of RUTF, including via bundled funding as a proxy 	MNC
Nutrition	<ul style="list-style-type: none"> International product standard for RUTF and therapeutic milk by 2017 50 per cent of RUTF sourced from local manufacturers by 2016 	MNC, Quality Assurance Centre, Director's Office
Outcomes that include but are not limited RUTF (health, nutrition)	<ul style="list-style-type: none"> Convene South-to-South procurement forums annually Publish results of three supply-chain assessments per year Support/conduct 20 in-country supply-chain optimization assessments per year Hold general and product focused courses 	MNC, Supply Chain, Director's Office

Table 7. RUTF-related outcomes in the 2018 Markets, Supplier Financing and Innovations Centre (MSFIC) workplan

UNICEF strategic plan linkage	Related SD outcome target	Activity/indicator
Harness the power of business and markets for children	N/A	Approved RUTF procurement strategy
	Publish validated list of RUTF suppliers	Support publication of lists
	Serve as normative agent for market information and regularly publish product/market information to advocate and influence markets for children	Work with MNC to publish note



for every child

© United Nations Children's Fund (UNICEF)
November 2019

3 United Nations Plaza
New York, NY 10017 USA
www.unicef.org/evaluation