The road to sustainable availability of ready-to-use therapeutic foods for the management of acute undernutrition in the Plurinational State of Bolivia

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Abstract

The Plurinational State of Bolivia has improved its social and health indicators and reached the nutrition-related Millennium Development Goals. The main objective of this paper is to describe the process of adding ready-to-use therapeutic foods (RUTFs) to the list of essential medicines for the management of moderate and severe acute malnutrition in the Plurinational State of Bolivia. A timeline analysis tool, in-depth interviews with key informants, and revision of selected documents were performed. Also, the Health Insurance Benefits database of the logistics of RUTFs was reviewed and an electronic survey conducted to illustrate current use. The initial process of adding RUTFs to the list of essential medicines was reconstructed with information provided by key informants, verified with available documentation. This paper highlights factors such as the existing legal framework, public health insurance, and implementation of the Programa Multisectorial Desnutrición Cero (Zero Malnutrition Programme) that seem to have facilitated the process and ensured the sustainability of use of RUTFs. RUTFs remained in the 2018 National Essential Medicines List and are currently available and used in primary health-care facilities. In summary, the process of incorporating RUTFs in the Bolivian essential medicines list, from inception to expansion, was a positive experience, was done in a timely manner and is regarded to have contributed to the reduction in infant mortality rate in the country.

Keywords: Bolivia; essential medicines list; ready-to-use therapeutic foods; RUTFs; severe acute malnutrition

Introduction

The first commercially available ready-to-use therapeutic food (RUTF) product was developed by the French Institute of Research for Development and a French manufacturer, and patented in 1997 (1). In 2007, the World Health Organization (WHO), the United Nations Children’s Fund and the World Food Programme released a statement on community-based management of severe acute malnutrition, with different activities for countries to undertake, including making RUTFs available to families of children with severe acute malnutrition through a network of community health workers or community-level health facilities, preferably by encouraging the local food industry to produce RUTFs in settings where families do not have access to appropriate local foods (2).
The Plurinational State of Bolivia is a multicultural country with remarkable geographical diversity. In recent years, the country has reduced extreme poverty from 41.2% in 1996 to 17.3% in 2014, accomplished the nutrition-related Millennium Development Goals (3), and reduced the infant mortality rate from 50% in 2008 (4) to 25% in 2016 (5).

The Plurinational State of Bolivia launched its National Policy of Medicines in 1996, supported by a specific law (6), with an updated regulation published in 1998 (7) and norms released in 2000 (see Table A3.5.1). To comply with the law’s mandate, the Bolivian Ministry of Health started to assemble an essential medicines list approved by a ministerial resolution (2003) (8); since 2003, the list has been updated every 2 years (9, 10).

Table A3.5.1. Legal framework for the regulation of medicines in the Plurinational State of Bolivia*

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<thead>
<tr>
<th>Policy</th>
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<td>Medicines Law</td>
<td>Law 1737</td>
<td>17 December 1996</td>
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<tr>
<td>Regulation of Medicines Law</td>
<td>Supreme Decree 25235</td>
<td>30 November 1998</td>
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<tr>
<td>Pharmacological Norms</td>
<td>Ministry of Health Resolution 0216</td>
<td>5 May 2000</td>
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<td>Ethical Rules for the Promotion of Medicines</td>
<td>Ministry of Health Resolution 0136</td>
<td>1 March 1994</td>
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<tr>
<td>Regulations of the National Pharmacological Commission</td>
<td>Ministry of Health Resolution 0138</td>
<td>14 April 1998</td>
</tr>
<tr>
<td>Guidelines of Sanitary Registry</td>
<td>Ministry of Health Resolution 0909</td>
<td>7 December 2005</td>
</tr>
<tr>
<td>National Supply System</td>
<td>Supreme Decree 26873</td>
<td>21 December 2002</td>
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<tr>
<td>Regulations to the National Supply System</td>
<td>Ministry of Health Resolution 0735</td>
<td>27 December 2002</td>
</tr>
<tr>
<td>National Medicine Control And Monitoring System</td>
<td>Ministry of Health Resolution 0250</td>
<td>14 May 2003</td>
</tr>
<tr>
<td>National List of Essential Medicines</td>
<td>Ministry of Health Resolution 0763</td>
<td>21 October 2005</td>
</tr>
<tr>
<td>Contract Model for the Acquisition of Pharmaceutical Products</td>
<td>Ministry of Health Resolution</td>
<td>1 April 2004</td>
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The Bolivian essential medicines list includes not only medicines for treatment of common infections and other health conditions but also nutrients and preventive medicines such as oral rehydration salts and other quality nutrition-related health products (11). The most recent essential medicines list includes vitamin A, zinc, fortified oil and a supplementary enriched food for children aged 6–24 months.

The Integrated Management of Childhood Illnesses (IMCI) (12) programme was adopted in the Plurinational State of Bolivia in 1996, as a strategy to reduce mortality and improve the health and development of children (13). Given that malnutrition was a main problem in this age group, the nutritional component of IMCI was strengthened and the modified package applied as IMCI plus Nutrition, starting in 2006 (14). This IMCI adaptation was developed as part of the Programa Multisectorial Desnutrición Cero (Zero Malnutrition Programme) (15), which targets chronic and acute malnutrition in children under 5 years of age and aims to reduce the prevalence of these problems and the deaths associated with severe acute malnutrition. The programme included evidence-based interventions recommended by nutrition experts worldwide (16–18).

RUTFs were officially included in this new version of the reviewed IMCI (19). Considering the situation of undernutrition and the fact that many children with acute undernutrition were managed in primary health-care centres and at home, it was decided to use RUTFs to treat severe and moderate acute undernutrition (20, 21).
A Maternal and Child National Insurance system started in the country in 1996, with the purpose of reducing maternal and under-five mortality. This expanded in 2002 to the Universal Maternal Child Insurance (SUMI), with coverage of all pathology in children aged under 5 years, pregnant women, and women with children under 6 months of age. In January 2006, SUMI was expanded to cover the population between 5 years and 59 years of age, linking with the Insurance for Older Adults, which covers people aged 60 years and older (22, 23). Since 2014, the public insurance system has included free and quality-assured medicines, vaccines and other health products (24).

This paper describes the process of inclusion of RUTFs in the national essential medicines list in the Plurinational State of Bolivia, the role of the partners involved, the resources, and the main lessons learnt in the process. Additionally, it describes the collaboration between government and non-state actors at the national level, and the trade-offs of RUTF use in health facilities.

Materials and methods

This is a case-study paper, developed considering the following general objective: to describe the process of adding RUTFs to the list of essential medicines for the management of moderate and severe acute malnutrition in Bolivia. It had the following specific objectives:

- to review the process of inclusion of RUTFs in IMCI;
- to describe the cooperation between the public and private sectors and nongovernmental organizations to include RUTFs in the national list of essential medicines and ensure their availability;
- to identify the main lessons learnt from the process of adding RUTFs to the national list of essential medicines.

Methodology

This exploratory study case used the methodological steps shown in Fig. A3.5.1. Based on the study objectives, a timeline analysis tool was developed. This tool incorporates the step-by-step sequence of events that occurred since the inclusion of RUTFs in the essential medicines list up to the current availability status of the product in Bolivia. The timeline analysis tool also allowed identification of key informants and selection of the documentation needed for the desk review.

Fig. A3.5.1. Sequence of methodological steps used
The desk review considered all available documents kept in the archive of the Ministry of Health, such as reports of meetings where the use of RUTFs was discussed, normative series (25), protocols (26), pertinent laws and regulations (27, 28) and demographic and health surveys (29).

In-depth interviews were conducted, based on semi-structured questionnaires (see Appendix A3.5.1) with selected key informants, including staff from the Ministry of Health, local health staff and selected partners.

All the findings were analysed, establishing converging lines of evidence to increase the robustness of findings and to establish the real facts, based on triangulation of multiple sources of evidence.

As the case-study used a qualitative methodology, the data were analysed and presented in that way. The secondary qualitative data were obtained from the database of the Public Insurance Unit of the Ministry of Health, which reports the delivery of supplies in each institutional municipal pharmacy (27, 30), and presented using frequencies.

Additionally, to provide information about the current use of RUTFs, an electronic questionnaire was applied to staff of primary health-care clinics in municipalities with the highest rates of attention to moderate and severe acute malnutrition (see Appendix A3.5.2).

Finally, the conclusions were established, based on discussions and validation with key people involved in the process.

**Results**

The study had the approval of the Nutrition Unit of the Ministry of Health, and access to available documentation was granted. All key selected informants agreed to be interviewed (see Appendix 3.5.2).

Each informant contributed to describing the context in which RUTFs were included in the essential medicines list for more than 10 years. The process of adding RUTFs to the essential medicines list is described in Fig. A3.5.2; the steps shown are generic and apply to all products with the potential to be included in the list.

**Fig. A3.5.2.** Process for incorporation of ready-to-use therapeutic foods (RUTFs) in the essential medicines list

1. UNIMED invites to propose products for the next essential medicines list (2006)
2. Unit of Nutrition requests the inclusion of RUTF (2007)
3. Petition is registered (2007)
4. RUTF inclusion is presented to the National Pharmacological Commission
   - 4.1. Approved
   - 4.2. Rejected
5. Verification of criteria of essential medicine
6. Workshop of discussion with selected guests and approval of selected medicines
7. Coding of selected medicines
8. RUTF included in the new is sent for ministerial resolution (2008)
The interviewers agreed that the inclusion of RUTFs in the essential medicines list was subject to a working system in place that called for new proposals every 2 years (step 1). The request for the inclusion (step 2) was done in the context of the implementation of the Programa Multisectorial Desnutrición Cero (15). The National Pharmacological Commission accepted the product with observations related to insufficient evidence. The observations were addressed and resolved with the presentation of an updated bibliography at the time.

Informants concurred that the cooperation between the public and private sectors, United Nations organizations and nongovernmental organizations was done within the framework of the Programa Multisectorial Desnutrición Cero (15).

Fig. A3.5.3, constructed with information from the interviews and revision of documents, gives an idea of the context and timing of the events that took place during the process of including RUTFs in the essential medicines list.

**Fig. A3.5.3.** Timeline followed in the Plurinational State of Bolivia for adding ready-to-use therapeutic foods (RUTFs) to the local essential medicines list

Before the inclusion of RUTFs in the essential medicines list, the components of the Programa Multisectorial Desnutrición Cero (15) were all in place and had been endorsed by international institutions, so RUTFs were available for use. These actions contributed to ensuring sustainability in the period 2012–2018, when all municipalities were purchasing the products with local funds.
The current use of RUTFs after a decade of their inclusion in the essential medicines list was provided by assessment of the information system of the institutional municipal pharmacy (30). Fig. A3.5.4 shows the trend of treatments dispensed for moderate acute malnutrition and prereferral treatment for severe acute malnutrition since 2012 in primary health-care facilities.

**Fig. A3.5.4. Cases of acute malnutrition, treated at first-level facilities, by year**

![Graph showing cases of acute malnutrition treated at first-level facilities by year](image)

MAM: moderate acute malnutrition; SAM: severe acute malnutrition.

The electronic survey conducted among primary health-care staff from 94 municipalities from all departments in the Plurinational State of Bolivia (see Appendix A3.5.2) indicated that all staff interviewed had used RUTFs in the past year; however, only 80.85% mentioned that RUTFs were available at the time of the interview. The experience with RUTFs was good in terms of child acceptability and recuperation of malnutrition (67.02% of staff surveyed); the remaining 32.98% found some limitations in younger children, such as low tolerance and patience of the family. Most RUTFs used in primary care facilities (74%) were purchased by the municipality.

**Discussion**

The process of inclusion of RUTFs in the Bolivian *National List of Essential Medicines*, according to the results presented, was constructive, was done in a timely manner, and benefited from high national and international support for the reduction of malnutrition prevalence and mortality in children under 5 years of age.

Three relevant factors were pointed out: (i) the legal framework for the regulation of medicines; (ii) the implementation of the Programa Multisectorial Desnutrición Cero; and (iii) the existence of national public health insurance for children aged under 5 years and pregnant women.

The national regulation system of medicines indicated the way forward for the inclusion (see Fig. A3.5.2) (31). Every 2 years, the *National List of Essential Medicines* is revised and a call for new proposals is opened. Products that are demonstrated to respond to national epidemiological problems and have documentation to endorse their validity have priority. In the case of RUTFs, the duration of inclusion was less than 1 year. The implementation of the Programa Multisectorial Desnutrición Cero, which upgraded the protocols of management of moderate and severe acute malnutrition and introduced RUTFs, among other new products, contributed to complying with all the steps required. However, long-term sustainability would have been difficult to achieve if RUTFs were not included in public insurance (23).

Background documentation presented to the National Pharmacological Commission (Fig. A3.5.2, step 4) included a nutrition-improved IMCI strategy according to international recommendations (19, 26, 32, 33);
in-service management of severe acute malnutrition and implementation of community-based interventions for the management of severe acute malnutrition without complications (34); and a summary of positive outcomes of the use of RUTFs in the field (35–37). The revised IMCI protocol extended the use of RUTFs to primary health-care facilities, to treat moderate acute malnutrition without complications, based on the fact that the prevalence of moderate acute malnutrition exceeded 4.4 times that of severe acute malnutrition (1.3% versus 0.3%) (25, 27), and at that time no protocols for the management of moderate acute malnutrition were in place.

The technical support given by United Nations organizations providing references and first-hand experience of use of RUTFs was critical to guaranteeing the approval. Moreover, the interinstitutional collaboration went beyond the registration process; it was crucial to ensure availability in the short term, by providing a donation of the first shipment of RUTFs and later promoting engagement of the private sector to import and distribute RUTFs in the country.

At present, RUTFs are part of the public health system. In 2017, their cost represented approximately 0.21% of the Bolivian Ministry of Health budget. They have been used almost uninterruptedly for the past 8 years and are valued by health staff for the treatment of moderate and severe acute malnutrition.

Given the benefit that the use of RUTFs presents for the management of children with malnutrition at the community level (38, 39), the way the process was conducted in the Plurinational State of Bolivia could be useful in other situations. The following points should be considered when the addition of RUTFs to a national essential medicines list is proposed: (i) a national or local policy for the reduction of malnutrition; (ii) coordination between decision-makers and technical staff; and (iii) a financing scheme to ensure sustainability over time.

In summary, the process of incorporating RUTFs into the Bolivian essential medicines list, from inception to expansion, was done in a timely manner and, among other actions of the Programa Multisectorial Desnutrición Cero, is regarded to have contributed to a reduction in the infant mortality rate in the country.

References


Appendix A3.5.1
Open questions for interview: English translation

Ask consent for the interview and permission for recording

According to their role:

To identify main milestones in the initial process of incorporation of ready-to-use therapeutic foods (RUTFs) in the essential medicines list

1. Could you please describe your position and role, regarding the process of incorporating RUTFs in the essential medicines list?
2. Could you please tell us the name of persons and institutions involved in the process?
3. Could you please tell us what was the role of United Nations organizations, nongovernmental organizations, academic institutions and medical associations?
4. Could you please tell us the main outcomes and how they were achieved?

To describe the initial implementation of RUTF use in health facilities

1. Could you please describe the framework of existing regulations that facilitated the process of incorporating of RUTFs in the essential medicines list?
2. In your view, which were the elements, institutions and programmes that facilitated the availability of RUTF in the country and later in the field?
3. Could you please describe how this new nutrition product was introduced in the protocols? In what way were the staff of the health centres trained in its use? Did some organizations refuse to use the product? Did any health staff complain after using the product?

To identify the main lessons learnt

1. Based on the experience of incorporating RUTFs in the essential medicines list, if you needed to incorporate a new product in the list what would be the main things you would search for to facilitate the process and what actions would you take or avoid?
2. Could you provide some examples of barriers and difficulties that interfered with the process of incorporating RUTFs in the essential medicines list? What successful actions were taken?
**Utilization of ready-to-use therapeutic foods (RUTFs)**

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<th>Department</th>
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1. Do you know about RUTF?  Yes  No
2. If, yes:
3. At the moment, are RUTFs available in the facility where you work?  Yes  No
4. How do you obtain RUTFs in your facility?
   - Bought by municipality
   - Donation
   - Given by department
   - Another health service
5. In the last six months have you used RUTFs?  Yes  No
   If Yes, what did you use them for? (Please mark as applicable)
   - Treatment of children with severe acute malnutrition
   - Treatment of children with chronic malnutrition
   - Treatment of children with moderate acute malnutrition
   - Other
6. How is your experience of using RUTFs for acute malnutrition (severe or moderate)?:
   - Good
   - Average
   - Bad
   - Don't know
7. Were you trained in the use of RUTFs?  Yes  No
   Date of training:       
   Would you like to make any other comments about RUTFs?