RECENT EXPERIENCES IN THE DEVELOPMENT OF LOCALLY-PRODUCED READY-TO-USE FOODS

Kelsey Ryan, PhD
Mark Manary, MD
RECENT EXPERIENCES IN THE DEVELOPMENT AND OPERATIONAL USE OF LOCALLY-PRODUCED READY-TO-USE FOODS

Kelsey Ryan, PhD
Mark Manary, MD
Local Foods for Moderate Acute Malnutrition (MAM)

- Corn-soy blends (CSB)
- Ready-to-eat foods
  - Ready-to-use Supplementary Food (RUSF)
  - Fortified spreads (FS)
  - Lipid Nutrient Supplement (LNS)
Local

• What is local?
  • Local ingredients
    • Locally grown
    • Locally available
  • Local production

• Why is local important?
  • Acceptability
  • Supports community
  • Lower cost?
Objectives

• Develop cost-effective foods that children will eat and that treat moderate malnutrition
  • Nutrient composition
  • Acceptability
  • Shelf-stability

• Operational program logistics important
Clinical Trials

CSB++ vs. RUSF

Effectiveness of a novel RUSF with whey permeate

Integrated treatment of SAM and MAM

Use of Linear Programming for local, low cost ready-to-use foods
Locally produced and imported RUSF are effective treatments for MAM

<table>
<thead>
<tr>
<th>Food</th>
<th>Production</th>
<th>Cost (/1000 kJ)</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSB++</td>
<td>Local</td>
<td>$0.07</td>
<td>• Corn</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Soybeans</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Soy Oil</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Nonfat dry milk</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Micronutrients</td>
</tr>
<tr>
<td>Soy RUSF</td>
<td>Local</td>
<td>$0.10</td>
<td>• Peanuts</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Extruded soybeans</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Soy oil</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Sugar</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Micronutrients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• + Calcium</td>
</tr>
<tr>
<td>Soy/Whey RUSF</td>
<td>Imported</td>
<td>$0.17</td>
<td>• Peanut</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Whey</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Soy protein isolate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Vegetable fat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Sugar</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Maltodextrin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Cocoa</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Micronutrients</td>
</tr>
</tbody>
</table>

LaGrone et al., 2012, AJCN 95:212-9
Locally produced and imported RUSF are effective treatments for MAM

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>CSB++ (n=888)</th>
<th>Soy RUSF (n=906)</th>
<th>Soy/whey RUSF (n=918)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovered, n (%)</td>
<td>763 (85.9)</td>
<td>795 (87.7)</td>
<td>807 (87.9)</td>
</tr>
<tr>
<td>Developed SAM (Severe Wasting), n (%)</td>
<td>59 (6.6)a</td>
<td>47 (5.2)</td>
<td>39 (4.2)</td>
</tr>
<tr>
<td>Developed SAM (Kwashiorkor), n (%)</td>
<td>38 (4.3)</td>
<td>35 (3.9)</td>
<td>47 (5.1)</td>
</tr>
<tr>
<td>Continued MAM, n (%)</td>
<td>8 (0.9)</td>
<td>5 (0.6)</td>
<td>8 (0.9)</td>
</tr>
<tr>
<td>Died, n (%)</td>
<td>8 (0.9)</td>
<td>10 (1.1)</td>
<td>8 (0.9)</td>
</tr>
<tr>
<td>Defaulted , n (%)</td>
<td>12 (1.4)</td>
<td>14 (1.5)</td>
<td>8 (0.9)</td>
</tr>
<tr>
<td>Transferred to inpatient therapy , n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Weight gain (g · kg⁻¹ · d⁻¹)</td>
<td>3.1 ± 2.45b</td>
<td>3.4 ± 2.6</td>
<td>3.6 ± 2.8</td>
</tr>
<tr>
<td>Length gain (mm/d)</td>
<td>0.13 ± 0.46</td>
<td>0.13 ± 0.44</td>
<td>0.15 ± 0.47</td>
</tr>
<tr>
<td>MUAC gain (mm/d)</td>
<td>0.13 ± 0.40b</td>
<td>0.13 ± 0.435b</td>
<td>0.21 ± 0.44</td>
</tr>
<tr>
<td>Time to recovery (d)</td>
<td>24.9 ± 17.5c,d</td>
<td>22.5 ± 14.2</td>
<td>22.6 ± 15.0</td>
</tr>
</tbody>
</table>

- a Significantly different (P<0.03) than soy/whey RUSF
- b Significantly different from soy/whey RUSF (P<0.001)
- c Significantly different from soy/whey RUSF (P<0.006)
- d Significantly different from soy RUSF (P<0.003)
Whey Permeate RUSF for treatment of MAM

- Whey permeate can replace a small amount of minerals in the RUSF
- Meet protein recommendations with addition of <5% whey protein concentrate (WPC)
- Acceptability trial showed equal liking between the Whey Permeate RUSF and control Soy RUSF

<table>
<thead>
<tr>
<th></th>
<th>Whey (n=30)</th>
<th>Soy (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average Time to Eat ± SD (min:s)</strong></td>
<td>7:14 ± 3:34 (n=17)</td>
<td>7:17 ± 3:50 (n=18)</td>
</tr>
<tr>
<td>Day 1 Child Liking</td>
<td>4.57 ± 0.73</td>
<td>4.59 ± 0.82</td>
</tr>
<tr>
<td>Day 1 Caregiver Liking</td>
<td>4.87 ± 0.43</td>
<td>4.72 ± 0.65</td>
</tr>
<tr>
<td>Day 4 Child Liking</td>
<td>4.97 ± 0.18</td>
<td>5.00 ± 0.00</td>
</tr>
<tr>
<td>No difficulty consuming over 4 days</td>
<td>28 Y / 2 N</td>
<td>26 Y / 3 N</td>
</tr>
</tbody>
</table>
Whey Permeate RUSF

• Primary outcome measures:
  • Recovery from MAM (achieving MUAC ≥ 12.5 cm by 12 weeks)

• 1584 completed study
• 1800 subjects anticipated to complete within a few months
Integrated treatment of SAM and MAM in Humanitarian Emergencies

With the International Medical Corps

- **Hypothesis:** An integrated management protocol for MAM and SAM will achieve greater community coverage and a greater individual recovery rate than standard care.
  - Same food (RUTF)
    - Step from SAM to MAM rations
  - Same measurements (MUAC)
  - Same treatment site
  - Potential for better efficiency and cost effectiveness
  - Medical interventions at discharge
    - LNS
    - Oral rehydration solution
    - Malaria prophylaxis
    - WHO immunizations
Integrated treatment of SAM and MAM in Humanitarian Emergencies

Located in Port Loko District in central Sierra Leone
International Medical Corp collaborated with Project Peanut Butter Sierra Leone to conduct the study

- A cluster randomized operational trial – 5 intervention sites and 5 control sites
- Primary outcomes: recovery rate, nutritional status 6 mo after successful treatment, program coverage
- Enrollment criteria MUAC < 12.5 and able to consume RUTF during feeding of test dose of 30g RUTF on enrollment
- Fed until MUAC > 12.4 cm
- Mothers participated in ‘mother care groups’ to promote continued breastfeeding during MAM treatment
Foods

• CSB vs. RUTF: Quite varied in macro- and micronutrient composition

• LNS:
  – Meets RDA for most micronutrients
  – 217 kcal
  – 5.3 g protein
  – 15.2 g fat
  – 40 g
Preliminary Results

- Enrollment was completed in November, 2013
- Integrated – 1187 subjects
  - 829 MAM
  - 358 SAM
- Standard – 909 subjects
  - 347 SFP
  - 562 OTP
- Finishing 6-month follow-ups (June, 2014)
### Coverage

- **SLEAC** (Simplified LQAS Evaluation of Access and Coverage) Sampling Design
- Method of surveying that helps to classify service coverage in large areas

<table>
<thead>
<tr>
<th>Site</th>
<th>GAM*</th>
<th>GAM covered</th>
<th>% Coverage</th>
<th>Coverage Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>61</td>
<td>35</td>
<td>57%</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>37</td>
<td>25</td>
<td>68%</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>53</td>
<td>51</td>
<td>96%</td>
<td>High</td>
</tr>
<tr>
<td>4</td>
<td>34</td>
<td>33</td>
<td>97%</td>
<td>High</td>
</tr>
<tr>
<td>5</td>
<td>53</td>
<td>25</td>
<td>47%</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

**Integrated**

Avg. = 73%

<table>
<thead>
<tr>
<th>Site</th>
<th>GAM*</th>
<th>GAM covered</th>
<th>% Coverage</th>
<th>Coverage Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>33</td>
<td>19</td>
<td>58%</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>25</td>
<td>22</td>
<td>88%</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>36</td>
<td>24</td>
<td>67%</td>
<td>High</td>
</tr>
<tr>
<td>4</td>
<td>34</td>
<td>28</td>
<td>82%</td>
<td>High</td>
</tr>
<tr>
<td>5</td>
<td>64</td>
<td>14</td>
<td>22%</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

**Standard**

Avg. = 63%

*GAM: Global Acute Malnutrition

Low = <20%
Moderate = 20-50%
High = >50%
Coverage Results

- Barriers to seeking services

- Child got sick fast: 1
- Caregiver sick: 1
- Thought program required money: 1
- Discharged as cured previously: 1
- No food at program site: 1
- Didn't know when to go to program: 3
- Caretaker is ashamed: 4
- No time/too busy to attend: 4
- Program too far away: 5
- New to the area: 7
- Caretaker thought child was fine: 11
- Rejected by program: 14
- Didn't know about program: 104
Objective: Lower the cost of RUTF

How?
- Use of local ingredients
- Evaluate importation of nutritionally valuable ingredients
- Optimized processing

With Steve Vosti and Katie Adams

Clinical Trial

Acceptability Trial

Identification of potential ingredients

Refine Ingredient List

Nutrient Compilation

Refine Nutrient Database

Develop LP Tool

Run LP

Paper formula analysis

anticipated processing ability or ingredient interactions; sensory prediction

Make formulas

Lab analysis

ability to process (qualitative); water activity; pH; informal sensory

Refine constraints

Selection of 3-4 final formulas and nutrient analysis

Research Processing Methods

Assign processing methods

Price of processing

Ingredient and Processing Price Database

Processing scale-up (3-4 formulas)

Acceptability Trial

Clinical Trial
What is local?

• For Linear Programming Research Project:
  • Having 500 mt or more of a given ingredient available, whether nationally produced or imported, in the locale of RUTF production
Cost of ingredients as “percent local” increases

<table>
<thead>
<tr>
<th>Minimum Percent Locally Available</th>
<th>Total Ingredient Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Min</td>
<td>$0.00</td>
</tr>
<tr>
<td>60%</td>
<td>$0.10</td>
</tr>
<tr>
<td>70%</td>
<td>$0.20</td>
</tr>
<tr>
<td>80%</td>
<td>$0.30</td>
</tr>
<tr>
<td>90%</td>
<td>$0.40</td>
</tr>
<tr>
<td>100%</td>
<td>$0.50</td>
</tr>
</tbody>
</table>

- Millet
- Dried egg yolks
- Soybeans
- Pumpkin seed
- Imported dairy*

- Fish
- Pumpkin seed
- Sunflower seed
- Imported*, protein-concentrated dairy

- Fish
- Pumpkin seeds
- Sunflower seeds
- Local dried milk

*e.g., whey powder, WPC
Other issues and findings

- Optimization of extrusion process different for every blend of ingredients
  - Anti-nutrients (e.g., trypsin inhibitor inactivation)
  - Cooking
    - Protein and starch digestibility
- Optimization of taste, texture, and viscosity
  - Micronutrient premix
  - Dairy powders
  - Solid vs. liquid oils
- Animal source foods and PDCAAS/DIAAS
- Cost-effectiveness
- Optimized RUTF composition
CSB++ vs. RUSF

Effectiveness of a novel RUSF with whey permeate

Integrated treatment of SAM and MAM

Use of Linear Programming for local, low cost ready-to-use foods

Different foods are effective for MAM

Novel formulations of foods are acceptable

Operational management may improve outcomes

Optimized for different localities

Themes:

Type of food

Ingredients in food

Use of food in operational setting

Local foods and lower cost

Nutrient Composition
Conclusions

• Local foods can be formulated and effectively used for treatment of MAM
• Logistics of operational programs is just as important as the food itself
• A new linear programming tool can be used to design new, local, ready-to-use supplementary and therapeutic foods
Acknowledgements

• IAEA
• Study sponsors

• Manary Team
  • Isabel Ordiz
  • Elizabeth Cimo
  • John Kimmins
  • Ellen Murray
  • Lauren Singh
  • Jennifer Stauber

• Malawi field team
  • Julie Kennedy

• Sierra Leone field team
  • Amanda Maust